April 6, 2015

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

SUBJECT: Announcement of Calendar Year (CY) 2016 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 2016 and the risk and other factors to be used in adjusting such rates. The capitation rate tables for 2016 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 2016 and the National Medicare Fee-for-Service (FFS) Growth Percentage for 2016. These growth rates will be used to calculate the 2016 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 5.04 percent, and the final estimate of the FFS Growth Percentage is 4.08 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 2013 are being posted on the above website.

Attachment III presents responses to comments on the Advance Notice of Methodological Changes for CY 2016 MA Capitation Rates and Part C and Part D Payment Policies (Advance Notice).

Attachment IV contains the changes in the payment methodology for Medicare Part D for CY 2016. Attachment V contains tables with the Part D benefit parameters.

Attachment VI contains details on Part D benefit parameters.

Attachment VII presents the final Call Letter.

We received many submissions in response to CMS' request for comments on the Advance Notice/Call Letter, published on February 20, 2015. Comments were received from professional

organizations, MA and Part D sponsors, advocacy groups, the pharmaceutical industry, pharmacy benefit managers, pharmacies, and concerned citizens.

Key Changes from the Advance Notice:

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

Proposals Adopted as Issued in the Advance Notice:

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

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

Calculation of FFS Rates: We rebased the FFS capitation rates for 2016, using historical claims data for 2009 through 2013. For 2016 we repriced the historical claims data to reflect the most current wage and cost indices, repriced the claims to account for the changes made by the ACA to payments to disproportionate share hospitals, and also repriced durable medical equipment claims to account for the change in prices associated with the competitive bid program.

IME Phase Out: For 2016, CMS will continue phasing out indirect medical education amounts from MA capitation rates.

ESRD State Rates: We will continue to determine the 2016 ESRD dialysis rates by state as we specified in the Advance Notice.

Clinical Trials: We are continuing the policy of paying on a FFS basis for qualified clinical trial items and services provided to MA plan members that are covered under the National Coverage Determinations on clinical trials as described in the Advance Notice.

Location of Network Areas for PFFS Plans in Plan Year 2017: The list of network areas for plan year 2017 is available on the CMS website at http://www.cms.gov/PrivateFeeforServicePlans/, under PFFS Plan Network Requirements.

CMS-HCC Risk Adjustment Model for CY2016: We will fully implement the 2014 CMS-HCC Risk Adjustment model as proposed in the Advance Notice. The risk adjustment factors for the 2014 CMS-HCC model were published in the 2014 Announcement.

Adjustment for MA Coding Pattern Differences: We will implement an MA coding pattern difference adjustment of 5.41 percent for payment year 2016.

Normalization Factors: The final 2016 normalization factors are:

CMS-HCC model used for MA plans is 0.992.
CMS-HCC model used for PACE organizations is 1.042.
CMS-HCC ESRD functioning graft model is 1.042.
CMS-HCC ESRD dialysis model is 0.990.
RxHCC model is 0.939.

Frailty Adjustment for PACE organizations and FIDE SNPs: We are finalizing the 2016 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).

International Classification of Diseases-10 (ICD-10) Code Sets: As proposed in the 2016 Advance Notice, the data collection year for risk scores used for 2016 payment will use diagnoses from the prior calendar year (CY2015).

Encounter Data as a Diagnosis Source for 2016: As proposed in the 2016 Advance Notice, CMS will blend the risk scores, weighting the risk score from Risk Adjustment Processing System (RAPS) and FFS by 90% and the risk score from the Encounter Data System (EDS) and FFS by 10%.

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.

Payment Reconciliation: The 2016 risk percentages and payment adjustments for Part D risk sharing will be finalized as stated in the Advance Notice.

Part D Benefit Parameters: Attachment V provides the 2016 Part D benefit parameters for the defined standard benefit, low-income subsidy, and retiree drug subsidy.

/ 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

2016 ANNOUNCEMENT
TABLE OF CONTENTS

Attachment I. Final Estimates of the National Per Capita Growth Percentage and the National Medicare Fee-for-Service Growth Percentage for Calendar Year 2016

The Table I-1 below shows the National Per Capita MA Growth Percentage (NPCMAGP) for 2016. Consistent with the 2014 and 2015 payment announcements, the basis for the growth percentage reflects an assumption that Congress will act to override the projected 21.2 percent reduction in Medicare physician payment rates from occurring in 2016; in addition, the growth percentage also contains an update of 0.5 percent for July-December 2015 and an additional 0.5 percent beginning January 2016. The Office of the Actuary has been directed by the Secretary to use this assumption on the grounds that these are the updates included in the legislation that has recently passed in the House and is thus a more reasonable expectation than the reduction required under the statutory "sustainable growth rate" (SGR) formula.

An adjustment of 2.83% 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 2016

	Prior Changes	Current Changes			
	2003 to 2015	2003 to 2015	2015 to 2016	2003 to 2016	NPCMAGP for 2016 With §1853(c)(6)(C) adjustment[1]
Aged+Disabled	43.00%	47.05%	2.14%	50.20%	5.04%

[1]Current changes for 2003-2016 divided by the prior changes for 2003 to 2015.

The Affordable Care Act of 2010 requires the Medicare Advantage benchmark amounts be tied to a percentage of the county FFS amounts. There will be a transition to the percentage of FFS over a number of years. Table I-2 below provides the change in the FFS USPCC which will be used for the county FFS portion of the benchmark. The percentage change in the FFS USPCC is shown as the current projected FFS USPCC for 2016 divided by projected FFS USPCC for 2015 as estimated in the 2015 Rate Announcement released on April 7, 2014.

Table I-2 – FFS USPCC Growth Percentage for CY 2016

	Aged + Disabled	Dialysis –only ESRD
Current projected 2016 FFS USPCC	$800.21	$7,155.20
Prior projected 2015 FFS USPCC	$768.84	$6,951.56
Percent change	4.08%	2.93%

Table I-3 below shows the monthly actuarial value of the Medicare deductible and coinsurance for 2015 and 2016. In addition, for 2016, the actuarial value of deductibles and coinsurance is being shown for non-ESRD only, since the plan bids will not include ESRD benefits in 2016. These data were furnished by the Office of the Actuary.

Table I-3 - Monthly Actuarial Value of Medicare Deductible and Coinsurance for 2015 and 2016

	2015	2016	Change	2016 non-ESRD
Part A Benefits	$37.23	$39.57	6.3%	$37.75
Part B Benefits[1]	$111.14	$118.86	6.9%	$109.08
Total Medicare	$148.37	$158.43	6.8%	$146.83

[1]Includes the amounts for outpatient psychiatric charges.

Medical Savings Account (MSA) Plans. The maximum deductible for current law MSA plans for 2016 is $11,300.

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 2017. In addition, this table shows the current projections of the USPCCs through 2018. 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 2018.

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	$295.77	$247.64	$247.41	$543.82	$543.18	1.001
2004	$314.08	$313.80	$271.03	$270.70	$585.11	$584.50	1.001
2005	$334.83	$334.52	$292.83	$292.49	$627.66	$627.01	1.001
2006	$345.30	$344.97	$313.67	$313.33	$658.97	$658.30	1.001
2007	$355.47	$355.59	$330.65	$330.32	$686.12	$685.91	1.000
2008	$371.93	$371.88	$351.01	$350.66	$722.94	$722.54	1.001
2009	$383.89	$385.42	$367.92	$367.56	$751.81	$752.98	0.998
2010	$385.42	$384.96	$376.84	$376.37	$762.26	$761.33	1.001
2011	$389.75	$387.89	$386.33	$385.86	$776.08	$773.75	1.003
2012	$379.07	$375.27	$392.90	$392.69	$771.97	$767.96	1.005
2013	$381.24	$376.48	$400.31	$397.25	$781.55	$773.73	1.010
2014	$371.91	$366.12	$419.91	$411.17	$791.82	$777.29	1.019
2015	$369.18	$360.16	$430.51	$416.59	$799.69	$776.75	1.030
2016	$375.14	$366.13	$441.69	$428.68	$816.83	$794.81	1.028
2017	$386.12	$377.41	$460.23	$447.97	$846.35	$825.38	1.025
2018	$405.23		$484.64		$889.87		

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	$373.09	$372.39	$374.89	$374.18	$747.98	$746.57	1.002
2011	$373.73	$371.16	$384.47	$383.77	$758.20	$754.93	1.004
2012	$359.23	$353.75	$392.02	$391.46	$751.25	$745.21	1.008
2013	$365.16	$359.28	$396.51	$393.53	$761.67	$752.81	1.012
2014	$364.88	$358.09	$409.90	$399.37	$774.78	$757.46	1.023
2015	$362.92	$358.67	$422.05	$410.17	$784.97	$768.84	1.021
2016	$368.54	$363.95	$431.67	$421.63	$800.21	$785.58	1.019
2017	$380.46	$374.25	$451.24	$439.41	$831.70	$813.66	1.022
2018	$398.27		$473.81		$872.08		

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	$6,780.23	1.000
2014	$6,863.06	$6,813.82	1.007
2015	$6,997.24	$6,951.56	1.007
2016	$7,155.20	$7,239.14	0.988
2017	$7,413.51	$7,529.40	0.985
2018	$7,731.47		

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
2014	1.0131	0.9992	1.0123
2015	1.0338	0.9984	1.0321
2016	1.0580	0.9975	1.0554
2017	1.0971	0.9967	1.0935
2018	1.1451	0.9959	1.1404

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%	3.3%
2011	3.6%	−0.6%	4.6%
2012	2.1%	−0.1%	0.5%
2013	1.4%	2.8%	4.5%
2014	1.5%	0.9%	0.6%
2015	0.2%	1.4%	2.2%
2016	3.0%	1.9%	4.4%
2017	2.8%	1.7%	5.4%
2018	2.7%	5.4%	8.2%

Part B[2]

Calendar Year	Physician Fee Schedule		Part B Hospital	Total
	Fees	Residual[3]		
2003	1.4%	4.5%	4.4%	6.8%
2004	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%	2.5%
2011	0.8%	2.3%	7.1%	2.3%
2012	−1.2%	1.0%	7.1%	1.7%
2013	−0.1%	0.2%	7.4%	0.9%
2014	0.5%	0.7%	12.9%	3.7%
2015	−1.0%	−0.7%	7.3%	1.2%
2016	−0.1%	1.2%	7.1%	2.5%
2017	0.4%	2.7%	8.5%	4.0%
2018	0.9%	2.5%	8.4%	5.1%

[1] Percent change over prior year

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

[3] Residual factors are factors other than price, including volume of services, intensity of services, and age/sex changes.

Medicare Enrollment Projections (In Millions)

Non-ESRD Total

	Part A		Part B	
Calendar Year	Aged	Disabled	Aged	Disabled
2003	34.437	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	7.833	36.517	6.938
2011	39.931	8.163	37.229	7.248
2012	41.667	8.404	38.527	7.496
2013	43.070	8.595	39.758	7.719
2014	44.349	8.652	41.019	7.849
2015	46.189	8.804	42.327	7.964
2016	47.711	8.848	43.646	8.015
2017	49.323	8.888	45.042	8.054
2018	50.990	8.961	46.498	8.115

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	28.904	6.456	26.261	5.556
2011	29.191	6.651	26.422	5.730
2012	29.941	6.685	26.725	5.773
2013	30.313	6.657	26.927	5.777
2014	30.418	6.494	27.015	5.687
2015	31.149	6.424	27.212	5.580
2016	31.799	6.327	27.656	5.489
2017	32.597	6.256	28.236	5.418
2018	33.640	6.323	29.066	5.472

ESRD

	ESRD-Total		ESRD-Fee for Service	
Calendar Year	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	0.441	0.427	0.387	0.372
2011	0.455	0.440	0.397	0.382
2012	0.469	0.454	0.407	0.391
2013	0.480	0.465	0.411	0.396
2014	0.491	0.476	0.412	0.398
2015	0.502	0.488	0.415	0.401
2016	0.512	0.498	0.421	0.406
2017	0.523	0.509	0.427	0.412
2018	0.534	0.520	0.437	0.422

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

Calendar Year	Inpatient Hospital Aged + Disabled	SNF Aged + Disabled	Home Health Aged + Disabled	Managed Care Aged + Disabled	Hospice: Total Reimbursement (in Millions) Aged + Disabled
2003	2,594.78	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	906.05	10,518
2008	2,695.88	536.68	151.00	1,075.32	11,404
2009	2,650.94	551.67	153.86	1,246.34	12,274
2010	2,642.35	573.21	155.46	1,250.44	13,088
2011	2,601.70	624.83	143.57	1,300.97	14,034
2012	2,501.71	543.28	136.15	1,361.20	15,044
2013	2,489.33	542.20	133.72	1,403.29	15,533
2014	2,414.25	538.27	129.56	1,374.57	15,779
2015	2,340.28	543.32	127.95	1,412.93	16,540
2016	2,325.61	565.31	128.58	1,477.67	17,756
2017	2,364.02	591.47	130.30	1,542.97	19,170
2018	2,469.78	620.49	136.66	1,632.29	20,641

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)

	Physician Fee Schedule	Part B Hospital	Durable Medical Equipment
Calendar Year	Aged + Disabled	Aged + Disabled	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	1413.74	628.53	183.75
2011	1440.67	668.49	175.53
2012	1396.88	703.02	173.24
2013	1354.26	741.90	152.32
2014	1336.32	820.78	127.90
2015	1327.73	867.81	129.45
2016	1314.85	914.14	118.09
2017	1342.86	978.42	118.56
2018	1386.27	1053.09	124.14

	Carrier Lab	Other Carrier	Intermediary Lab
Calendar Year	Aged + Disabled	Aged + Disabled	Aged + Disabled
2003	73.41	329.81	75.18
2004	78.14	354.00	80.47
2005	82.36	362.81	84.16
2006	85.25	361.08	84.51
2007	90.29	363.52	84.38
2008	94.11	366.62	85.78
2009	101.43	385.20	79.19
2010	100.75	393.77	80.22
2011	101.82	406.92	83.18
2012	109.30	410.22	84.49
2013	109.22	409.60	81.68
2014	113.50	413.38	55.63
2015	116.02	404.00	56.30
2016	119.34	400.64	57.59
2017	116.00	413.41	55.41
2018	120.77	428.78	57.53

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	1204.11
2010	193.08	283.49	1222.03
2011	198.29	262.78	1277.96
2012	204.67	248.22	1369.36
2013	194.36	245.80	1501.02
2014	200.64	237.32	1721.91
2015	180.31	236.26	1836.45
2016	177.77	237.54	1948.20
2017	183.63	240.83	2060.97
2018	191.90	252.64	2189.30

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

2016 Projections by Service Category for non-ESRD (Aged+Disabled)*

Service Type	Current Estimate	Last Year's Estimate	Ratio
Part A			
Inpatient Hospital	2,325.61	2,366.91	0.983
SNF	565.31	605.18	0.934
Home Health	128.58	134.33	0.957
Managed Care	1,477.67	1,282.84	1.152
Part B			
Physician Fee Schedule	1314.85	1,363.73	0.964
Part B Hospital	914.14	960.38	0.952
Durable Medical Equipment	118.09	116.18	1.016
Carrier Lab	119.34	119.04	1.003
Other Carrier	400.64	426.21	0.940
Intermediary Lab	57.59	36.35	1.584
Other Intermediary	177.77	154.37	1.152
Home Health	237.54	246.18	0.965
Managed Care	1948.20	1,707.08	1.141

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	0.002299
2015	0.001003	0.002299
2016	0.001003	0.002299
2017	0.001003	0.002299
2018	0.001003	0.002299

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 2016 (before adjustment for prior years' over/under estimates) is calculated by adding the USPCCs for Part A and Part B for 2016 and then dividing by the sum of the current estimates of the USPCCs for Part A and Part B for 2015.

The FFS USPCC:

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

Attachment III. Responses to Public Comments

Section A. Final Estimate of the National Per Capita Growth Percentage and the Fee-for-Service (FFS) Growth Percentage for Calendar Year 2016

Comment: CMS received several comments supporting CMS' Part C payment methodologies to reduce excessive payments to MA plans relative to FFS Medicare. Commenters stated that these policies are critical to stabilizing the fiscal health of the Medicare program and to ensuring efficient spending of taxpayer dollars. The commenters urged CMS to make final its proposed MA payment rates.

Response: CMS appreciates the support.

Comment: Two commenters stated that since both Medicare cost growth and national health expenditures have grown at historically low rates over the last several years, it is appropriate that this slower growth is reflected in the MA payment methodology. Commenters stated that the MA payment rates proposed by CMS appropriately reflect this slower growth.

Response: CMS appreciates the support.

Comment: Several commenters expressed appreciation for CMS' continuing efforts to provide timely data to the industry about potential future changes impacting the program, including preliminary estimates of growth rates. Commenters stated that they appreciated CMS' increased transparency in developing the growth rates in recent years, and stated that OACT's recent December releases of early preview estimates is a significant step forward in providing plans with the information they need for their bid development and advance planning activities.

Response: CMS appreciates the support.

Comment: CMS received a few comments expressing concern about the cumulative impact that the current mandatory changes and the proposed discretionary policy changes will have on the stability of the MA program. One commenter stated that the lower than expected FFS growth percentage adds to the reduction in payment caused by CMS policy changes, and will create an unfavorable revenue trend for fully phased-in counties. Another commenter stated that, in order for the MA program to continue to thrive and offer beneficiaries efficient, high quality care, CMS must ensure that it retains sufficient funding to address cost growth and regulatory reforms.

Response: CMS is committed to a strong, stable Medicare Advantage program and to continued access to high quality plan choices for Medicare beneficiaries. Over the past several years, even as the Medicare Advantage program has transitioned to payments that are more aligned with FFS Medicare costs, enrollment in Medicare Advantage has continued to increase. We believe that the policies for 2016 will continue the transition to payments that are more comparable to FFS

costs, while at the same time continuing the trend toward greater enrollment in high quality plans.

Comment: Several commenters requested CMS provide more detail on the factors used in the calculation of projected growth rates. One commenter asked CMS to include details such as the impact of demographic changes in the FFS Medicare population; and expected utilization, unit cost, and intensity changes for major categories of service. Commenters urged CMS to provide, at the time of the December announcement, and in the Advance Notice, the detailed assumptions on which these estimates are based, as well as a discussion of ongoing trends with the potential to further affect the growth percentage prior to the release of the Final Notice. Commenters suggested that CMS provide as much information and explanation regarding the rate updates as possible, including explanations and updated data regarding growth rate estimates and changes, prior to the publication of the Rate Announcement, including adjustments made to prior year growth rates. In addition, one commenter asked CMS to provide trends and assumptions by type of service, including utilization and unit cost. The commenter stated that this information would help plans fully analyze and prepare comments in response to the proposed growth percentages. One commenter expressed concern that the adjustments between the preliminary and final growth rates have led to a significant negative impact on MA payments. This commenter suggests that CMS use a balanced approach in making these corrections, and make positive adjustments when evidence justifies an increase.

Response: CMS believes that we are providing useful information and support pertaining to USPCC levels and trends. We have been providing an "Early Preview" of the growth rates two to three months before the release of the Advance Notice with the aim of providing additional transparency and sharing the latest information available about growth rates. In addition, beginning with the 2015 Advance Notice, we have included historical and projected USPCC values by trust fund and year in a format consistent with the Rate Announcement.

Key economic assumptions underlying the USPCCs are included in Attachment II of this Payment Notice. As we have in previous years, we will publish additional information regarding the trends for the prior five years at http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/index.html and will discuss this material on an actuarial user group call.

Comment: CMS received a few comments highlighting the fact that the growth rates released in the Advance Notice were lower than the preliminary estimates provided by the Office of the Actuary (OACT) in December 2014. The commenter stated that this continues a pattern from last year when the growth rates for 2015 declined from the preliminary estimates announced in December 2013 to the growth rates included in the 2015 Advance Notice and once again in the 2015 Rate Announcement. The commenter expressed concern that the significant changes in these estimates from the preliminary announcement in December to the Rate Announcement are

not improving predictability crucial for MA plan activities to sustain program participation and provide continuity of coverage and stability of benefits for their enrollees.

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

Comment: One commenter noted that CMS usually holds a conference call around the time of release of the Advance Notice, in which OACT provides additional information regarding rate components, assumptions, and emerging trends, that underlie the agency's calculation of the estimated growth rates. The commenter asks that CMS share this information in writing as well, to assist plan actuaries in understanding the growth rates and trends, thereby assisting with modeling and planning. The commenter requests that CMS publish this detailed information in the final 2016 Rate Announcement, and urges CMS, in future years, to do so in the Advance Notice.

Response: OACT provides significant documentation of trends following the release of the Rate Announcement through the five-year trend narrative and analysis, key components of the unit cost increases, and documentation of the responses to questions sent in advance for the spring user group calls.

Comment: CMS received several comments requesting that CMS publish the FFS USPCC for dialysis-only ESRD in the Advance Notice in the future. One commenter stated that CMS should release its best estimate of the ESRD trends in the Advance Notice, as CMS does for the other growth rates. Commenters ask that CMS provide this information as quickly as possible, before the publication of the final Rate Announcement.

Response: We were unable to provide a preliminary estimate of the FFS USPCC for dialysis-only ESRD in the Advance Notice this year. However, we are currently working on enhancing our ESRD data systems and projection methodology and are hopeful that we will be able to consistently provide this information in future Advance Notices.

Comment: Several commenters stated that they appreciated CMS continuing to operate under the assumption that the Medicare physician fee schedule reduction, required under the statutory "sustainable growth rate" formula, will not be implemented as a result of Congressional action. Commenters recommended that CMS continue this approach in the future.

Response: CMS appreciates the support. As noted in Attachment I, the growth percentage contains an update of 0.5 percent for July-December 2015 and an additional 0.5 percent beginning January 2016. The Office of the Actuary has been directed by the Secretary to use this assumption on the grounds that these are the updates included in the legislation that has recently passed in the House and is thus a more reasonable expectation than the reduction required under the statutory SGR formula.

Comment: One commenter stated that they opposed CMS' assumption that Congress will act to prevent the reduction in physician payment due to the sustainable growth rate (SGR). The commenter expressed concern that CMS is setting the precedent of using assumptions regarding expected, rather than actual, changes to current law.

Response: Consistent with the 2015 Rate Announcement, the basis for the preliminary growth percentages reflects an assumption that Congress will act to prevent the projected 21.2 percent reduction in Medicare physician payment rates from occurring in 2016; in addition, the growth percentage also contains an update of 0.5 percent for July-December 2015 and an additional 0.5 percent beginning January 2016. The Office of the Actuary has been directed by the Secretary to use this assumption, on the grounds that these are the updates included in the legislation that has recently passed in the House and is thus a more reasonable expectation than the reduction required under the statutory SGR formula.

Comment: CMS received one comment requesting clarification on whether the demographic changes, due to the baby boomers, are included in the Aged+Disabled FFS USPCC Growth Percentage for CY 2016. In addition, the commenter requested clarification on whether the FFS USPCC Growth Percentage is intended to include the impact of program demographic changes. If so, are the effects of demographics adequately removed by the FFS normalization factor?

Response: The FFS USPCC growth rate reflects the experience and includes the impact of all beneficiaries enrolled in Medicare fee-for-service, including "baby boomers." The normalization factor reflects both historical changes in beneficiary demographics as well as other trends that would affect risk scores, including coding and utilization.

Comment: One commenter asked CMS to increase the MA growth rate to account for rising prescription drug costs. The commenter stated that plans will be unable to sustain further reductions and cost increases. The commenter indicated that plans will have no choice but to limit formularies and pharmacy networks, along with increasing member cost share. The commenter has asked CMS to increase the growth rate to account for this.

Response: The MA ratebook growth rates reflect the historical experience and projected trends for the Part A and B trust funds. The applicable statutes do not allow for the inclusion of Part D trends in the USPCCs.

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 payments from the benchmark cap calculation. Commenters believe 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. Three of the commenters believe that the

statute can be interpreted to allow the Secretary the discretion to exclude quality payments from the benchmark cap calculation. One commenter suggested that the bonus payment not be included in the cap calculation in floor counties. One commenter requested that CMS use its demonstration authority to temporarily remove the pre-ACA rate cap entirely, or at a minimum remove the cap for qualifying plans in qualifying counties.

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.

Comment: One commenter stated that MA plans do not have financial incentive to pursue quality improvement to attain a Star Rating higher than 4 stars, since all plans with a rating of 4 or more stars receive the same level of bonus payment. The commenter suggested that CMS consider ways to encourage plans to strive for the highest possible quality, such as varying the bonus payment levels for 4.0, 4.5 and 5.0 star plans, and increasing the level and differentiation of rebate amounts for 4.5 and 5.0 star plans.

Response: While we appreciate the concerns of commenters, we do not believe this approach would be consistent with the statute at section 1853(o).

Note that beginning in 2012, CMS established a Special Election Period (SEP) to allow Medicare beneficiaries eligible for Medicare Advantage plans to enroll in 5-star MA plans at any point during the year. The creation of this SEP is part of CMS' overall quality effort, and to give MA plans greater incentive to achieve 5-star status.

Comment: One commenter stated that they disagree with CMS' treatment of new MA plans as eligible for 3.5 QBP percentage points. Under this proposal, an existing MAO that has an average Star Rating of 3.5 stars across all of its existing contracts and is considering entering a new market would be at a disadvantage compared to a new MA plan offered by a parent organization without any existing contracts that is entering that same market.

Response: Our treatment of new plans is consistent with the statutory definition of a new plan at section 1853(o)(3)(A)(iii)(II).

Comment: A contingent of commenters suggested that CMS establish a minimum benchmark level for the lowest cost counties in Puerto Rico to prevent disparity in county benchmarks. Commenters suggested setting the minimum benchmark at 85% or 90% of the lowest average MA benchmarks among states, or freezing the MA benchmarks in Puerto Rico at 2011 levels.

Response: We appreciate the extent of the concerns raised by the commenters, recognize that Puerto Rico has a very large percentage of its beneficiaries in MA, and that plans operating in Puerto Rico face challenges different than those faced by plans on the mainland. We share many of the commenter's concerns regarding the impact of the benchmarks in the Commonwealth; however, we do not believe the approach suggested by these comments would be permissible under statute.

Section C. Calculation of Fee for Service Rates

Comment: Several commenters expressed concern regarding CMS rebasing in 2016. Commenters noted that this is the fifth year in a row of rebasing, and noted that it is not required annually by statute. Commenters questioned if rebasing has resulted in greater predictability or substantially greater accuracy of FFS rates. One commenter proposed rebasing FFS county rates every other year. Another commenter asked that CMS institute a regular schedule of rebasing once every three years. Two other 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 now based exclusively or primarily on FFS costs, we believe it is important to update the FFS rates using the most current FFS data available. We stated in last year's Rate Announcement that we anticipate to rebase 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 the 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 repricing historical claims data, including the DSH/UCP repricing.

Response: We appreciate the support.

Comment: A few commenters requested more transparency on the calculation of the FFS rates. One commenter asked that CMS release the historical FFS claims data used to determine the AGA by county as soon as the data are available so that plans can estimate the potential impacts and better predict county benchmarks. Another commenter requested greater transparency of the methodological changes (ex: repricing) and their impact on county rates in future years' Advance Notices.

Response: We are publishing with the final Rate Announcement files that contain the wage indices in each claim year (*i.e.*, 2009-2013), and the wage indices for 2015 by county. We will consider publishing additional data with the Advance Notice in future years that can help stakeholders understand the potential impacts of proposed changes in the Advance Notice.

Comment: One commenter requested that CMS base Hawaii's benchmarks only on beneficiaries with both Part A and Part B coverage, as is done in Puerto Rico. The commenter noted that Hawaii has a large share of FFS beneficiaries without Part B (20% in Hawaii versus 10% nationally) due to low-income beneficiaries who cannot afford the Part B premium. Furthermore, since beneficiaries must have Part B to join an MA plan, the proportion of Hawaii's FFS population without Part B is increased because Hawaii has a large proportion of its beneficiaries in an MA plan (46% in Hawaii versus 28% nationally).

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 believed it was 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 the Part A and Part B adjustment to all counties in the future.

Comment: A contingent of commenters requested that CMS make an actuarial adjustment to the Puerto Rico MA payment rates to reflect the much lower dual eligible penetration in the FFS data than exists in MA. Commenters noted that the Puerto Rico FFS rates do not adequately capture the cost of the FFS benefit because dual-eligible beneficiaries are under-represented, and standardized costs for the dual eligible population enrolled in FFS may be higher than standardized costs of the non-dual population. Commenters believe that the FFS data used by CMS to set the MA rates for Puerto Rico are not representative of the population to which the rates are being applied, and consistent with standard actuarial pricing practices, an adjustment is needed to accurately reflect the characteristics of the Puerto Rico Medicare population.

Response: Consistent with the MA rates for all other counties, the FFS rates in Puerto Rico are currently based on the experience of beneficiaries enrolled in the Medicare fee-for-service program. We will consider whether any refinements to the methodology may be warranted in future years.

Comment: A few commenters in Puerto Rico requested that CMS restore hospice carve-outs to MA benchmark calculations, or use demonstration authority to integrate the hospice benefit into MA (allowing plans to submit the integrated hospice benefit in 2016 bids).

Response: Pursuant to sections 1852(a) and 1853(h)(2), hospice benefits for all Medicare beneficiaries, including those enrolled in MA, are provided through FFS Medicare. For this reason, hospice claims are excluded from FFS data used to determine MA capitation rates. The development of the FFS USPCC has excluded hospice claims since rates were developed on an adjusted average per capita cost basis. Excluding claims for beneficiaries in hospice status from the AGA calculation aligns the calculation of the AGAs with how they are applied. As a result, these claims are excluded. We appreciate the commenter's suggestion for a hospice demonstration, and will consider whether it could be appropriate in the future.

Comment: One commenter requested that CMS adjust MA Rates for the significant 2014 increase in the Inpatient Prospective Payment System (IPPS) DSH payment for hospitals in Puerto Rico.

Response: We have re-priced 75 percent of original DSH based on the Uncompensated Care Payment (UCP) levels as reflected in the FY 2015 IPPS regulation. We are studying the remaining 25 percent of original DSH to determine a solid approach to repricing it.

Comment: One commenter requested that CMS delay the phase-in of the new ACA formula, to prevent payment cuts in Puerto Rico.

Response: We appreciate the concerns commenters have raised regarding Puerto Rico. However, we do not believe this approach would be consistent with the statute.

Section D. ESRD State Rates

Comment: Two commenters requested that the FFS USPCC for dialysis-only ESRD and State Rates be released before the final Rate Announcement is published.

Response: The FFS USPCC for dialysis-only ESRD and State Rates are being released with this final Rate Announcement.

Comment: One commenter recommended that CMS apply similar re-pricing to the ESRD state average geographic adjustments as are being used to update the Aged+Disabled county rates. The commenter stated that they were specifically concerned that if this is not done for the DSH/UCP payments, the Puerto Rico ESRD AGA will potentially be understated.

Response: Our current ESRD data system and projection methodology do not support making these adjustments at this time. However, we are enhancing this system and will evaluate the appropriateness of such adjustments once the system improvements have been implemented.

Comment: Two commenters requested that CMS apply the quartile adjustment (i.e., applicable percentages) to ESRD dialysis payment rates to MA plans.

Response: We do not believe this approach would be consistent with the statute.

Comment: One of the commenters cited recent decreases in ESRD payment rates in Puerto Rico and questioned whether the ESRD MA payments in PR comply with the actuarial equivalence requirement under SSA § 1853(a)(1)(H).

Response: The ESRD payment rates for all jurisdictions, including Puerto Rico, are developed in accordance with SSA §1853(a)(1)(H).

Section E. Clinical Trials

Comment: Several commenters expressed concern about CMS's Clinical Trial policy, stating mistakenly that CMS "exempts" MA plans from the requirement to follow the clinical trial National Coverage Determination instead of requiring MA plans to provide coverage for clinical trials. Commenters also indicated that the policy creates barriers 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. Several commenters noted that MA enrollees typically chose MA plans because of lower copayments, lower out-of-pocket costs, and more comprehensive coverage compared to FFS. One commenter erroneously stated that, under CMS' current policy, beneficiaries who wish to participate in clinical trials are forced to switch to traditional FFS, 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 added that the current policy discourages beneficiaries from accessing clinical trials because FFS Medicare will increase their out-of-pocket costs. One commenter stated that this current policy is especially a concern as Medicare Advantage enrollment grows. The commenter stated that CMS' policy creates a serious inequity that disadvantages low-income beneficiaries who cannot afford the out of pocket costs in FFS. Several commenters noted that, if individuals are discouraged from participating in clinical trials for cost reasons, there will be little to no data available upon therapy approval, making it more difficult for physicians to appropriately assess the therapeutic value of new drugs and devices once they are available.

Response: CMS appreciates the comments and the opportunity to clarify the clinical trial policy that has been in effect since 2011.

MA plan beneficiaries are able to participate in any qualifying clinical trial that a FFS beneficiary may participate in pursuant to National Coverage Determination (NCD) 310.1. CMS does not require MA beneficiaries to relinquish their MA coverage if they wish to participate in a clinical trial.

CMS requires MA organizations, in accordance with 42 CFR §422.109(c)(2), 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 MA organization. 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 FFS costs for a qualifying clinical trial. As finalized in the CY 2011 Rate Announcement, effective for CY 2011 and subsequent years, MAOs must reimburse beneficiaries for cost-sharing incurred for clinical trial services that exceed the MA plans' in-network cost sharing for the same category of service. The MAO owes this difference even if the beneficiary has not yet paid the clinical trial provider. The beneficiaries' clinical trial cost sharing must also count towards their in-network out-or-pocket maximum. This cost-sharing requirement applies to all qualifying clinical trials; MAOs cannot choose which clinical trials or clinical trial items and services for which this policy applies.

By requiring MAOs to provide in-network cost sharing for clinical trial services, CMS is requiring MAOs to provide MA plan members with coverage for clinical trial services consistent with the coverage they have for all other services. These policies ensure that MA plan enrollees do not have unexpected cost sharing for clinical trials, as those cost sharing amounts will not be different from the cost sharing amounts applicable to in-network services of a similar kind.

If an MAO conducts its own clinical trial, the MAO can explain to its enrollees the benefits of participating in its clinical trial; however, the MAO may not require prior authorization for participation in a Medicare-qualified clinical trial not sponsored by the plan, nor may it create impediments to an enrollee's participation in a non-plan-sponsored clinical trial, even if the MAO believes it is sponsoring a clinical trial of a similar nature. However, an MAO may request, but not require, enrollees to notify the plan in advance when they choose to participate in Medicare-qualified clinical trials.

In addition, clinical trial sponsors/providers are permitted to submit original Medicare "paid" clinical trial claims to MAOs on behalf of MA plan beneficiaries in order to obtain reimbursement for the difference between original Medicare cost sharing liabilities and in-network MA plan cost sharing liabilities. A sponsor/provider need only collect cost sharing from such an enrollee once both original Medicare and the MAO have paid.

The policy of requiring MAOs to pay the difference between original Medicare cost sharing and in-network cost sharing for clinical trial services is unchanged from 2011. For more information on these policies, please refer to the Medicare Managed Care Manual, Chapter 4 (Benefits and Beneficiary Protections), section 10.7 (Clinical Trials).

Section F. CMS-HCC Risk Adjustment Model for CY 2016

Comment: The majority of commenters opposed the proposed policy of fully transitioning to the newer model first implemented in 2014 as part of a blended risk score. Commenters requested a continued delay, or a more gradual transition to the full implementation of the new 2014 model. Many commenters asked CMS not to implement the new model at all, and to use the 2013 model entirely.

Response: While we appreciate the comments, we have been using the new model to some degree for two years and believe the industry should be ready for a full transition to the 2014-CMS-HCC model. Therefore, we are fully implementing the new model as discussed in the 2016 Advance Notice. In response to concerns from plans in Puerto Rico, while we recognize the special challenges that Medicare Advantage Organizations in Puerto Rico face, we note that the risk adjustment model is calibrated to be used across the entire industry and is designed to be applied in all geographic areas.

Comment: Some MAOs requested that specific conditions be put back in the model (e.g. Chronic Kidney Disease (CKD) 1-3, nephritis, and other co-morbidities associated with diabetes), stating

their belief that the original introduction of the 2014 model was a mistake as it began to fundamentally alter the incentives built into the program to provide early intervention and support to individuals with chronic diseases. Several commenters stated that implementing the new model is inconsistent with CMS initiatives to encourage more value-based care in the Medicare Advantage program.

Response: CMS understands the clinical significance of these conditions and the importance of appropriately managing patients to slow the progression of kidney disease. Given the goal of managed care organizations, we expect plans will appropriately manage chronic conditions for their beneficiaries, irrespective of model refinements.

Comment: Several commenters felt that the model disproportionately affects low-income and minority beneficiaries residing in areas with a high concentration of fully integrated health care delivery systems. Several other commenters objected to full use of the 2014 model because they felt the model did not adequately account for specific populations such as beneficiaries with chronic care conditions or dual eligibles. A few commenters also mentioned their belief that the model overpays for very low-cost beneficiaries and underpays for very high-cost beneficiaries.

Response: We believe that the 2014 model improves payment accuracy and results in more payment equity across plans. Furthermore, as shown in our evaluation of the CMS-HCC risk adjustment model, the model underpredicts the cost of the lowest-risk decile of beneficiaries, and has nearly a 1.0 predictive ratio for the highest-risk decile of beneficiaries. However, we take very seriously the concerns raised by commenters that the model may disproportionately affect specific populations, particularly dual eligibles. We will evaluate the impact of the model on these populations (including exploring ideas raised by MedPAC and others such as whether partial duals and full duals should be treated differently) in the coming months, we will share our analysis with stakeholders, and, if appropriate, propose modifications to the model to improve predictive accuracy in a future year's process.

Comment: One commenter encouraged CMS to complete the 2014 transition as it is more clinically appropriate.

Response: CMS appreciates the support.

Section G. Medicare Advantage Coding Pattern Adjustment

Comment: Several commenters were pleased that CMS is not going above the statutory minimum coding pattern adjustment.

Response: CMS appreciates the support of the commenters.

Comment: A few commenters expressed concern about the coding pattern adjustment level and requested that CMS apply the coding adjuster by different categories (e.g. by plan, geography, or age category), instead of applying an across the board adjuster equally to all plans.

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

Comment: We received a large number of comments on the proposed alternate methodology for coding pattern adjustment. None of the commenters were in favor of implementing the proposed methodology, with many indicating that they required more detailed information on the methodology to appropriately respond. Several commenters stated their belief that CMS does not have authority to cap MA risk adjustment payments, while a number of commenters challenged the use of the AAPCC demographic model, noting that CMS has previously shown that its ability to predict costs is not as accurate as the CMS-HCC Model. They also noted that the statute requires CMS to replace the AAPCC model with a risk adjustment model that takes into account both health status and demographic characteristics.

Furthermore, several commenters noted limitations of the three analyses that served as CMS' basis for better health status of beneficiaries enrolled in MA compared to those who are in FFS. The commenters stated that MA enrollees may appear healthier compared to FFS enrollees, not because they are necessarily healthier, but for other reasons, including: the positive impact of better care coordination and management by MA plans; surveys are less reliable than claims data; and enrollees who are benefitting from care coordination and management will report better health status than those who do not have access to these services.

Instead of the proposed alternate methodology, a few commenters recommended that CMS consider other risk adjustment options, such as creating a CMS-HCC model that uses only MA encounter data or creating risk models that use a combination of inpatient and outpatient diagnoses plus outpatient prescription drug data. Other commenters urged CMS to continue improving the current risk adjusted models to ensure that payments are aligned with costs and avoid adverse selection.

Response: We thank commenters for their responses and will take these comments into consideration as we consider options for the coding pattern adjustment in the future. For CY 2016, we will implement the proposed statutory minimum.

Comment: A few commenters expressed concern that the changes in the CMS-HCC model are duplicative of the coding pattern adjustment. A few commenters, while acknowledging CMS' response in the CY 2014 Announcement that the coding-related aspects of the CMS-HCC model are not duplicated by the application of the coding intensity adjustment to the risk scores, stated that CMS did not explain how the Agency takes the coding aspects of the risk adjustment model into account when finalizing the coding intensity adjustment.

Response: We understand that different model versions may affect the coding difference trend differently. When CMS determines the MA coding adjustment factor, we take into account the version of the model that will be in use during the payment year. Because we make determinations regarding the appropriate level of the MA coding adjustment by taking into

account the impact of coding on the risk score calculated using the payment year model, the model adjustments made to address coding do not duplicate the MA coding adjustment factor applied to the risk scores. As discussed in the 2010 Announcement, we first calculate the coding adjustment factor using an annual average of coding differences. When we measure these differences, we use the model from the payment year.

Comment: One commenter asked CMS to consider removing the "stayers" component of the existing design and not apply the coding intensity adjustment to members whose payments are based on the new enrollee risk score.

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

Comment: One commenter requested a proposed timeline for when CMS is likely to phase-in an MA risk adjustment model calibrated to MA data.

Response: CMS will continue its development efforts and will give further updates in the future. CMS expects the policy finalized in this rate notice to phase-in the use of encounter data for risk score calculation will accelerate our ability to move fully to a risk model based on encounter data.

Section H. Normalization Factors

Comment: A number of commenters were expecting that the CMS-HCC model normalization factor would continue to decrease given the more recent demographic changes in the Medicare population, e.g. the increase of younger beneficiaries ("baby boomers") in the program. They also requested more transparency with respect to the methodology used to develop the 2016 normalization factors, and how CMS is accounting for the influx of the "baby boomers."

Response: The goal of normalization is to assure that the average risk score is 1.0 in the payment year. There are a number of factors underlying the risk score trend, including not only demographics trends, but also coding and utilization patterns. In order to maintain a 1.0 risk score, CMS develops a risk score trend using historical data, and then projects the risk score to the payment year. In 2015, we changed our normalization methodology to better reflect more recent changes in the population trends (e.g., "baby boomers"). Specifically, we applied a quadratic functional form to the historical risk score data and used the resulting coefficients to

estimate the payment risk score. For 2016, we continue to believe that the quadratic functional form is the preferred method to predict payment year risk scores.

Comment: A commenter asked for clarification on how CMS derived the 2016 RxHCC model normalization factor using the risk scores published in the 2016 Advance Notice.

Response: As with the other normalization factors, we calculated the RxHCC model normalization factor using a quadratic functional form fit to risk scores over four years; this functional form allows for a nonlinear trend. Additionally, for the RxHCC model normalization factor, the functional form is applied to risk scores from 2010 through 2013. This is slightly older data than is used for the Part C model normalization factors, since the RxHCC model factor incorporates MA risk scores, which were complete only through 2013 at the time of the 2016 Advance Notice. Using this older set of historical data, CMS is projecting three years to the payment year, past the last data point, instead of just two, which will further emphasize the trend observed in the historical data.

Comment: A commenter asked if the risk scores used to calculate the normalization factor are the same for PACE and ESRD Functioning Graft.

Response: The functioning graft model is essentially the same as the aged-disabled CMS-HCC model, with a key difference being the inclusion of the add-on factors to reflect the higher costs of beneficiaries who have had a kidney transplant. Because the base model is the same as the Part C model, we use the same normalization factor for both models. The functioning graft model that CMS is currently using is based on the CMS-HCC model that we are using to pay PACE organizations, hence their normalization factors are the same.

Comment: Commenters from Puerto Rico requested that CMS make an adjustment to the normalization factors applied to risk scores for beneficiaries in Puerto Rico to account for high MA and D-SNP penetration.

Response: While CMS notes the commenters' recommendation, the purpose of the normalization factors is to set the average risk score for each model to 1.0 in the payment year. In order for risk adjustment to work appropriately, we need to set the 1.0 across the plans that are in the risk pool. Both the ratebook and the risk scores depend on having risk scores in a single year average to 1.0, such that each person or county's risk is relative to the same national average.

Section I. Frailty Adjustment for PACE organizations and FIDE SNPs

Comment: We received several comments in support of the method of using frailty to explain costs not fully predicted by the CMS-HCC model.

Response: CMS appreciates the support.

Comment: A few commenters recommended that CMS apply frailty adjustments more broadly to all SNPs enrolling frail beneficiaries, including non-FIDE D-SNPs and I-SNPs, traditional Medicare, and Medicare Advantage.

Response: Under section 1853(a)(1)(B)(iv), CMS has special statutory authority to pay frailty adjustments to FIDE-SNPs; the application of a frailty adjustment to all MA plans would need to be done on a budget neutral basis with consideration to the fact that some plans would have a negative adjustment. CMS has explored ways of capturing frailty by all MA plans and found challenges with a number of approaches (see the "Evaluation of the CMS-HCC Risk Adjustment Model," published March 2011, at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Evaluation_Risk_Adj_Model_2011.pdf). The CMS-HCC model is intended to accurately pay plans with average frailty levels, unlike PACE organizations and the subset of qualifying FIDE SNPs that have levels of frailty that are similar to PACE.

Section J. Medical Loss Ratio Credibility Adjustment

Comment: CMS received one comment in support of maintaining the same MLR credibility adjustment for CY 2016.

Response: CMS appreciates the support.

Comment: One commenter expressed concern that MLR requirements and the bidding rules contain standards that are duplicative, conflicting, or no longer necessary. The commenter requests that CMS reconcile these requirements, stating that simplifying the bid submission and MLR requirements would reduce administrative burden for both CMS and plans.

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

Section K. International Classification of Diseases-10 (ICD-10) Code Set

Comment: Most commenters support the transition, but expressed concerns regarding provider readiness for ICD-10, including: coding ability under ICD-10, under reporting of diagnoses and the negative impact it could have on MA plan payment.

Response: We appreciate the support for the transition to ICD-10. We understand that the healthcare industry has been working with providers to prepare for the transition to ICD-10 since the final rule was published on January 16, 2009 (45 CFR 162), and encourage continued provider education to meet the targeted transition date of October 1, 2015. 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). Specifically, MAOs have until January 2017 to submit encounter data and RAPS risk adjustment data from 2015 dates of service.

Comment: Several commenters recommended that CMS establish a transition period during which CMS would hold plans harmless for any negative changes to risk scores and medical record documentation resulting from inaccurate ICD-10 coding. Some also requested that CMS make a temporary adjustment to payment rates for 2016 that accounts for differences in coding patterns that result from the transition to mitigate any potential negative payment impact, or creating a separate normalization factor for the impacted data collection period.

Response: Given the extended period providers and plans have had to transition to ICD-10, we do not believe a payment adjustment or hold harmless policy is warranted.

Comment: Some commenters suggested we accept ICD-9 codes in some manner after the October 1, 2015 transition date by either allowing plans to crosswalk ICD-9 codes submitted by providers to ICD-10 codes for dates of service after October 1, 2015 or accept both ICD-9 and ICD-10 for a set period of time to allow for the proper recalibration of the risk adjustment models based on ICD-10 diagnoses. Some commenters requested that we delay the use of ICD-10 until January 2017. Others asked how to address claims submitted after the implementation date from providers that continue to use ICD-9 codes.

Response: On January 16, 2009, CMS published the final rule mandating that all entities covered by the Health Insurance Portability and Accountability Act (HIPAA), which includes most providers and health plans, implement ICD-10 for medical coding. Thus, CMS cannot accept or process ICD-9 codes for risk adjustment for services with dates of service beginning October 1, 2015. It is important to note that all entities covered by HIPAA must use ICD-10 for dates of service starting October 1, 2015, which includes health care providers and payers who do not deal with Medicare claims but are covered entities under HIPAA.

Comment: A few commenters requested that CMS release an updated preliminary mapping of ICD-10 codes to the existing HCCs to aid plans in their preparations.

Response: CMS will release updated ICD-10 mappings in the near future.

Section L. Encounter Data as a Diagnosis Source for 2016

Comment: The majority of commenters indicated that while they are supportive of the encounter data submission project, they oppose this proposal, believing it is premature to solely rely on encounter data for MA-reported diagnoses in risk scores. These commenters request that CMS delay this change. Several commenters opposed the proposal by citing their inability to measure the impact of the encounter-based risk score on payment until the filtering logic and final report layout has been shared and vetted by the industry. Some plans also raised the concern that their risk scores will decrease using encounter data.

Response: We appreciate the support for the encounter data project. We understand your concerns and will release the filtering logic as soon as possible.

Comment: Several other commenters requested that CMS provide additional data for the encounter data-based risk scores to aid in an impact analysis, and some commenters specifically requested that CMS provide encounter data-based risk scores for the projection of their 2016 bids.

Response: CMS will provide the filtering logic and work with MAOs to support their efforts to assess the impact of using encounter data-based diagnoses on risk scores. CMS is not planning to calculate encounter data-based risk scores using data collection for years prior to 2014.

Comment: Several commenters oppose the proposal citing concerns that encounter data is not yet complete or stable enough to warrant its use for determining risk adjusted payments at this time.

Response: CMS requires that plans submit complete, accurate, and timely encounter data. CMS has been working with plans since 2012 to assist in the submissions of encounter data, and we will continue to do so. We believe that our proposal for 2016 is a reasonable, modest step toward ultimately relying exclusively on encounter data for plan-submitted diagnosis information, particularly given that it will be the fourth year of the encounter data initiative.

Comment: A few commenters stated that CMS should not apply the MA coding pattern adjustment to the portion of the risk score calculated using encounter data. These commenters believe that coding differences between FFS and MA, which the coding intensity adjustment is intended to account for, cannot exist when using EDS data.

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 expressed support for maintaining the 2015 RAPS/Encounter Data policy for PACE organizations.

Response: We appreciate the support.

Comment: A few commenters were concerned that blending risk scores from two sources would distort the accuracy of measuring the illness burden of the Medicare population for Part C and Part D.

Response: CMS notes that the method of blending the RAPS-based risk score with the encounter data-based risk score is our transition policy. We will be phasing out RAPS over time and will eventually move to an encounter data-based risk score. As mentioned above, since the same diagnoses that are submitted into RAPS can be submitted into the encounter data system, we anticipate that the scores should be similar.

Comment: One commenter believes that proposing to use encounter data, even in part, without providing any information regarding how it will operate, is inconsistent with the Social Security Act and the Administrative Procedures Act.

Response: As we have previously stated, CMS plans to share its operational approach for filtering diagnoses from encounter data and allow for comment. The policy being implemented through this filtering logic is the one that CMS has already established (e.g., which service types and physician specialties are allowable sources of diagnoses) and the filtering logic will not change the rules regarding risk adjustment allowable diagnoses. While we understand the interest that the industry has in the approach that CMS will use to filter diagnoses from encounter data, we believe that the information we provide in the Advance Notice meets the statutory requirements for providing advance notice of a change in payment methodology and that providing operational information outside of the Notice process at a later date is appropriate, since we are not proposing to change the methodology for identifying risk adjustment allowable diagnoses. We note that the risk adjustment methodology proposed in the 2016 Advance Notice is 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."* Section 1853(b)(1) in turn provides for a final announcement in which the "risk and other factors to be used in adjusting" payment will be published.

Attachment IV. Changes in the Payment Methodology for Medicare Part D for CY 2016

Section A. Update of the RxHCC Model

Comment: Several commenters supported the approach to updating the model and the inclusion of MA-PD data into the model.

Response: We appreciate the support.

Comment: Several commenters raised concerns that including MA-PD data in the Part D risk adjustment model may negatively impact risk scores, disproportionately affect the risk scores of subsets of beneficiary populations (e.g. low-income) and may result in premium increases or negative benefit changes. These commenters requested that the model be phased in instead of fully incorporated for 2016.

Response: We recognize that MA-PDs have unique cost and utilization patterns and that including their data can change the risk scores for some populations. We believe that basing the model on the data from all beneficiaries enrolled in the program improves the predictive accuracy of the model. As is true of all risk adjustment models, impacts are plan and beneficiary specific, and plan distribution of certain beneficiary types may result in varying risk score impacts.

Comment: Several commenters inquired about the clinical updates and exclusions of certain RxHCC's in the model, citing underestimation of the costs, the potential to discourage detection and management, potential disproportionate impact on plans with high low-income enrollment, and risk of furnishing services to beneficiaries with these conditions, in particular Chronic Kidney Disease.

Response: When CMS makes clinical updates to the risk adjustment models, we take into account the ability of individual HCCs to predict program costs; changes are made with the input of a panel of clinical experts. Decisions to include or exclude a specific diagnosis in the model are based by balancing a variety of considerations, including: clinical significance; a category's ability to accurately predict costs; coding patterns; and whether or not the diagnosis has significant cost implications beyond screening and/or diagnostic pertinence.

Comment: While many commenters supported the inclusion of the Hepatitis C actuarial adjustment, a few cautioned that making such adjustments should only be made in the most extreme of cases, such as Hepatitis C, and not become an annual part of the D model updates. A commenter suggested that the actuarial adjustment may not be sufficient to cover the cost of the new medications to treat Hepatitis C. In addition, some commenters expressed concern regarding the indication that the actuarial adjustment will be a temporary measure and encouraged CMS to release additional information regarding prevalence assumptions of Hepatitis C in the Medicare population. Several other commenters requested that similar

actuarial adjustments be made for other high-cost drug categories.

Response: We appreciate the recommendation that CMS consider the implications of other high-cost medications and will take it into consideration, as well as the concerns about making adjustments such as the one for Hepatitis C outside of extreme cases. As noted in the 2016 Advance Notice, given the clinical ramifications of the new Hepatitis C treatment options and uncertainty regarding the future prevalence and pattern of Hepatitis C among Medicare beneficiaries, CMS will revisit the need for an adjustment in the future.

Comment: One commenter was pleased with our approach to numbering the RxHCC going forward.

Response: We appreciate the support.

Section B. International Classification of Diseases-10 (ICD-10) Code Set

See Section K for comments and responses related to ICD-10.

Section C. Encounter Data as a Diagnosis Source for 2016

See section L. for comments and responses related to using Encounter Data as a diagnosis source for 2016.

Section D. Payment Reconciliation

Comment: We received two comments supporting the continuation of the Part D risk corridors. One commenter stated that they believe that the risk corridors should be a fixture in Part D.

Response: CMS appreciates the support.

Comment: One commenter stated that the Part D risk corridors are no longer as necessary, as plans have now had several years of experience with Part D bidding. The commenter stated that the existence of the risk corridors implies an incentive to assume a lower pharmacy cost trend, which can cause inaccurate estimates and require repayment during reconciliation. The commenter stressed that plans should be encouraged to use the most accurate estimates possible to avoid such outcomes. The commenter recommended that CMS eliminate the risk corridors or, at a minimum, consider widening them for 2016.

Response: CMS disagrees with the commenter. CMS reviewed the annual reconciliation data and observed the usual significant variances between the target amount and the adjusted allowable risk corridor costs, which supports the continued need for risk-sharing. Therefore, CMS is not widening the risk corridors for 2016.

Section E. Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2016

Comment: Several commenters expressed concern in regards to the growth in the Part D benefit parameters in 2016. Two commenters stated that the increase in this factor means out-of-pocket costs for Part D beneficiaries will increase under the defined standard Part D benefit. One commenter expressed concern about the underlying trends driving the annual Part D benefit parameter updates. The 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. Another 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 monitoring Part D spending trends and their impact on enrollees, CMS must update the parameters for the defined standard Part D prescription drug benefit 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 pointed out that, except for eligible members in the LIS category code 1, the 2016 low-income cost share is identical to that of 2015. The commenter added that there have been significant drug cost increases among the low income population, especially given rising utilization of the high-cost Hepatitis-C drugs. The commenter stated that, to better align the underlying cost increase and the member cost share so as to incentivize more efficient use of drug benefits (thereby helping to control the cost increases), CMS should consider

utilizing the same cost share increase percentage as applied to category code 1 for the other category codes as well.

Response: CMS is required by statute to update the parameters for the low income subsidy benefit using the annual percentage increase for CPI, All Urban Consumers (all items, U.S. city average) as of September of the previous year.

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 2015	Prior year revisions	Annual percentage increase for 2015
Applied to all parameters but (1)	6.37%	5.07%	11.76%
CPI (all items, U.S. city average): Applied to (1)	1.45%	0.17%	1.62%

Part D Benefit Parameters

	2015	2016
Standard Benefit		
Deductible	$320	$360
Initial Coverage Limit	$2,960	$3,310
Out-of-Pocket Threshold	$4,700	$4,850
Total Covered Part D Spending at Out-of-Pocket Threshold for Non-Applicable Beneficiaries (2)	$6,680.00	$7,062.50
Estimated Total Covered Part D Spending for Applicable Beneficiaries (3)	$7,061.76	$7,515.22
Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit		
Generic/Preferred Multi-Source Drug	$2.65	$2.95
Other	$6.60	$7.40
Full Subsidy-Full Benefit Dual Eligible (FBDE) Individuals (5)		
Deductible	$0.00	$0.00
Copayments for Institutionalized Beneficiaries (category code 3)	$0.00	$0.00
Copayments for Beneficiaries Receiving Home and Community-Based Services (4) (category code 3)	$0.00	$0.00
Maximum Copayments for Non-Institutionalized Beneficiaries		
Up to or at 100% FPL (category code 2)		
Up to Out-of-Pocket Threshold (1)		
Generic/Preferred Multi-Source Drug (4)	$1.20	$1.20
Other (4)	$3.60	$3.60
Above Out-of-Pocket Threshold	$0.00	$0.00
Over 100% FPL (category code 1)		
Up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.65	$2.95
Other	$6.60	$7.40
Above Out-of-Pocket Threshold	$0.00	$0.00
Full Subsidy-Non-FBDE Individuals		
Eligible for QMB/SLMB/QI, SSI or applied and income at or below 135% FPL and resources ≤ $8,780 (individuals) or ≤ $13,930 (couples) (6) (category code 1)		
Deductible	$0.00	$0.00
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.65	$2.95
Other	$6.60	$7.40
Maximum Copayments above Out-of-Pocket Threshold	$0.00	$0.00

	2015	2016
Partial Subsidy		
Applied and income below 150% FPL and resources below $13,640 (individual) or $27,250 (couples) (6)		
Deductible	$66.00	$74.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.65	$2.95
Other	$6.60	$7.40
Retiree Drug Subsidy Amounts		
Cost Threshold	$320	$360
Cost Limit	$6,600	$7,400

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

(2) For beneficiaries who are not considered an "applicable beneficiary" as defined at section 1860D-14A(g)(1) and are not eligible for the coverage gap program, this is the amount of total drug spending required to reach the out-of-pocket threshold in the defined standard benefit.

(3) For beneficiaries who are considered an "applicable beneficiary" as defined at section 1860D-14A(g)(1) and are eligible for the coverage gap discount program, this is the estimated average amount of total drug spending required to reach the out-of-pocket threshold in the defined standard benefit.

(4) Per section 1860D-14(a)(1)(D)(i), full-benefit dual eligibles who would be institutionalized individuals (or couple) if the individual (couple) was not receiving home and community-based services qualify for zero cost-sharing as of January 1, 2015, as specified by the Secretary.

(5) The increases to the LIS deductible, generic/preferred multi-source drugs and other drugs copayments are applied to the unrounded 2015 values of $66.03, $1.19, and $3.58, respectively.

(6) The actual amount of resources allowable will be updated for contract year 2016.

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

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

Deductible: From $320 in 2015 and rounded to the nearest multiple of $5.

Initial Coverage Limit: From $2,960 in 2015 and rounded to the nearest multiple of $10.

Out-of-Pocket Threshold: From $4,700 in 2015 and rounded to the nearest multiple of $50. The "annual percentage increase" applied to the out-of-pocket threshold is CPI+2% which is the lesser of API and CPI+2% as required by the ACA.

Minimum Cost-Sharing in the Catastrophic Coverage Portion of the Benefit: From $2.65 per generic or preferred drug that is a multi-source drug, and $6.60 for all other drugs in 2015, and rounded to the nearest multiple of $0.05.

Maximum Copayments below the Out-of-Pocket Threshold for certain Low Income Full Subsidy Eligible Enrollees: From $2.65 per generic or preferred drug that is a multi-source drug, and $6.60 for all other drugs in 2015, and rounded to the nearest multiple of $0.05.

Deductible for Low Income (Partial) Subsidy Eligible Enrollees: From $66[1] in 2015 and rounded to the nearest $1.

Maximum Copayments above the Out-of-Pocket Threshold for Low Income (Partial) Subsidy Eligible Enrollees: From $2.65 per generic or preferred drug that is a multi-source drug, and $6.60 for all other drugs in 2015, and rounded to the nearest multiple of $0.05.

[1] Consistent with the statutory requirements of 1860D-14(a)(4)(B) of the Social Security Act, the update for the deductible for low income (partial) subsidy eligible enrollees is applied to the unrounded 2015 value of $66.03.

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

Section 1860D-14(a)(4) of the Social Security Act specifies that the annual percentage increase in the CPI, All Urban Consumers (all items, U.S. city average) as of September of the previous year is used to update the maximum copayments below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes that do not exceed 100 percent of the Federal poverty line. These copayments are increased from $1.20 per generic or preferred drug that is a multi-source drug, and $3.60 for all other drugs in 2015[2], and rounded to the nearest multiple of $0.05 and $0.10, respectively.

Section C. Calculation Methodology

Annual Percentage Increase

For the 2007 and 2008 contract years, the annual percentage increases, as defined in section 1860D-2(b)(6) of the Social Security Act, were based on the National Health Expenditure (NHE) prescription drug per capita estimates because sufficient Part D program data was not available. Beginning with the 2009 contract year, the annual percentage increases are based on Part D program data. For the 2016 contract year benefit parameters, Part D program data is used to calculate the annual percentage trend as follows:

$$\frac{August\ 2014 – July\ 2015}{August\ 2013 – July\ 2014} = \frac{\$3{,}263.64}{\$3{,}068.21} = 1.0637$$

In the formula, the average per capita cost for August 2013 – July 2014 ($3,068.21) is calculated from actual Part D prescription drug event (PDE) data, and the average per capita cost for August 2014 – July 2015 ($3,263.64) is calculated based on actual Part D PDE data incurred from August – December 2014 and projected through July 2015.

The 2016 benefit parameters reflect the 2015 annual percentage trend as well as a revision to the prior estimates for prior years' annual percentage increases. Based on updated NHE prescription drug per capita costs and PDE data, the annual percentage increases are now estimated as summarized by Table V-2.

[2] Consistent with the statutory requirements of 1860D-14(a)(4)(A) of the Social Security Act, the copayments are increased from the unrounded 2015 values of $1.19 per generic or preferred drug that is a multi-source drug, and $3.58 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%	4.17%
2010	3.02%	3.07%
2011	2.44%	2.48%
2012	2.44%	2.45%
2013	2.01%	1.95%
2014	−2.82%	−2.72%
2015	4.07%	9.18%

Accordingly, the 2016 benefit parameters reflect a multiplicative update of 5.07 percent for prior year revisions. In summary, the 2015 parameters outlined in Section A are updated by 11.76 percent for 2016 as summarized by Table V-3.

Table V-3. Annual Percentage Increase

Annual percentage trend for July 2015	6.37%
Prior year revisions	5.07%
Annual percentage increase for 2016	11.76%

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

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

The annual percentage increase in the CPI as of September of the previous year referenced in section 1860D-14(a)(4)(A)(ii) is interpreted to mean that, for contract year 2016, the September 2015 CPI should be used in the calculation of the index. To ensure that plan sponsors and CMS have sufficient time to incorporate the cost-sharing requirements into benefit, marketing material and systems development, the methodology to calculate this update includes an estimate of the September 2015 CPI based on the projected amount included in the President's FY2016 Budget.

The September 2014 value is from the Bureau of Labor Statistics. The annual percentage trend in CPI for contract year 2016 is calculated as follows:

$$\frac{\text{Projected September 2015 CPI}}{\text{Actual September 2014 CPI}} \; or \; \frac{241.481}{238.031} = 1.0145$$

(Source: President's FY2016 Budget and Bureau of Labor Statistics, Department of Labor)

The 2016 benefit parameters reflect the 2015 annual percentage trend in the CPI, as well as a revision to the prior estimate for the 2014 annual percentage increase. The 2015 parameter update reflected an annual percentage trend in CPI of 1.48 percent. Based on the actual reported CPI for September 2014, the September 2014 CPI increase is now estimated to be 1.66 percent. Accordingly, the 2016 update reflects a multiplicative 0.17 percent correction for prior year revisions. In summary, the cost sharing items outlined in Section B are updated by 1.62 percent for 2016 as summarized by Table V-4.

Table V-4. Cumulative Annual Percentage Increase in CPI

Annual percentage trend for September 2015	1.45%
Prior year revisions	0.17%
Annual percentage increase for 2015	1.62%

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

As outlined in §423.886(b)(3) of the regulations implementing the Part D benefit, the cost threshold and cost limit for qualified retiree prescription drug plans that end in years after 2006 are adjusted in the same manner as the annual Part D deductible and out-of-pocket threshold are adjusted under §423.104(d)(1)(ii) and (d)(5)(iii)(B), respectively. Specifically, they are adjusted by the "annual percentage increase" as defined previously in this document and the cost threshold is rounded the nearest multiple of $5 and the cost limit is rounded to the nearest multiple of $50. The cost threshold and cost limit are defined as $310 and $6,350, respectively, for plans that end in 2014, and, as $320 and $6,660, respectively, for plans that end in 2015. For 2016, the cost threshold is $360 and the cost limit is $7,400.

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

For 2016, the total covered Part D spending at out-of-pocket threshold for applicable beneficiaries is $7,515.22. It is calculated as the ICL plus 100 percent beneficiary cost sharing divided by the weighted gap coinsurance factor. The factor is calculated assuming 100 percent cost sharing in the deductible phase, 25 percent in the initial coverage phase and in the coverage gap, 58 percent for non-applicable (generic) drugs and 95 percent of the ingredient cost and sales tax for applicable (brand) drugs and 45 percent of the dispensing and vaccine administration fees for applicable (brand) drugs. In this estimate, it is assumed that the dispensing and vaccine administration fees account for 0.15 percent of the gross covered brand drug costs used by non-LIS beneficiaries in the coverage gap. Therefore, a 55 percent reduction in cost sharing for

dispensing and vaccine administration fees results in an overall reduction of 0.08 percent to 94.92 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:

$$\text{ICL} + \frac{100\%\text{ beneficiary cost sharing in the gap}}{\text{weighted gap coinsurance factor}} \quad or \quad \$3{,}310 + \frac{\$3{,}752.50}{89.234\%} = \$7{,}515.22$$

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 beneficiary cost sharing in the gap is calculated as follows:

OOP threshold − OOP costs up to the ICL *or* $4,850 − $1,097.50 = $3,752.50

- Weighted gap coinsurance factor is calculated as follows:

  (Brand GDCB % for non-LIS × 94.92% cost sharing for applicable drugs) + (Generic GDCB % for non-LIS × 58% cost sharing for non-applicable drugs)

  or

  (84.6% × 94.92%) + (15.4% × 58%) = 89.234%

- Brand GDCB % for non-LIS is the percentage of gross covered drug costs below the out-of-pocket threshold for applicable beneficiaries attributable to applicable (brand) drugs as reported on the 2014 PDEs.

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

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

  or

  94.92% = [(99.85% × 95%) + (0.15% × 45%)]

- Generic GDCB % for non-LIS is the percentage of gross covered drug costs below the out-of-pocket threshold for applicable beneficiaries attributable to non-applicable (generic) drugs as reported on the 2014 PDEs.

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

Attachment VI. RxHCC Risk Adjustment Factors

Table 1. RxHCC Model Relative Factors for Continuing Enrollees

		Continuing Enrollee (CE) RxHCC Model Segments				
Variable	**Disease Group**	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
Female						
0-34 Years		-	0.255	-	0.403	1.784
35-44 Years		-	0.426	-	0.617	1.840
45-54 Years		-	0.522	-	0.708	1.646
55-59 Years		-	0.507	-	0.681	1.534
60-64 Years		-	0.468	-	0.624	1.439
65-69 Years		0.270	-	0.398	-	1.520
70-74 Years		0.270	-	0.402	-	1.431
75-79 Years		0.258	-	0.393	-	1.341
80-84 Years		0.248	-	0.369	-	1.263
85-89 Years		0.233	-	0.340	-	1.183
90-94 Years		0.204	-	0.279	-	1.072
95 Years or Over		0.149	-	0.195	-	0.880
Male						
0-34 Years		-	0.213	-	0.438	1.733
35-44 Years		-	0.345	-	0.570	1.736
45-54 Years		-	0.433	-	0.618	1.583
55-59 Years		-	0.448	-	0.592	1.450
60-64 Years		-	0.419	-	0.541	1.337
65-69 Years		0.275	-	0.331	-	1.395
70-74 Years		0.275	-	0.346	-	1.330
75-79 Years		0.235	-	0.337	-	1.283
80-84 Years		0.184	-	0.325	-	1.225
85-89 Years		0.143	-	0.289	-	1.164
90-94 Years		0.105	-	0.256	-	1.084
95 Years or Over		0.085	-	0.216	-	0.945
Originally Disabled Interactions with Sex						
Originally Disabled_Female		0.084	-	0.170	-	0.050
Originally Disabled_Male		-	-	0.114	-	0.050
Variable	**Description Label**					
RXHCC1	HIV/AIDS	2.431	2.844	3.139	3.594	1.802
RXHCC5	Opportunistic Infections	0.205	0.122	0.128	0.175	0.104

Continuing Enrollee (CE) RxHCC Model Segments

Variable	Disease Group	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
RXHCC15	Chronic Myeloid Leukemia	5.276	5.842	6.032	7.795	3.566
RXHCC16	Multiple Myeloma and Other Neoplastic Disorders	2.873	3.191	2.404	2.870	0.942
RXHCC17	Secondary Cancers of Bone, Lung, Brain, and Other Specified Sites; Liver Cancer	1.040	0.916	1.137	1.058	0.320
RXHCC18	Lung, Kidney, and Other Cancers	0.219	0.239	0.275	0.271	0.051
RXHCC19	Breast and Other Cancers and Tumors	0.081	0.040	0.074	0.081	0.042
RXHCC30	Diabetes with Complications	0.379	0.418	0.446	0.545	0.381
RXHCC31	Diabetes without Complication	0.249	0.229	0.298	0.323	0.268
RXHCC40	Specified Hereditary Metabolic/Immune Disorders	2.151	7.700	2.644	8.226	0.477
RXHCC41	Pituitary, Adrenal Gland, and Other Endocrine and Metabolic Disorders	0.114	0.168	0.057	0.172	0.060
RXHCC42	Thyroid Disorders	0.078	0.146	0.076	0.145	0.053
RXHCC43	Morbid Obesity	0.084	0.030	0.065	0.065	0.138
RXHCC45	Disorders of Lipoid Metabolism	0.067	0.079	0.116	0.167	0.076
RXHCC54	Chronic Viral Hepatitis C	4.273	4.273	4.231	4.231	4.231
RXHCC55	Chronic Viral Hepatitis, Except Hepatitis C	0.289	0.420	0.835	0.568	0.281
RXHCC65	Chronic Pancreatitis	0.202	0.160	0.112	0.109	0.120
RXHCC66	Pancreatic Disorders and Intestinal Malabsorption, Except Pancreatitis	0.091	0.160	0.076	0.109	0.050
RXHCC67	Inflammatory Bowel Disease	0.419	0.330	0.344	0.600	0.152
RXHCC68	Esophageal Reflux and Other Disorders of Esophagus	0.111	0.081	0.156	0.171	0.075
RXHCC80	Aseptic Necrosis of Bone	0.117	0.173	0.123	0.190	0.108
RXHCC82	Psoriatic Arthropathy and Systemic Sclerosis	0.627	0.646	0.963	1.496	0.429
RXHCC83	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	0.277	0.319	0.354	0.612	0.148

Continuing Enrollee (CE) RxHCC Model Segments

Variable	Disease Group	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
RXHCC84	Systemic Lupus Erythematosus, Other Connective Tissue Disorders, and Inflammatory Spondylopathies	0.186	0.283	0.213	0.312	0.121
RXHCC87	Osteoporosis, Vertebral and Pathological Fractures	0.051	0.138	0.130	0.191	-
RXHCC95	Sickle Cell Anemia	0.090	0.211	0.086	0.622	0.358
RXHCC96	Myelodysplastic Syndromes and Myelofibrosis	0.555	0.793	0.547	0.646	0.477
RXHCC97	Immune Disorders	0.305	0.284	0.312	0.358	0.247
RXHCC98	Aplastic Anemia and Other Significant Blood Disorders	0.090	0.106	0.058	0.209	0.056
RXHCC111	Alzheimer's Disease	0.471	0.273	0.209	0.130	-
RXHCC112	Dementia, Except Alzheimer's Disease	0.207	0.102	0.054	-	-
RXHCC130	Schizophrenia	0.286	0.385	0.470	0.778	0.212
RXHCC131	Bipolar Disorders	0.286	0.348	0.331	0.533	0.212
RXHCC132	Major Depression	0.171	0.303	0.220	0.392	0.198
RXHCC133	Specified Anxiety, Personality, and Behavior Disorders	0.171	0.230	0.184	0.389	0.117
RXHCC134	Depression	0.148	0.177	0.145	0.241	0.117
RXHCC135	Anxiety Disorders	0.064	0.115	0.098	0.187	0.099
RXHCC145	Autism	0.171	0.230	0.396	0.437	0.117
RXHCC146	Profound or Severe Intellectual Disability/Developmental Disorder	0.060	0.099	0.396	0.323	-
RXHCC147	Moderate Intellectual Disability/Developmental Disorder	0.060	-	0.245	0.185	-
RXHCC148	Mild or Unspecified Intellectual Disability/Developmental Disorder	-	-	0.115	0.050	-
RXHCC156	Myasthenia Gravis, Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.304	0.501	0.336	0.573	0.143
RXHCC157	Spinal Cord Disorders	0.134	0.149	0.104	0.080	0.079

Continuing Enrollee (CE) RxHCC Model Segments

Variable	Disease Group	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
RXHCC159	Inflammatory and Toxic Neuropathy	0.216	0.456	0.224	0.358	0.084
RXHCC160	Multiple Sclerosis	1.470	2.464	1.558	3.345	0.722
RXHCC161	Parkinson's and Huntington's Diseases	0.502	0.729	0.321	0.422	0.193
RXHCC163	Intractable Epilepsy	0.291	0.461	0.261	0.828	0.047
RXHCC164	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	0.114	0.066	0.047	0.155	-
RXHCC165	Convulsions	0.058	0.044	0.035	0.096	-
RXHCC166	Migraine Headaches	0.135	0.221	0.140	0.162	0.121
RXHCC168	Trigeminal and Postherpetic Neuralgia	0.116	0.280	0.144	0.212	0.188
RXHCC185	Primary Pulmonary Hypertension	0.543	1.488	0.544	1.264	0.235
RXHCC186	Congestive Heart Failure	0.178	0.130	0.248	0.140	0.142
RXHCC187	Hypertension	0.152	0.079	0.221	0.111	0.074
RXHCC188	Coronary Artery Disease	0.143	0.061	0.157	0.033	0.021
RXHCC193	Atrial Arrhythmias	0.173	0.096	0.062	0.019	0.049
RXHCC206	Cerebrovascular Disease, Except Hemorrhage or Aneurysm	0.058	-	0.045	-	-
RXHCC207	Spastic Hemiplegia	0.159	0.268	0.053	0.151	-
RXHCC215	Venous Thromboembolism	0.074	0.127	0.032	0.120	0.028
RXHCC216	Peripheral Vascular Disease	-	-	0.058	0.023	-
RXHCC225	Cystic Fibrosis	0.311	3.162	0.359	3.216	0.218
RXHCC226	Chronic Obstructive Pulmonary Disease and Asthma	0.311	0.158	0.359	0.265	0.191
RXHCC227	Pulmonary Fibrosis and Other Chronic Lung Disorders	0.157	0.158	0.136	0.248	0.089
RXHCC241	Diabetic Retinopathy	0.229	0.174	0.164	0.095	0.118
RXHCC243	Glaucoma	0.256	0.186	0.296	0.244	0.222
RXHCC260	Kidney Transplant Status	0.329	0.164	0.384	0.350	0.213
RXHCC261	Dialysis Status	0.180	0.295	0.352	0.752	0.231
RXHCC262	Chronic Kidney Disease Stage 5	0.100	0.085	0.107	0.092	0.068
RXHCC263	Chronic Kidney Disease Stage 4	0.100	0.085	0.098	0.092	0.068

		Continuing Enrollee (CE) RxHCC Model Segments				
Variable	**Disease Group**	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
RXHCC311	Chronic Ulcer of Skin, Except Pressure	0.124	0.150	0.060	0.085	0.048
RXHCC314	Pemphigus	0.299	0.574	0.197	0.309	0.085
RXHCC316	Psoriasis, Except with Arthropathy	0.164	0.206	0.297	0.521	0.199
RXHCC355	Narcolepsy and Cataplexy	0.653	1.030	0.664	1.215	0.252
RXHCC395	Lung Transplant Status	1.173	0.481	0.962	0.928	0.592
RXHCC396	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	0.804	0.381	0.585	0.395	0.273
RXHCC397	Pancreas Transplant Status	0.284	0.164	0.384	0.320	0.213
Non-Aged Disease Interactions						
Variable	**Disease Group**					
NonAged_RXHCC1	NonAged * HIV/AIDS	-	-	-	-	1.279
NonAged_RXHCC130	NonAged * Schizophrenia	-	-	-	-	0.268
NonAged_RXHCC131	NonAged * Bipolar Disorders	-	-	-	-	0.268
NonAged_RXHCC132	NonAged * Major Depression	-	-	-	-	0.179
NonAged_RXHCC133	NonAged * Specified Anxiety, Personality, and Behavior Disorders	-	-	-	-	0.157
NonAged_RXHCC134	NonAged * Depression	-	-	-	-	0.111
NonAged_RXHCC135	NonAged * Anxiety Disorders	-	-	-	-	0.115
NonAged_RXHCC160	NonAged * Multiple Sclerosis	-	-	-	-	1.146
NonAged_RXHCC163	NonAged * Intractable Epilepsy	-	-	-	-	0.174

Note: The 2013 denominator of $1002.93 used to calculate the RxHCC model factors is the national annual cost under the model. This Part D denominator is based on the combined PDP and MA-PD populations. 'Originally Disabled' is defined as originally entitled to Medicare by disability only and are now entitled due to age.

Source: RTI Analysis of 100% 2013 PDE, 2012 Carrier NCH, 2012 Inpatient SAF, 2012 Outpatient SAF, 2013 HPMS, 2013 CME, 2012-2013 Denominator, Part D Intermediate File, and 2012 Medicare Advantage Diagnoses File.

Table 2. RxHCC Model Relative Factors for New Enrollees, Non-Low Income

Variable	Not Concurrently ESRD and Not Originally Disabled	Concurrently ESRD Only – Not Originally Disabled	Originally Disabled Only – Not Concurrently ESRD	Originally Disabled and Concurrently ESRD
Female				
0-34 Years	0.648	0.648	-	-
35-44 Years	1.034	1.056	-	-
45-54 Years	1.219	1.314	-	-
55-59 Years	1.162	1.563	-	-
60-64 Years	1.162	1.726	-	-
65 Years	0.577	1.778	1.079	1.778
66 Years	0.626	1.778	1.081	1.778
67 Years	0.633	1.778	1.081	1.778
68 Years	0.663	1.778	1.081	1.778
69 Years	0.672	1.778	1.081	1.778
70-74 Years	0.674	1.778	0.896	1.778
75-79 Years	0.658	1.778	0.658	1.778
80-84 Years	0.600	1.778	0.600	1.778
85-89 Years	0.461	1.778	0.461	1.778
90-94 Years	0.219	1.778	0.219	1.778
95 Years or Over	0.219	1.778	0.219	1.778
Male				
0-34 Years	0.353	0.641	-	-
35-44 Years	0.741	0.741	-	-
45-54 Years	0.976	1.208	-	-
55-59 Years	0.999	1.379	-	-
60-64 Years	0.983	1.548	-	-
65 Years	0.584	1.751	0.898	1.751
66 Years	0.649	1.751	0.852	1.751
67 Years	0.666	1.751	0.835	1.751
68 Years	0.684	1.751	0.800	1.751
69 Years	0.718	1.751	0.800	1.751
70-74 Years	0.723	1.751	0.774	1.751
75-79 Years	0.696	1.751	0.696	1.751
80-84 Years	0.575	1.751	0.575	1.751
85-89 Years	0.457	1.751	0.457	1.751
90-94 Years	0.343	1.751	0.343	1.751
95 Years or Over	0.343	1.751	0.343	1.751

Notes: The 2013 denominator of $1002.93 used to calculate the RxHCC model factors is the national annual cost under the model. This Part D denominator is based on the combined PDP and MA-PD populations. 'Originally Disabled' is defined as originally entitled to Medicare by disability only and are now entitled due to age. 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% 2013 PDE, 2012 NCH, 2013 HPMS, 2013 CME, 2012-2013 Denominator, and Part D Intermediate File.

Table 3. RxHCC Model Relative Factors for New Enrollees, Low Income

Variable	Not Concurrently ESRD and Not Originally Disabled	Concurrently ESRD Only – Not Originally Disabled	Originally Disabled Only – Not Concurrently ESRD	Originally Disabled and Concurrently ESRD
Female				
0-34 Years	0.999	1.890	-	-
35-44 Years	1.444	1.894	-	-
45-54 Years	1.470	2.010	-	-
55-59 Years	1.337	2.053	-	-
60-64 Years	1.264	1.974	-	-
65 Years	0.931	2.102	1.138	2.102
66 Years	0.622	2.102	0.892	2.102
67 Years	0.622	2.102	0.892	2.102
68 Years	0.622	2.102	0.892	2.102
69 Years	0.622	2.102	0.742	2.102
70-74 Years	0.644	2.102	0.742	2.102
75-79 Years	0.706	2.102	0.706	2.102
80-84 Years	0.706	2.102	0.706	2.102
85-89 Years	0.706	2.102	0.706	2.102
90-94 Years	0.559	2.102	0.559	2.102
95 Years or Over	0.559	2.102	0.559	2.102
Male				
0-34 Years	0.867	2.016	-	-
35-44 Years	1.228	1.925	-	-
45-54 Years	1.255	2.022	-	-
55-59 Years	1.103	1.836	-	-
60-64 Years	1.038	1.691	-	-
65 Years	0.775	1.711	0.941	1.711
66 Years	0.481	1.711	0.515	1.711
67 Years	0.481	1.711	0.515	1.711
68 Years	0.481	1.711	0.515	1.711
69 Years	0.481	1.711	0.515	1.711
70-74 Years	0.523	1.711	0.555	1.711
75-79 Years	0.557	1.711	0.557	1.711
80-84 Years	0.546	1.711	0.546	1.711
85-89 Years	0.527	1.711	0.527	1.711
90-94 Years	0.441	1.711	0.441	1.711
95 Years or Over	0.441	1.711	0.441	1.711

Notes: The 2013 denominator of $1002.93 used to calculate the RxHCC model factors is the national annual cost under the model. This Part D denominator is based on the combined PDP and MA-PD populations. 'Originally Disabled' is defined as originally entitled to Medicare by disability only and are now entitled due to age. 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% 2013 PDE, 2012 NCH, 2013 HPMS, 2013 CME, 2012-2013 Denominator, and Part D Intermediate File.

Table 4. RxHCC Model Relative Factors for New Enrollees, Institutional

Variable	Not Concurrently ESRD	Concurrently ESRD
Female		
0-34 Years	2.452	2.738
35-44 Years	2.452	2.738
45-54 Years	2.423	2.738
55-59 Years	2.423	2.738
60-64 Years	2.227	2.738
65 Years	2.267	2.738
66 Years	2.022	2.738
67 Years	2.022	2.738
68 Years	2.022	2.738
69 Years	2.022	2.738
70-74 Years	1.842	2.738
75-79 Years	1.648	2.738
80-84 Years	1.564	2.738
85-89 Years	1.304	2.738
90-94 Years	1.304	2.738
95 Years or Over	1.304	2.738
Male		
0-34 Years	2.179	2.644
35-44 Years	2.530	2.644
45-54 Years	2.319	2.644
55-59 Years	2.112	2.644
60-64 Years	2.017	2.644
65 Years	2.025	2.644
66 Years	1.804	2.644
67 Years	1.804	2.644
68 Years	1.804	2.644
69 Years	1.804	2.644
70-74 Years	1.794	2.644
75-79 Years	1.700	2.644
80-84 Years	1.560	2.644
85-89 Years	1.445	2.644
90-94 Years	1.445	2.644
95 Years or Over	1.445	2.644

Notes: The 2013 denominator of $1002.93 used to calculate the RxHCC model factors is the national annual cost under the model. This Part D denominator is based on the combined PDP and MA-PD populations. 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% 2013 PDE, 2012 NCH, 2013 HPMS, 2013 CME, 2012-2013 Denominator, and Part D Intermediate File.

Table 5. List of Disease Hierarchies for the RxHCC Model

Prescription Drug Hierarchical Condition Category (RxHCC)	If the Disease Group is Listed in this column…	…Then drop the Disease Group(s) listed in this column
	Prescription Drug Hierarchical Condition Category (RxHCC) LABEL	
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.

Table 6. Comparison of Current and 2016 RxHCC Risk Adjustment Model RxHCCs

Current RxHCC Risk Adjustment Model RxHCCs		2016 RxHCC Risk Adjustment Model RxHCCs		
RxHCC	**Description**	**RxHCC**	**Description**	**Category Short Name**
1	HIV/AIDS	1	HIV/AIDS	Infection
5	Opportunistic Infections	5	Opportunistic Infections	
8	Chronic Myeloid Leukemia	*15*	*Chronic Myeloid Leukemia*	Neoplasm
9	Multiple Myeloma and Other Neoplastic Disorders	*16*	*Multiple Myeloma and Other Neoplastic Disorders*	
		17	**Secondary Cancers of Bone, Lung, Brain, and Other Specified Sites; Liver Cancer**	
10	Breast, Lung, and Other Cancers and Tumors	*18*	*Lung, Kidney, and Other Cancers*	
11	Prostate and Other Cancers and Tumors	*19*	*Breast and Other Cancers and Tumors*	
14	Diabetes with Complications	30	Diabetes with Complications	Diabetes
15	Diabetes without Complication	31	Diabetes without Complication	
18	Diabetes Insipidus and Other Endocrine and Metabolic Disorders	*40*	*Specified Hereditary Metabolic/Immune Disorders*	Metabolic
19	Pituitary, Adrenal Gland, and Other Endocrine and Metabolic Disorders	*41*	*Pituitary, Adrenal Gland, and Other Endocrine and Metabolic Disorders*	
20	Thyroid Disorders	42	Thyroid Disorders	
21	Morbid Obesity	43	Morbid Obesity	
23	Disorders of Lipoid Metabolism	45	Disorders of Lipoid Metabolism	
		54	**Chronic Viral Hepatitis C**	Liver
25	Chronic Viral Hepatitis	*55*	*Chronic Viral Hepatitis, Except Hepatitis C*	
30	Chronic Pancreatitis	65	Chronic Pancreatitis	Gastrointestinal
31	Pancreatic Disorders and Intestinal Malabsorption, Except Pancreatitis	66	Pancreatic Disorders and Intestinal Malabsorption, Except Pancreatitis	
32	Inflammatory Bowel Disease	67	Inflammatory Bowel Disease	
33	Esophageal Reflux and Other Disorders of Esophagus	68	Esophageal Reflux and Other Disorders of Esophagus	
38	Aseptic Necrosis of Bone	80	Aseptic Necrosis of Bone	Musculoskeletal
40	Psoriatic Arthropathy	*82*	*Psoriatic Arthropathy and Systemic Sclerosis*	
41	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	83	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	
42	Systemic Lupus Erythematosus, Other Connective Tissue Disorders, and Inflammatory Spondylopathies	84	Systemic Lupus Erythematosus, Other Connective Tissue Disorders, and Inflammatory Spondylopathies	
45	Osteoporosis, Vertebral and Pathological Fractures	87	Osteoporosis, Vertebral and Pathological Fractures	
47	Sickle Cell Anemia	95	Sickle Cell Anemia	Blood
48	Myelodysplastic Syndromes, Except High-Grade	*96*	*Myelodysplastic Syndromes and Myelofibrosis*	
49	Immune Disorders	97	Immune Disorders	
50	Aplastic Anemia and Other Significant Blood Disorders	*98*	*Aplastic Anemia and Other Significant Blood Disorders*	

Current RxHCC Risk Adjustment Model RxHCCs		2016 RxHCC Risk Adjustment Model RxHCCs		
RxHCC	**Description**	**RxHCC**	**Description**	**Category Short Name**
54	Alzheimer's Disease	111	Alzheimer's Disease	Cognitive
55	Dementia, Except Alzheimer's Disease	112	Dementia, Except Alzheimer's Disease	
58	Schizophrenia	130	Schizophrenia	Psychiatric
59	Bipolar Disorders	131	Bipolar Disorders	
60	Major Depression	132	Major Depression	
61	Specified Anxiety, Personality, and Behavior Disorders	133	Specified Anxiety, Personality, and Behavior Disorders	
62	Depression	134	Depression	
63	Anxiety Disorders	135	Anxiety Disorders	
65	Autism	145	Autism	Developmental Disorder
66	Profound or Severe Mental Retardation/Developmental Disability	146	Profound or Severe Intellectual Disability/Developmental Disorder	
67	Moderate Mental Retardation/Developmental Disability	147	Moderate Intellectual Disability/Developmental Disorder	
68	Mild or Unspecified Mental Retardation/Developmental Disability	148	Mild or Unspecified Intellectual Disability/Developmental Disorder	
71	Myasthenia Gravis, Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	156	Myasthenia Gravis, Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	Neurological
72	Spinal Cord Disorders	*157*	*Spinal Cord Disorders*	
74	Polyneuropathy	*159*	*Inflammatory and Toxic Neuropathy*	
75	Multiple Sclerosis	160	Multiple Sclerosis	
76	Parkinson's Disease	*161*	*Parkinson's and Huntington's Diseases*	
78	Intractable Epilepsy	163	Intractable Epilepsy	
79	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	164	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	
80	Convulsions	165	Convulsions	
81	Migraine Headaches	166	Migraine Headaches	
83	Trigeminal and Postherpetic Neuralgia	168	Trigeminal and Postherpetic Neuralgia	
86	Pulmonary Hypertension and Other Pulmonary Heart Disease	*185*	*Primary Pulmonary Hypertension*	Heart
87	Congestive Heart Failure	*186*	*Congestive Heart Failure*	
88	Hypertension	187	Hypertension	
89	Coronary Artery Disease	188	Coronary Artery Disease	
93	Atrial Arrhythmias	193	Atrial Arrhythmias	
97	Cerebrovascular Disease, Except Hemorrhage or Aneurysm	206	Cerebrovascular Disease, Except Hemorrhage or Aneurysm	Cerebrovascular Disease
98	Spastic Hemiplegia	207	Spastic Hemiplegia	
100	Venous Thromboembolism	215	Venous Thromboembolism	Vascular
101	Peripheral Vascular Disease	216	Peripheral Vascular Disease	

Current RxHCC Risk Adjustment Model RxHCCs		2016 RxHCC Risk Adjustment Model RxHCCs		
RxHCC	**Description**	**RxHCC**	**Description**	**Category Short Name**
103	Cystic Fibrosis	225	Cystic Fibrosis	Lung
104	Chronic Obstructive Pulmonary Disease and Asthma	226	Chronic Obstructive Pulmonary Disease and Asthma	
105	Pulmonary Fibrosis and Other Chronic Lung Disorders	227	Pulmonary Fibrosis and Other Chronic Lung Disorders	
106	Gram-Negative/Staphylococcus Pneumonia and Other Lung Infections			
111	Diabetic Retinopathy	241	Diabetic Retinopathy	Eye
113	Open-Angle Glaucoma	243	Open-Angle Glaucoma	
120	Kidney Transplant Status	260	Kidney Transplant Status	Kidney
121	Dialysis Status	261	Dialysis Status	
122	Chronic Kidney Disease Stage 5	262	Chronic Kidney Disease Stage 5	
123	Chronic Kidney Disease Stage 4	263	Chronic Kidney Disease Stage 4	
124	Chronic Kidney Disease Stage 3			
125	Chronic Kidney Disease Stage 1, 2, or Unspecified			
126	Nephritis			
142	Chronic Ulcer of Skin, Except Pressure	311	Chronic Ulcer of Skin, Except Pressure	Skin
145	Pemphigus	314	Pemphigus	
147	Psoriasis, Except with Arthropathy	316	Psoriasis, Except with Arthropathy	
156	Narcolepsy and Cataplexy	355	Narcolepsy and Cataplexy	Sleep
166	Lung Transplant Status	395	Lung Transplant Status	Transplant
167	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	*396*	*Major Organ Transplant Status, Except Lung, Kidney, and Pancreas*	
168	Pancreas Transplant Status	397	Pancreas Transplant Status	

Note: RxHCCs were re-numbered to leave spaces of RxHCC numbers between disease groups (category short names). This will allow for future changes to the classification without requiring the entire set of RxHCCs to be re-numbered.

Source: RTI International

Attachment VII: 2016 Call Letter

2016 Announcement
Table of Contents

How to Use This Call Letter

The 2016 Call Letter contains information on the Part C and Part D programs that Medicare Advantage Organizations (MAOs) and Part D sponsors need to take into consideration in preparing their 2016 bids. Guidance on Medicare-Medicaid Plan (MMP)-specific requirements was released on February 23, 2015 (refer to https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/2016MMPAnnualRequirements.pdf). CMS will provide additional guidance regarding the applicability of this final Call Letter to MMPs following its release.

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) continued program vibrancy and stability, 2) value for beneficiaries and tax-payers, 3) better quality care for beneficiaries, and 4) improved compliance for plans and sponsors. 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: Nishamarie Sherry at Nishamarie.Sherry@cms.hhs.gov (Part C issues) and Lucia Patrone at Lucia.Patrone@cms.hhs.gov (Part D issues).

Section I – Parts C and D

Annual Calendar

Below is a combined calendar listing of side-by-side key dates and timelines for operational activities that pertain to 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.

2016*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
January 13, 2015	Release of the Contract Year (CY) 2016 MA/MA-PD/PDP and 1876 Cost Plan Expansion Applications	✓	✓	✓	
January 13 & 15, 2015	Industry Training and Technical Assistance for CY 2016 Model of Care (MOC) Submissions	✓			
January 14 & 21, 2015	Industry training on 2016 Applications	✓	✓	✓	
January 30, 2015	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 18, 2015	2016 Expansion Applications are due to CMS by 8 PM EST	✓	✓	✓	
February 18, 2015	Renewing Dual Eligible Special Needs Plans (D-SNPs) required to complete attestations in HPMS	✓			
February 18, 2015	Special Needs Plans (SNPs), whose MOC approval expires at the end of CY 2015, are required to resubmit their MOCs for NCQA review.	✓			
Late February, 2015	Submission of meaningful use HITECH attestation for qualifying MA Employer Plans and MA-affiliated hospitals	✓			
Late February, 2015	D-SNPs that requested to offer additional supplemental benefits are notified by CMS as to whether they meet required qualifications				
March 2, 2015	CMS releases guidance concerning updates to Parent Organization designations in HPMS	✓	✓	✓	✓
March 17, 2015	Parent Organization Update requests from sponsors due to CMS (instructional memo released in February 2015)	✓	✓		✓
Mid-Late March, 2015	Release of CY 2016 Formulary Training Video and 2016 Formulary Reference File (FRF)	✓	✓	✓	✓
March 27, 2015	Release of the Fiscal Soundness Module in HPMS	✓	✓		✓
March/April, 2015	CMS coordinates with MAOs and PDP Sponsors to resolve low enrollment issues for CY 2016	✓	✓	✓	

2016*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
Early April, 2015	CY 2016 Out Of Pocket Cost (OOPC) model and OOPC estimates for each plan made available to MAOs and Part D sponsors for download from the CMS website. Information will assist plans in meeting meaningful difference and MA Total Beneficiary Cost (TBC) requirements prior to bid submission	✓	✓		
Early April, 2015	Information about renewal options for contract year 2016 (including HPMS crosswalk charts) provided to plans	✓	✓		
April 2015	Conference call with industry to discuss the 2016 Call Letter	✓	✓	✓	✓
April 6, 2015	2016 Final Call Letter released 2016 Final Announcement of Medicare Advantage Capitation Rates and MA and Part D Payment Policies released	✓	✓	✓	✓
April 8, 2015	Industry training on CY 2016 Formulary Submission	✓	✓	✓	✓
April 10, 2015	Release of the 2016 Plan Benefit Package (PBP) online training module	✓	✓	✓	✓
April 10, 2015	Release of the 2016 Plan Creation Module, PBP, and Bid Pricing Tool (BPT) software in HPMS	✓	✓	✓	✓
April 15, 2015	Deadline for MAOs to submit requests for full contract consolidations for CY 2016	✓		✓	
Mid-April, 2015	Release of HPMS Memo: Contract Year 2016 Medicare Advantage Bid Review and Operations Guidance	✓			
April 20, 2015	Release of the 2016 Medication Therapy Management (MTM) Program Submission in HPMS		✓		✓
April 22, 2015	Industry training dedicated to Annual Part D Formulary and Benefit Compliance Training	✓	✓	✓	✓
Mid/Late April, 2015	Plan submit requests for tiering of medical benefits and justifications to CMS for review and consideration	✓			
Late April, 2015	Total Beneficiary Cost data for CY 2016 Bid Preparation Release	✓			
May, 2015	Final ANOC/EOC, LIS rider, Part D EOB, formularies, transition notice, provider directory, and pharmacy directory models for 2016 available for all organizations	✓	✓	✓	✓
May 1, 2015	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	✓	✓	✓	
May 4, 2015	Deadline for submission of CY 2016 MTM Programs from all sponsors offering Part D including Medicare-Medicaid Plans (11:59pm PDT)		✓		✓
May 6, 2015	2015 Medicare Advantage & Prescription Drug Plan Spring Conference & Webcast	✓	✓	✓	
May 8, 2015	Release of the 2016 Bid Upload Functionality in HPMS	✓	✓	✓	✓
May 8, 2015	Release of 2016 Actuarial Certification Module in HPMS	✓	✓	✓	

2016*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
May 8, 2015	Release of 2016 Formulary Submission Module in HPMS	✓	✓	✓	✓
Mid-Late May 2015	Release of CY 2016 Formulary Reference File Update	✓	✓	✓	✓
May 29, 2015	Plans/Part D Sponsors begin to upload agent/broker compensation information in HPMS	✓	✓	✓	✓
May 29, 2015	Release of the 2016 Marketing Module in HPMS. Plans/Part D Sponsors begin to submit 2016 marketing materials	✓	✓	✓	✓
Late May/Early June, 2015	Release of the 2016 Medicare Marketing Guidelines in HPMS (Chapter 3 of the Medicare Managed Care Manual/Chapter 2 of the Prescription Drug Benefit Manual)	✓	✓	✓	✓
Late May/June, 2015	CMS sends qualification determinations to applicants based on review of the 2016 applications for new contracts or service area expansions	✓	✓		
June 1, 2015	Release of the 2014 DIR Submission Module in HPMS	✓	✓		
June 1, 2015	Deadline for submission of CY 2016 bids for all MA plans, MA-PD plans, PDP, cost-based plans offering a Part D benefit, Medicare-Medicaid Plans (MMPs), "800 series" EGWP and direct contract EGWP applicants and renewing organizations; deadline for cost-based plans wishing to appear in the 2016 Medicare Plan Finder to submit PBPs (11:59 p.m. PDT) Deadline for submission of CY 2016 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 2016 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 2016	✓	✓	✓	✓ *Bid related items only*
Early June to Early September, 2015	CMS completes review and approval of 2016 bid data. Submit attestations, contracts, initial actuarial certifications, and final actuarial certifications	✓	✓	✓	
June 2, 2015 - June 5, 2015	Window for submitting first round of crosswalk exception requests through HPMS	✓	✓	✓	
June 5, 2015	Deadline for submission of CY 2016 Supplemental Formulary files, Free First Fill file, Partial Gap file, Excluded Drug file, Over the Counter (OTC) drug file, and Home Infusion file through HPMS (12 p.m. EDT)	✓	✓	✓	✓
June 5, 2015	Deadline for submission of Additional Demonstration Drug (ADD) file *(Medicare-Medicaid Plans Only)*(12 p.m. EDT)				✓
Late June, 2015	Release of the CY 2016 Summary of Benefits (SB) hard copy change request module in HPMS	✓	✓	✓	

2016*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
Late June, 2015	CMS sends an acknowledgement letter to all MA, MA-PD, PDP and Medicare cost-based plans that are non-renewing or reducing their service area	✓	✓	✓	
June 30, 2015	Final date to submit CY 2015 marketing materials to guarantee timely CMS review and approval. Plans/Part D Sponsors may continue to submit CY 2015 file and use materials as these may be filed in HPMS five calendar days prior to their use	✓	✓	✓	
Early July, 2015	2016 Plan Finder pricing test submissions begin	✓	✓	✓	✓
July 1, 2015	Deadline for D-SNPs to upload required State Medicaid Agency Contract and Contract Matrix to HPMS	✓	✓	✓	
July 1, 2015	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, 2015	Plans' deadline to submit non-model Low Income Subsidy (LIS) riders to the appropriate Regional Office for review.	✓			
Mid July 2015	Release of CY 2016 FRF Update in advance of the Limited Formulary Update Window	✓	✓	✓	✓
Mid-Late July, 2015	CY 2016 Limited Formulary Update Window	✓	✓	✓	✓
Late July, 2015	Submission deadline for agent/broker compensation information via HPMS	✓	✓	✓	✓
Late July 2015	Second window for submitting HPMS crosswalk exceptions	✓	✓	✓	
Late July / Early August, 2015	CMS releases the 2016 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, 2015	Rebate reallocation period begins after release of the above bid amounts	✓	✓	✓	
No Later Than July 31, 2015	CMS informs currently contracted organizations of its decision to not renew a contract for 2016	✓	✓	✓	
August 1, 2015	Plans expected to submit model Low Income Subsidy (LIS) riders in HPMS	✓	✓	✓	
August 20-24, 2015	CY 2016 preview of the 2016 *Medicare & You* plan data in HPMS prior to printing of the CMS publication (not applicable to EGWPs)	✓	✓		✓
August 26 – August 28, 2015	First CY 2016 Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HPMS	✓	✓	✓	✓ *MPF only*
August 31, 2015	2016 MTM Program Annual Review completed		✓		✓
Late August 2015	Contracting Materials submitted to CMS	✓	✓	✓	
End of August/Early September 2015	Plan preview periods of Star Ratings in HPMS	✓	✓	✓	

2016*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
Early September 2015	CMS begins accepting plan correction requests upon contract approval	✓	✓	✓	
Mid- September 2015	All 2016 contracts fully executed (signed by both parties: Part C/Part D Sponsor and CMS)	✓	✓	✓	
September 8 - 11, 2015	Second CY 2016 Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HPMS	✓	✓	✓	✓ *MPF only*
September 16 -30, 2015	CMS mails the 2016 *Medicare & You* handbook to Medicare beneficiaries	✓	✓	✓	✓
Late September, 2015	D-SNPs that requested review for FIDE SNP determination notified as to whether they meet required qualifications	✓			
September 23, 2015	Deadline for Part D sponsors, cost-based, MA and MA-PD organizations to request a plan correction to the plan benefit package (PBP) via HPMS. Deadline for Part D sponsors, cost-based, MA and MA-PD organizations to request any SB hard copy change	✓	✓	✓	
September 30, 2015	The following documents are due to current enrollees by September 30, 2015: • Standardized Annual Notice of Change/Evidence of Coverage (ANOC/EOC) for all MA, MA-PD, PDP, and cost-based plans offering 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 documents permitted to be sent prior to October 1, 2015	✓	✓	✓	✓
Mid October, 2015	Release of the online CY 2017 Notice of Intent to Apply for a New Contract or a Contract Expansion (MA, MA-PD, PDPs, and "800 series" EGWPs and Direct Contract EGWPs)	✓	✓	✓	✓
October 1, 2015	Organizations may begin marketing their CY 2016 plan benefits. Note: Once an organization begins marketing CY 2016 plans, the organization must cease marketing CY 2015 plans through mass media or direct mail marketing (except for age-in mailings). Organizations may still provide CY 2015 materials upon request, conduct one-on-one sales appointments, and process enrollment applications	✓	✓	✓	✓
October 1, 2015	Tentative date for 2016 plan and drug benefit data to be displayed on Medicare Plan Finder on Medicare.gov (not applicable to EGWPs)	✓	✓	✓	✓

2016*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
October 2, 2015	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, 2015	✓	✓	✓	
October 8, 2015	Star Ratings go live on medicare.gov on or around October 8, 2015	✓	✓	✓	
October 15, 2015	Part D sponsors must post PA and ST criteria on their websites for the 2016 contract year		✓		✓
October 15, 2015	2016 Annual Election Period begins All organizations/sponsors must hold open enrollment (for EGWPs, see Chapter 2 of the Medicare Managed Care Manual, Section 30.1)	✓	✓		✓
November 13, 2015	Notices of Intent to Apply (NOIA) for CY 2017 due for MA and MA-PD plans, PDPs, and "800 series" EGWPs and Direct Contract EGWPs.	✓	✓		
Early November, 2015	First display of Plan Finder data for sponsors/MA organizations that submitted a plan correction request after bid approval	✓	✓	✓	✓
Late November, 2015	Display measures data are posted in HPMS for plan preview	✓	✓	✓	
November – December, 2015	CMS issues "close out" information and instructions to MA plans, MA-PD plans, PDPs, and cost-based plans that are non-renewing or reducing service areas	✓	✓		
December 1, 2015	Enrollees in Medicare cost-based plans not offering Part D must receive the combined ANOC/EOC			✓	
December 1, 2015	Cost-based plans must publish notice of non-renewal			✓	
December 7, 2015	End of the Annual Election Period	✓	✓		✓
Mid December, 2015	Display measures data on cms.gov updated	✓	✓	✓	
December 31, 2015	Deadline for D-SNPs and MMPs that separated the ANOC from the EOC to provide the EOC to enrollees	✓			✓
2016					
January 1, 2016	Plan Benefit Period Begins	✓	✓	✓	✓
January 1 – February 14, 2016	Annual 45-Day Medicare Advantage Disenrollment Period (MADP)	✓			
Early January 2016	Release of CY 2017 MAO/MA-PD/PDP/SAE/EGWP applications	✓	✓		
Mid-January, 2016	Industry training on CY 2017 applications	✓	✓	✓	
Late February 2016	Applications due for CY 2017	✓	✓	✓	

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 2016, the bid submission deadline is June 1, 2015 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)

MA, MA-PD, PDP, and cost-based plans are responsible for ensuring 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) 2015 Bid Upload Functionality in HPMS," dated May 9, 2014).

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. All organizations should ensure that appropriate personnel are available both before and after the bid submission deadline to address any ongoing bid upload and/or validation issues that 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.

This year, CMS reminds organizations that submit clearly inaccurate bids that fail to meet Part C and D requirements and 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 might not be allowed to revise their bids to correct inaccuracies, and the bids will 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 for a plan correction indicates the presence of inaccuracies and/or the incompleteness of a bid and calls into question an organization's ability to submit correct bids and the validity of the final actuarial certification and bid attestation.

After bids are approved, CMS will not reopen the submission gates to correct errors identified by the organization until the plan correction window in September. The plan correction window will be open from early September to late September 2015. 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 2015.

Formulary Submissions

CY 2016 Formulary Submission Window

The CY 2016 HPMS formulary submission window will open this year on May 8, 2015 and close at 11:59 pm PDT on June 1, 2015. CMS must be in receipt of a successfully submitted and validated formulary submission by the deadline of June 1, 2015 in order for the formulary to be considered for review. The formulary used in a Part D plan 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 1st deadline will result in denial of that bid submission.

CY 2016 Formulary Reference File

CMS released the first CY 2016 Formulary Reference File (FRF) in March 2015. 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 2015, 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 2015, CMS is planning to provide a release of the 2016 FRF just prior to the June 1st formulary submission deadline. Given the limited timeframe between the May release of the 2016 FRF and the June 1st deadline, CMS is unable to accommodate an updated version of the 2016 OOPC model to incorporate the May FRF changes. Therefore, CMS cautions plan sponsors that any newly added drugs on the May release of the 2016 FRF will not be included in the 2016 OOPC model.

CMS will continue to offer a summer formulary update; however, formulary changes during this particular update submission will be limited to: 1) the addition of drugs that are new to the summer release of the FRF (historically posted in July); and 2) the submission of negative changes on brand drugs, only if the equivalent generic is added to the summer FRF and corresponding formulary file. Thus, plan sponsors need to carefully consider any newly added drugs on the May release of the 2016 FRF, since additional limitations will be imposed on the summer formulary update window.

Submission of Formulary Quantity Limits

In an effort to improve the preciseness of formulary quantity limit (QL) submission and review, as well as the transparency of these limits to Part D enrollees and their prescribers, CMS is enhancing the QL submission process for CY 2016. CMS understands that there are generally two types of QLs: daily QLs and quantity over time restrictions. Since these two types of QLs are not differentiated on the HPMS formulary file submitted for review, CMS must interpret sponsors' submissions with respect to how the QL will be implemented. Through Part D audits and other interactions with plan sponsors, we have become aware of differences between how CMS and plans have interpreted certain QL submissions. As a result, the HPMS formulary file field descriptors and allowable values will be changed for CY 2016. The Quantity_Limit_YN field will be changed to a Quantity_Limit_Type field. Sponsors will designate each formulary drug with a "0" (No QL), "1" (Daily QL), or "2" (QL over time). The respective QL amount and QL days will continue to be submitted as they were for CY 2015. For example, if the QL for a given drug is 1 tablet per day, and the drug is dispensed in days supplies consistent with the approved plan benefit package (e.g., 30 days per month), the QL type field value would be "1", and the corresponding amount and days fields could be "30" and "30", respectively. However, if the amount allowed per 30 days is 5 tablets, the QL type field would be "2" and the amount and days fields would be "5" and "30", respectively. Additional submission instructions are provided in the CY 2016 formulary submission training and technical manual.

Midyear Formulary Changes

CMS continues to gain experience with midyear formulary changes submitted by Part D sponsors. Both maintenance (e.g., generic substitution) and non-maintenance changes (e.g., therapeutic substitution) must be submitted to and approved by CMS (our longstanding midyear formulary change policy is outlined in detail in Chapter 6 of the Prescription Drug Benefit Manual, http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter6.pdf). However, the submission deadline and notification timeframes currently differ between the two types of changes. Consistent with the date first set forth in the June 20, 2007 HPMS memo outlining formulary change operational guidance, maintenance changes may be submitted to CMS through July 31 of the plan year. In contrast, the operational deadline for non-maintenance changes is April 30th, as established in the January 7, 2010 HPMS memo pertaining to CY 2010 formulary change operational guidance.

Submission deadlines are necessary so that CMS has sufficient time to review proposed changes and for Part D sponsors to provide notices to effectuate changes. Further, as outlined in section 30.3.4 of Chapter 6, sponsors may elect to provide notice to all required parties prior to receiving CMS approval of a maintenance change, although in doing so they risk having to rescind the notice should the change not be approved by CMS. However, sponsors are currently prohibited from sending notice for non-maintenance changes until CMS has explicitly approved the change.

For CY 2016, we will be aligning maintenance and non-maintenance changes with respect to submission timeframes and notification requirements. First, given the later initial formulary submission deadline for the upcoming plan year that was established for CY 2015, P&T committees may not be meeting until just before this deadline. Thus, the evaluation and decisions regarding the current year's formulary may be occurring later than what CMS envisioned when establishing the April 30 non-maintenance deadline. As a result, we implemented a July 31 deadline for the submission of both maintenance and non-maintenance changes for CY 2015 and will maintain this deadline for CY 2016.

With respect to non-maintenance changes, we are eliminating the prohibition on sponsors of providing advanced notice to required parties until CMS explicitly approves the change. Beneficiaries that are taking the drug affected by a change are exempt from that change for the remainder of the plan year, and thus there are no "affected enrollees" that must receive notice. In addition, CMS's approval rates for maintenance and non-maintenance changes are similar. If sponsors do opt to notify the required parties at the same time as CMS, they should make certain that they only submit changes to CMS that would be approvable, in accordance with the annual formulary update operational guidance, in order to reduce the risk of needing to rescind change notices.

While we do not anticipate that these changes will result in significant increases in non-maintenance formulary change requests, we remind sponsors that substantial changes to the formulary that was initially approved will not be permitted. Non-LIS beneficiaries generally may make only one plan election per year, usually during the annual election period, so CMS must verify that beneficiaries' drug benefits do not materially change mid-year. Also, formularies must remain consistent with the plan pricing CMS approved during the annual bid review cycle. Therefore, CMS will continue to monitor the number of changes submitted per each formulary and retains the right to reject changes if they appear to result in a "bait and switch" or significant deviation from the formulary content that was approved.

Revisions to Good Cause Processes

In April 2011, we published final regulations to allow reinstatement into an MA, MA-PD, or PDP plan when an individual is disenrolled for failure to pay premiums or the Part D income related monthly adjustment amount (Part D-IRMAA), but is determined to have good cause for failure to pay (76 FR 21456, 21511). We published coordinating regulations in April 2012,

extending the same rights to beneficiaries enrolled in cost-based plans (77 FR 22096). These good cause provisions authorize CMS to reinstate a disenrolled individual's enrollment without an interruption in coverage in certain circumstances where the non-payment was due to circumstances that the individual could not reasonably have been expected to foresee or could not control, such as an unexpected hospitalization.

On February 12, 2015, we published final regulations providing CMS with the authority to designate an entity to act on behalf of CMS (e.g., MA organization, Part D plan sponsor, or entity offering a cost plan) to effectuate reinstatements when good cause criteria are met (80 FR 7912, 7941).

CMS intends to assign the responsibility to conduct good cause reviews to MAOs, Part D plan sponsors and cost plans for CY 2016 and will expect that they perform the work from start to finish (i.e., intake, research, decision, notification, and effectuation). We will provide guidance regarding the application of the good cause criteria and related activities in our enrollment manuals (Chapter 2 and Chapter 17, Subchapter D, of the Medicare Managed Care Manual and Chapter 3 of the Medicare Prescription Drug Benefit Manual). Our expectation is that plans will develop their own internal processes for reviews, based on our guidance, and carry out the majority of this workload without involving CMS. CMS will develop an oversight protocol for any activities assigned to plans that are currently carried out by CMS to verify that plans appropriately apply the regulatory standards associated with the good cause process. As part of this oversight, CMS will retain the authority to review both favorable and unfavorable decisions to make certain that results are fair and sound, and based on regulatory standards for reinstatement.

We believe that with proper guidelines, instructions, and oversight, organizations and sponsors are well positioned to efficiently resolve good cause reinstatement requests, since most individuals contact the plan regarding their disenrollment. Also, plans can readily access a former enrollee's premium billing and payment history and can address possible allegations of plan error without having a complaint entered into CMS's Complaint Tracking Module.

In the draft Call Letter, we requested comments on ways in which this responsibility can be transitioned from CMS to plans in the most effective and least disruptive manner. The comments we received were generally supportive of this transfer of responsibility. In response to questions raised by commenters, we are clarifying that CMS will continue to process good cause reinstatement requests from individuals disenrolled by CMS for failure to pay Part D-IRMAA. Also, in response to a question regarding the option of an individual to challenge a plan's unfavorable good cause determination, we reiterate that such determinations cannot be appealed as they are not organization or coverage determinations subject to the appeal requirements in parts 417 subpart Q (cost plans), part 422 subpart M (MA plans) and part 423 subpart M (Part D plans). Complaints received by CMS subsequent to a plan's determination will be reviewed by CMS and, if CMS determines the plan acted inappropriately, may be included in CTM metrics.

In response to comments from beneficiary advocates regarding CMS oversight of this transferred responsibility, we reiterate that the monitoring protocol CMS will implement will include CMS review of both favorable and unfavorable good cause determinations.

CMS will transfer this responsibility to plans starting January 1, 2016, such that plans will be responsible for the intake and processing of good cause reinstatement requests for individuals disenrolled effective December 31, 2015, and later.

Enrollment Eligibility for Individuals Not Lawfully Present in the United States

On February 12, 2015, we published final regulations to establish U.S. citizenship or lawful presence as a requirement to be eligible to enroll in or remain enrolled in MA, MA-PD, PDP, and cost-based plans (80 FR 7912). This criteria is part of our compliance with Section 401 of the Personal Responsibility and Work opportunity Act of 1996 (PRWORA), amended by section 5561 of the Balanced Budget Act, which generally prohibits providing Medicare benefits to individuals who are not U.S. citizens or nationals, or lawfully present. 8 U.S.C. 1611 and 1641. Individuals who are determined by the Social Security Administration (SSA), based on information from Department of Homeland Security (DHS) and other sources, to be not lawfully present will not be eligible for enrollment. As part of this process, SSA notifies individuals of their unlawful presence status and they are given an opportunity to contest the determination. Unlawful presence data will be provided by SSA to CMS, which will provide this information to plans; plans should not request evidence of citizenship or lawful presence status at the time of enrollment. Plans will be expected to check an individual's eligibility via CMS systems when processing enrollment requests following normal processes. Enrollment requests for ineligible individuals will be denied and, as required by regulation, individuals must receive written notice of the enrollment denial.

Further, CMS will involuntarily disenroll any current plan members for which we receive data of their unlawful presence status. Plans will be notified of such disenrollments via the Daily Transaction Reply Report (DTRR). The effective date of the involuntary disenrollments will be the first of the month following notice by CMS that the individual is ineligible. Disenrolling such beneficiaries in the month following when CMS notifies the plan of the individual's ineligibility allows plans to terminate such enrollments quickly and prevents future improper payments, as recommended by the OIG in its January 2013 report regarding improper Medicare payments for services rendered to unlawfully present beneficiaries. Although a disenrollment notice is not required by regulation, plans are strongly encouraged to notify individuals who are involuntarily disenrolled for this reason.

In response to a comment, we are clarifying that beneficiary complaints related to unlawful presence status will not be attributed to plans in CTM metrics, as CMS effectuates these disenrollments based on the determination of lawful presence status by SSA.

We will be releasing subregulatory guidance (Chapter 2 and Chapter 17, Subchapter D, of the Medicare Managed Care Manual and Chapter 3 of the Medicare Prescription Drug Benefit Manual) to provide updated model notices and additional details on processing such cases.

Making the Exceptions and Appeals Processes More Accessible for Beneficiaries

Based on comments received on the draft 2016 Call Letter, CMS will continue working to identify and implement improvements that result in MA organization determination, appeal, and grievance (ODAG) and the Part D coverage determination, appeal and grievance (CDAG) processes that are more understandable and accessible for Medicare beneficiaries. As a corollary to that goal, clarifications and guidance on existing requirements should promote plan compliance and increase successful ODAG and CDAG audit findings. We thank commenters for their feedback in the following areas:

Coverage Denial Notices and Requests for Clinical Documentation

In the draft 2016 Call Letter, we expressed our ongoing concern related to plan denial notices that fail to provide the required level of specificity to understand the plan's rationale for the denial and insufficient outreach to providers to obtain information necessary to make an appropriate clinical decision. The majority of commenters were in favor of CMS issuing guidance to clarify the information that must be included in the denial rationale section of the standardized denial notices. Many commenters were also supportive of CMS issuing guidance to more clearly describe the parameters of what constitutes reasonable attempts by a plan to obtain necessary clinical documentation.

Denial Notices

Our existing requirements related to the standardized denial notices state that MAOs and Part D plan sponsors must include accurate, clear and detailed information related to the specific reason(s) for the coverage denial. See: 42 CFR §§ 422.568, 423.568. For interpretive guidance on these regulatory provisions, see Managed Care Manual Ch. 13, §40.2.1, 40.2.2 and Prescription Drug Benefit Manual, Ch. 18 §40.3.4. For example, the applicable Medicare coverage rule or plan policy (e.g., EOC provision) must be described in the denial notice, including any specific coverage requirement that must be met to obtain the item or service. In the Part D context, the denial notice should reference specific formulary requirements related to the requested drug (e.g., non-formulary, prior authorization (PA), step therapy, safety edits). Information on formulary requirements must comport with the CMS-approved formulary.

The majority of the comments came from advocacy organizations supporting the proposal, with requests for CMS to share examples of best practices. Physicians and other providers supported efforts to increase transparency in the process, but had concerns about the additional workload this could place on providers. PBMs and plans were either opposed to the proposal or requested clarification, citing similar concerns regarding additional workload. Plans stated that the addition

of clinical information to denial notices would not necessarily give a beneficiary a better understanding of the rationale for the denial, and would possibly confuse beneficiaries. Additionally, several commenters noted that simply having CMS enforce the existing requirements for content of denial notices would help to reduce enrollee confusion.

Denial Notices – Next Steps

While our existing guidance explains the level of detail that plans must include in the denial rationale, we believe there is room for improving the denial notice, instructions for completing the denial notice and related subregulatory guidance. To that end, we will continue working with stakeholders to identify a range of options for improving the existing Part C and Part D notices, including providing examples of plan decision rationales that satisfy our notice requirements. Once we identify specific additional guidance, CMS will solicit input from a broad group of stakeholders. Until such guidance is in place, we will continue enforcing the regulations using our existing guidance and interpretations related to denial notices that require plans to include clear and detailed information related to the specific reason coverage is being denied.

Requesting Clinical Documentation

As noted above, commenters generally supported the concept of clarifying parameters about what constitutes reasonable plan outreach to providers. Plans and PBMs that commented on this proposal either offered suggestions for a standard that they believe constitutes a "reasonable attempt" to obtain clinical documentation or requested that CMS clarify the number of attempts that would be considered reasonable.

Requesting Clinical Documentation – Next Steps

Based on the feedback we received, CMS will revise Chapter 13 of the Medicare Managed Care Manual and Chapter 18 of the Medicare Prescription Drug Benefit Manual to include guidance on what constitutes "reasonable attempts" on the part of a plan to obtain clinical documentation. We envision that there will be separate parameters for expedited and standard requests because what is reasonable in each scenario is likely to be different. The guidance may address the number and timing of the attempts made to contact a provider, as well as the method(s) of contact and the content of any messaging to the provider.

Improved Information at the Point of Sale

In the draft call letter, we stated our intention to work with stakeholders to further explore the feasibility of various approaches for certain types of POS rejections, such as those based on prior authorization (PA) criteria, step therapy requirements and quantity limits. We reiterated that collaboration with the National Council of Prescription Drug Programs (NCPDP) would be necessary to develop and standardize codes that would assist Part D sponsors, processors and pharmacies with generating detailed information related to certain POS transactions, such as specific reasons for the rejection of a claim. We requested comments on the benefits and costs of

implementing these potential changes, developing new standardized codes, suggestions about reasonable timeframes for implementing changes and other considerations that we should keep in mind as we pursue potential refinements to our programs.

We received numerous comments both supportive of and opposed to the potential changes we said we were exploring on this section of the draft call letter, particularly with respect to requiring plans to treat certain POS rejected claim transactions as adverse coverage determinations. Several commenters expressed strong support for treating rejected claim transactions as adverse coverage decisions, stating that it would resolve beneficiary confusion about next steps by providing the detailed information required in the standardized denial notice, which would reduce delays in obtaining needed medications and expedite access to the appeals process.

Other commenters were strongly opposed to this approach and cited a variety of concerns related to requiring plans to treat some or all POS rejected claim transactions as adverse coverage decisions. Commenters cited a number of significant logistical concerns, including substantially increased burden on Part D plans, PBMs and pharmacies; potentially several years to implement the necessary coding, transaction and systems changes; significantly increased plan and IRE costs to adjudicate increased appeal volumes requiring physician review; and several other challenges for network pharmacies, related to HIPAA privacy compliance, printing capabilities and software updates.

Commenters are also concerned that treating POS transactions as coverage decisions would adversely affect beneficiaries in several ways:

- Part D sponsors indicated that the POS reject is not a coverage determination because the plan has not conducted a review to determine whether Medicare or plan coverage criteria were met;
- It could interfere with current processes where pharmacist works with the prescriber to resolve the issue;
- Treating a POS reject as a coverage determination would fail to optimize plan resources. Plans should have the opportunity to efficiently leverage resources by conducting an initial review at a lower level of adjudication to determine whether Medicare or plan coverage criteria have been satisfied. Permitting plans to review a coverage determination request following a POS reject allows favorable coverage decisions to be made at a lower level of review; and
- It could cause increased beneficiary confusion that may delay access to needed drugs.

Improved Information at the Point of Sale – Next Steps

After consideration of the numerous comments received, our existing requirement for delivery of the pharmacy notice for certain rejected claims will remain in place per 42 CFR §423.562(a)(3),

Chapter 18 of the Medicare Prescription Drug Manual and NCPDP guidance. At this time, CMS will not require plans to treat any POS pharmacy transaction as a coverage determination.

We acknowledge that commenters identified a number of real obstacles and challenges to making the changes discussed in the 2016 draft Call Letter. However, it is critically important that plan sponsors and CMS continue working collaboratively on this issue so that beneficiaries have unimpeded and timely access to medically necessary Part D drugs. This will continue to be a top priority for us and to that end; CMS will be conducting a POS pilot to help identify options for resolving certain POS claims rejections without an enrollee having to request a coverage determination from a plan. We will be soliciting assistance from plans and PBMs on this effort and look forward to partnering with organizations to identify which POS claim rejections to include in this process and options for proactively resolving these POS claims rejections. In addition, we recognize that the coding changes needed to improve the information provided at POS will require significant time commitments and involve multi-year development and implementation timelines. Nevertheless, we believe that these changes will yield important program and process improvements. Therefore, CMS will begin working with NCPDP to develop and implement strategies for enhanced messaging at POS that strike the right balance between improving beneficiary access and keeping to a minimum any additional program costs or burden on plans, pharmacies, PBMs and appeals adjudicators.

Expanded Data Collection for Part D Appeals

We noted in the draft Call Letter that our ongoing efforts to monitor and improve plan compliance with established CDAG and ODAG appeals and grievance requirements and ensuring beneficiary access both to the appeals process and to needed drugs include obtaining accurate and complete information about plan coverage determination and appeal processes.

Because the data currently available to CMS (aggregate quarterly data submitted by plans via annual reporting) do not provide sufficient information to allow us to determine whether plans are providing appropriate access to Part D drugs through their coverage determination and redetermination processes, we also indicated in the draft Call Letter that we are exploring the development of an appeals tracking system to receive regular data feeds for all coverage requests received and processed by plans in order to obtain a full data-stream of information from beginning (coverage determination) to end (IRE). We stated that these data feeds could provide case-level data that CMS could link to PDE, IRE and other program data. We are also expecting to be able to obtain these data on a more contemporary basis than we currently obtain plan reported data (e.g., daily, monthly or quarterly).

CMS's main objectives for the expanded data reporting would be to:

- Assist plans in their compliance efforts, strengthen CMS oversight of beneficiary access to needed drugs and more accurately identify and evaluate beneficiary harm.
- Reduce or eliminate information gaps in current appeals data.

- Obtain more accurate and detailed information about overall volumes of coverage determinations and redeterminations, as well as drug utilization data for beneficiaries who receive denials at the coverage determination or redetermination levels.
- Perform more detailed data analysis to understand trends seen in aggregate data (e.g., is the low redetermination rate caused by enrollees being able to obtain a formulary alternative or because they do not have adequate information to request an appeal?).

We asked for feedback from our partners on potential vehicles and methodologies we could use to collect these data, specific data elements necessary to meet the stated objectives, and potential challenges we may face collecting expanded appeals data, as well as possible solutions to those challenges.

Feedback received in response to the draft Call Letter was largely supportive of creating this type of reporting; however, there are clear concerns about additional reporting burden, and timing of CMS's implementation. We are mindful of balancing administrative burden on Part D sponsors, as well as the need to coordinate with CMS's more broad efforts in improving beneficiary access to the exceptions and appeals process before beginning the development of system requirements for collection of case-level data. This type of reporting would replace the current aggregate reporting, and as noted in the draft Call Letter, we envision this expanded reporting would mirror many of the data elements included in the universe for CMS program audits to minimize necessary changes to systems functionality and reduce burden on plans. While we expect to begin discussing and evaluating feedback received on the proposals in 2015, we would look for potential Part D program implementation in 2018. Due to program and data collection differences and comments received on the draft Call Letter, a similar expansion of data collection for Part C appeals data is not being explored at this time, but may be in the future.

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

CMS reminds MAOs and PDP sponsors that we 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, upon the release of the 2016 star ratings in October 2015, have failed in three consecutive years (i.e., the 2014, 2015, and 2016 sets of ratings) to achieve at least three stars on their Part C or Part D performance. This authority only recently became applicable, and our policies for carrying out star rating-based terminations continue to evolve as we evaluate the effect of such terminations on the Part C and Part D programs, including the impact on beneficiaries of the timing of the issuance of notices to affected beneficiaries.

As a result of our ongoing analysis, CMS has modified our timeline for conducting star rating-based terminations for contracts that meet the regulatory criteria for termination for the first time with the release of the CY 2016 star ratings (i.e., contracts rated at or above 3 stars for CY 2013, but below 3 stars for CY 2014, CY 2015, and CY 2016). After the 2016 ratings are released in

late 2015, these contracts will receive non-renewal notices from CMS in February 2016 with an effective date of December 31, 2016 at 11:59 PM EST (under 42 C.F.R. §§ 422.506(b)(1)(ii) and 423.507(b)(1), CMS may non-renew a contract for any of the reasons for which it may terminate a contract). In March 2016, CMS will issue notices to beneficiaries enrolled in plans offered under the non-renewed contracts advising them that they will need to choose a new plan during the Fall 2016 annual election period to continue their Part C and Part D plan enrollment without interruption in 2017. CMS will not calculate or publish 2017 star ratings associated with the non-renewed contracts, so affected organizations should not expect that an improved 2017 star rating performance would cause CMS to reverse its non-renewal determination. While CMS has committed to conducting additional research into what is driving differential performance on a subset of measures in the Star Ratings, we do not need to delay terminations. At this time, CMS has not determined that contracts with significant dual-eligible enrollment face unique obstacles in achieving 3-star ratings. Plans subject to termination show a sustained below-average overall rating for at least three years, and there is no evidence to show that a low-rated plan cannot improve its performance to at least an average (i.e., 3-star) level.

Enhancements to the 2016 Star Ratings and Beyond

One of CMS's most important strategic goals is to improve the quality of care and general health status for Medicare beneficiaries. For the 2016 Star Ratings, CMS continues to make enhancements to the current methodology to further align it with our policy goals. Our priorities include enhancing the measures and methodology to reflect the true performance of organizations and sponsors, maintaining stability because of the link to payment, and providing advance notice of future changes. Unless noted below, we do not anticipate methodology changing from the 2015 Star Ratings.

For reference, the list of measures and methodology included in the 2015 Star Ratings is described in the Technical Notes: http://go.cms.gov/partcanddstarratings. The star cut points for all measures and case-mix coefficients for the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey and Health Outcomes Survey (HOS) will be updated for 2016 with the most current data available.

As announced in previous years, we will annually 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.

CMS is exploring the development of an integrated Star Rating system for Medicare-Medicaid Plans (MMPs) participating in the capitated Financial Alignment Initiative. Although all CMS quality measurement programs are studying if and how socioeconomic status (SES) affects the ability of plans and providers to provide high-quality care to low-income beneficiaries, this exploration is not derived from those concerns. The purpose of this effort is to develop a rating system that acknowledges the additional needs of Medicare-Medicaid enrollees and measure the

performance of the MMPs in integrating the Medicare and Medicaid benefits. CMS received a number of comments on this effort. We will address those comments when we release additional information on this effort later in 2015.

We appreciate the feedback we received on the 2016 Request for Comments and draft Call Letter. Summaries of comments and responses to the draft Call Letter are included in Appendix 5 to this final Call Letter. We have included more detail in this Call Letter about the elimination of pre-determined 4-star thresholds, the decision to remove the Diabetes Treatment measure from the 2016 Star Ratings, and evaluations of Dual/LIS status effects. We will continue to publish detailed technical specifications and provide contract specific technical guidance in understanding how a contract scored on a measure.

A. Changes to the Calculation of the Overall Rating and the Part C and D Summary Ratings

- *Background*

  CMS is interested in improving the accuracy of the assignment of overall and Part C and D summary Star Ratings and making sure the system creates incentives for quality improvement. In constructing the Star Ratings, a key concern is the potential for generating Star Ratings that do not reflect a contract's "true" performance, otherwise referred to as the risk of "misclassification." For example a "true" 4-star could be scored as a 3-star contract, or vice versa. Misclassification occurs in any measurement system because all measurement is a mixture of *signal* (true performance) and *noise* (random measurement error due to rounding, sampling variation and similar factors). In recent years several features have been implemented in the quality rating system to simplify information for consumers, as well as to make the information more transparent for organizations and sponsors. For example, we group the measure scores into star categories and round the measure data to whole numbers to make it easier for consumers to understand what a particular score means. Since the 2011 Star Ratings, we have also implemented pre-determined 4-star thresholds for some measures to increase transparency for organizations and sponsors and set expectations for high performance. However, all of these features create more "noise" or measurement error in the system. As the uses of a quality rating system expand (e.g., from being a basis for a beneficiary to select a plan, to the basis for a plan to be rewarded for the quality of services provided to its enrollees), the impacts of misclassification grow as well.

- *Current Scoring Method*

  The 2015 overall Star Rating is a composite measure constructed from 33 measures for Part C and 13 measures for Part D. The measures are numeric scores such as counts and percentages of screening and testing, chronic care, patient experience, customer service, and patient safety measures. Currently, each measure is assigned a rating from 1-5 stars. Scores are grouped using statistical techniques to minimize the distance between scores

within a grouping (or "cluster") and to maximize the distance between scores in different groupings.

There are two methods for calculating the measure stars:

- Clustering. Clusters are defined as contracts with similar distances between their data values and the center data value. The measure scores are inputs for a clustering algorithm, which determines break points in the distribution and groups the scores into star categories.
- Significance testing. The measure scores are assigned stars with a combination of percentile-based categories and whether the score is significantly different from the mean of all contracts.

For the 2015 Star Ratings, 22 Part C and 5 Part D measures have pre-determined 4-star thresholds (67% of Part C measures, and 39% of Part D measures). We did not introduce any new 4-star thresholds for the 2015 Star Ratings. For those measures with pre-determined 4-star thresholds, any contract with a measure score above the threshold receives 4 or 5 stars, and any contract with a score below the threshold receives 1, 2, or 3 stars. The pre-determined 4-star threshold is applied before the clustering or significance testing. For example, for clustered measures, first the contracts that score above the pre-determined threshold are selected, and then this subset is clustered into two categories to determine which contracts receive 4 stars and which receive 5 stars.

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

To incorporate this consistency indicator into the rating process, CMS has applied a "Reward Factor", previously called an i-Factor, to the mean overall and Part C and D summary ratings since 2009 in order to reward contracts if they have both consistently high and stable relative performance. Specifically, the Reward Factor calculation adds a value of 0, 0.1, 0.2, 0.3, or 0.4 to each contract's overall and summary ratings according to the variability and mean performance of its measure stars, and in doing so it increases the number of contracts at the high end of the rating scale that have low variation and high

mean performance in their individual measure scores. The 2015 Part C & D Star Rating Technical Notes provides more information about the calculations.

- *Pre-determined Thresholds*

  As announced in the 2015 Call Letter and based on CMS's analyses, we will remove the pre-determined measure thresholds for the 2016 Star Ratings. The cut points will be determined using the same methodology used in the past (e.g., relative distribution and clustering of the data), and we will continue to use the "Reward Factor" for contracts with consistently high performance. All cut points will be based on the data submitted from all contracts for the rating year.

  Our primary goal in eliminating the thresholds is to improve the accuracy of the assignment of overall and Part C and D summary Star Ratings and to make certain the system creates incentives for quality improvement. While there is general support for this change, some sponsors and stakeholders remain concerned that it is difficult to improve without published targets for achieving 4 or more stars on a measure. We also understand that some sponsors are concerned that eliminating pre-determined 4-star thresholds will make it more difficult to set targets for performance or value-based contracting. CMS's removal of pre-set 4-star thresholds does not preclude sponsors from setting their own benchmarks for performance. Plans should incent their providers to achieve the highest levels of quality possible, instead of meeting artificial minimum thresholds.

  Other commenters suggested that CMS set all cut points retrospectively, which would only further increase misclassification. We understand the perceptions that pre-determined 4-star thresholds provide stability by setting performance expectations, but in reality the use of pre-determined thresholds violates a core principle of assigning stars that maximize the difference between star categories. Pre-determined 4-star thresholds can cause contracts to receive different ratings when there is no significant difference in their scores (e.g., if a 4-star threshold is 80%, a contract that scores 79.4% would receive 3 stars while a contract that scores 80.1% would receive 4 stars when there may be no meaningful difference between a score of 79.4% and a score of 80.1%). The use of pre-determined 4-star thresholds is also problematic when there is general improvement in measure performance over time or when there are changes to a measure's specifications but pre-determined thresholds remain constant. We have also found issues when there are large distributional changes in the scores across contracts. In these cases, pre-determined 4-star thresholds may result in no contracts being assigned 4 or 5 stars (above the threshold), or no contracts being assigned 1, 2, or 3 stars (below the threshold) for a particular measure. These examples illustrate how pre-determined thresholds increase noise in the Star Ratings and are counter to industry feedback that thresholds assist sponsors in targeting their improvement efforts.

A significant negative consequence of pre-determined thresholds is the potential to restrict continued quality improvement. Currently, 33% of the Part C measures and 61% of the Part D measures do not have pre-determined 4-star thresholds. CMS's analyses of past Star Ratings found that sponsors on average have more significant levels of improvements in Part C and D measures **without** pre-determined thresholds, as compared to measures where there are pre-set thresholds. Using the 2015 Star Ratings, our analysis showed that on average only 28% of contracts improved significantly across the 20 Part C measures with 4-star thresholds included in the improvement measure, compared to 51% of contracts that improved significantly across the nine Part C measures without 4-star thresholds. We found similar findings for Part D, where on average, only 24% of contracts showed significant improvement across the five measures with 4-star thresholds included in the improvement measure, while 63% of contracts showed significant improvement across the five Part D measures without 4-star thresholds. Although some of this difference in improvement in measures without pre-determined thresholds may be due to the measures with pre-determined thresholds being older, some of the measures without pre-determined thresholds such as adherence have been collected and reported for at least five years. These findings continue to suggest that pre-set thresholds hamper continuous quality improvement in MA and Part D contracts.

Lastly, some commenters continued to express concern that all thresholds would go up with this change. Based on simulations using 2015 Star Ratings, for the Part C measures with pre-determined 4-star thresholds in 2015, close to half of the 4-star cut points would remain the same or go down, while the remaining would go up. For the Part D measures for MA-PDs, 60% or 3 measures would remain the same or go down and 40% or 2 measures would go up. For the PDPs, 20% or 1 measure would have a lower 4-star cut point and 80% or 4 measures would go up. This simulation does not show that the removal of pre-determined 4-star thresholds leads to significant increases in thresholds across all measures.

We further simulated the impact of this change to contracts' overall ratings. Most contracts (83%) would have no change in their overall rating. Approximately 7% of contracts' overall ratings would go up 0.5 stars and 10% would go down by 0.5 stars. Simulations found that for contracts with no SNPs and for SNP-only contracts, 82% of contracts would not change their overall rating. For contracts with some SNPs as plan benefit packages, 87% of contracts would not change their overall rating.

CMS provided contract-specific information on the impact of removing pre-determined 4-star thresholds, as well as results of our analyses of performance trends in Star Rating measures, and as applicable, pre-determined 4-star thresholds in both 2014 and 2015 through HPMS. A document showing trends overtime in cut points is available at http://go.cms.gov/partcanddstarratings. We will continue to update this document to help sponsors target their quality improvement efforts.

- *New 2016 Measure:*

  CMS will add the following measure to the 2016 Star Ratings.

  1. *Medication Therapy Management Program Completion Rate for Comprehensive Medication Reviews (Part D).* A majority of commenters supported adding this measure to the 2016 Star Ratings. This measure is based on the Pharmacy Quality Alliance (PQA) endorsed measure, Completion Rate for Comprehensive Medication Review (CMR), which is used to calculate the percentage of beneficiaries who met eligibility criteria for the Medication Therapy Management (MTM) program and who received a CMR with a written summary in CMS standardized format. As a new measure, it will be assigned a weight of "1"; in future years it will continue to receive a weight of "1" as a process measure. The specifications used for the 2015 display measure will also be used for the 2016 Star Rating measure. The denominator is the number of beneficiaries who were at least 18 years or older as of the beginning of the reporting period and who were enrolled in the MTM program for at least 60 days during the reporting period. Only those beneficiaries that meet the contracts' specified targeting criteria per CMS – Part D requirements pursuant to §423.153(d) of the regulations at any time in the reporting period are included in this measure. Sponsors are statutorily required to offer a CMR to all beneficiaries enrolled in their MTM program at least annually, and this includes enrollees who are in LTC settings. Therefore, LTC beneficiaries are included in the measure calculation. However, beneficiaries that were in hospice at any point during the reporting period are excluded from this measure because the beneficiary's drugs may be covered under the hospice benefit or waived through the beneficiary's hospice election and sponsors may not be fully responsible for the management of the beneficiary's medication use during this time. The numerator is the number of beneficiaries included in the denominator who received a CMR at any time during the reporting period. MTM CMR rates will not be calculated for contracts scoring less than 95% on data validation for their plan reporting of the MTM Program section, or found by the data validator to be non-compliant with data validation standards/sub-standards for the specific data elements used for the measure. Contracts excluded from the measure due to data validation issues will be assigned 1 star in this measure, and shown as "CMS identified issues with this plan's data." Sponsors are reminded that they should not restrict their MTM eligibility criteria to limit the number and percent of beneficiaries who qualify for these programs and to whom they must offer a CMR. Some commenters remained concerned that the variability in MTM program eligibility criteria may bias the measure calculation. As stated in the 2015 Call Letter, analyses have not found a correlation between a sponsor's rate of MTM program eligibility and the CMR completion rate.

- *Additional 2016 Star Ratings Measures:*

  CMS intends to return these measures to the 2016 Star Ratings.

  1. *Breast Cancer Screening (Part C).* The HEDIS specification for 2014 changed the age range from 40 to 69 years old to 50 to 74 years old and increased the numerator time frame for documentation of a mammogram from 24 months to 27 months. These changes were a result of the National Committee for Quality Assurance's (NCQA) measure re-evaluation process that included: a scan of clinical guidelines and evidence; feedback from variety of stakeholders, including women's health experts, clinicians, consumer advocates, and health plans; and a public comment period. The revised age range aligns with current recommendations from the U.S. Preventive Services Task Force (Grade B recommendation, with additional research underway), American Academy of Family Physicians, and others. The increased numerator time frame from 24 to 27 months provides a 3-month grace period to account for logistics of obtaining a mammogram and is in response to concerns that the lack of a grace period results in women being screened more often than every two years. We are returning this measure to the 2016 Star Ratings, after moving it to the 2015 Display Page for one year since the measure specification changed during the 2013 measurement year (i.e., it expanded the members included in the denominator). Since this is a process measure, it will continue to be assigned a weight of "1."
  2. *Call Center – Foreign Language Interpreter and TTY Availability measures (Part C & D).* These measures were excluded from the 2015 Star Ratings due to concerns about data quality. For the 2016 Star Ratings, we plan to use a similar data collection timeframe as past years – March through June 2015. All contracts will be monitored using the same timeframe. Since this is an access measure and there is no change in methodology, it will be assigned a weight of "1.5."
  3. *Beneficiary Access and Performance Problems (Part C & D).* This measure had moved out of the 2015 Star Ratings and into the display measures since there were significant methodological changes to the 2013 audit process and scoring. Based on feedback from plans and CMS's expectations of regular methodology updates for calculating audit results, we have removed audit results from this measure for stability in the specifications and will include it in the 2016 Star Ratings. The data currently displayed on the 2015 Display Page use this revised methodology. Appendix 3 includes the detailed specifications. For the 2016 Star Ratings, we will assign this measure a weight of "1" as the methodology change causes this to be considered a "new" measure for weighting purposes. For the 2017 Star Ratings, it will revert to the weight of "1.5" as it had in 2014, as an access measure.

- *Changes to Measures for 2016*

  CMS's general policies regarding specification changes to measures for 2016 Star Ratings:

  - 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 is announced during the measurement period that 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 is announced during the measurement period and does not significantly impact the numerator or denominator of the measure, the measure will continue 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).

  We received a comment to the draft Call Letter raising concerns about modifications to the SNP Care Management measure. During 2014 CMS issued a clarification to this measure to make it explicit that the initial Health Risk Assessment (HRA) must occur on or after the date of the member's initial enrollment in the plan. That is, the initial HRA must occur when members are already eligible to receive benefits. The reasoning behind this requirement is that in its absence, plans could base enrollment decisions on the results of the HRA. This is not the purpose of the HRA.

  The methodology for the following measures is being modified:

  4. *Controlling Blood Pressure (Part C).* In December 2013, the eighth Joint National Committee (JNC 8) released updated guidance for the treatment of hypertension. These recommendations set the treatment goal for patients 60 years of age and older to <150/90 mm Hg and keep the treatment goal for patients ages 18-59 years at <140/90 mm Hg. This guideline also recommended that all diabetic patients age 18 and older should be treated to a goal of <140/90 mm Hg and questioned the use of other targets. NCQA staff worked with the NCQA advisory committees, including the Cardiovascular Measurement Advisory Panels, Technical Measurement Advisory Panel, and additional stakeholders. The revised measure went to public comment in February-March 2014 and was approved by the Committee on Performance Measurement and Board of Directors in June 2014. We will use the updated measure for the 2016 Star Ratings, and this measure will not be transitioned to the Display Page because beneficiaries that meet the old guidelines will automatically meet the newer more lenient guidelines.

  5. *Plan Makes Timely Decisions about Appeals (Part C).* Effective January 2014, organizations are responsible for reviewing requests for dismissal from an enrollee and making the decision; MAOs should not be forwarding requests for dismissal to the

Independent Review Entity (IRE) for the dismissal decision. (MAOs should be forwarding to the IRE any reconsideration if the MAO upholds any part of an adverse organization determination under §422.590.) Therefore, the IRE no longer captures data around the timeliness of dismissal cases, and consequently, we will exclude dismissals from this measure for the 2016 Star Ratings. If CMS collects information about Part C dismissals in the future, we may modify this measure to account for these cases.

6. *Plan All-Cause Readmissions (Part C).* This is a measure of the percentage of hospital discharges that result in a readmission for any cause within 30 days of discharge. This measure is reported as a ratio of a health plan's observed rate of readmission compared to an expected rate of readmission based on a case-mix adjusted model (the model takes into account how sick patients were when they went into the hospital the first time.). As discussed in last year's Request for Comments, NCQA has made two changes to this measure which we will use for the 2016 Star Ratings: 1) excluding planned readmissions from the measure and 2) removing the current exclusion from the denominator for hospitalizations with a discharge date in the 30 days prior to the Index Admission Date.

   As commenters to our Request for Comments noted, observation stays present challenges for health systems, payers, consumers and measure developers. Currently, observation stays are not included in this measure; however, NCQA is exploring this. In terms of risk adjustment, we are not aware of a valid scale or other measure that defines the appropriateness of a discharge across all clinical conditions. Therefore, the risk adjustment model used by NCQA for this measure cannot take this into account. NCQA's work shows that with the revised specifications of defining hospital stays, contracts show on average little change in their observed to expected ratio for readmissions.

7. *Osteoporosis Management in Women who had a Fracture (Part C).* It is essential for older women to have adequate assessment for osteoporosis following a fragility fracture and/or to be provided treatment to prevent future fractures if indicated. This measure assesses the percentage of women who had a fracture and received either screening or treatment for osteoporosis. NCQA has added an upper age limit, extended the look back period for exclusions due to prior bone mineral testing, removed estrogens from this measure, and removed single-photon absorptiometry and dual-photon absorptiometry tests from the list of eligible bone-density tests. We will use the modified measure for the 2016 Star Ratings. For this measure, the denominator changes make the measure specifications easier to meet, while the numerator changes should have very little impact on the measure. Estrogens are in the Part D High Risk Medication measure as drugs to be avoided so they are not commonly being used for treating osteoporosis.

   We appreciate the comments to the draft Call Letter either supporting or opposing the exclusion of women in long-term care facilities or eligible for long-term care. Those in

support were concerned about excluding a very vulnerable population that is at risk for falls. NCQA has considered exclusions for members in long term care facilities or those that are nursing home certifiable living in the community, but its advisory panels have suggested this blanket exclusion is not appropriate. Members in these types of facilities are often frail and may be particularly susceptible to fragility fractures. Individuals who have a fragility fracture would benefit from screening and/or treatment for osteoporosis to reduce risk of future fractures. Additionally, the measure allows for bone mineral density tests that are portable and can be brought to patients who are in long term care facilities.

For dementia, current coding cannot distinguish between women who have mild versus severe dementia using claims data. Women with mild dementia and those with chronic or severe and persistent mental illness may still benefit from screening and treatment of osteoporosis following a fragility fracture. NCQA will continue to explore this as a potential exclusion in the future. Further, the measure allows for numerous bone mineral density tests and pharmacologic therapies, which gives providers and patients flexibility in determining the best course of intervention.

8. *Complaints about the Health/Drug Plan (CTM) (Part C & D)*. CMS is finalizing our proposal to modify the measurement period from 6 months of the current contract year to 12 months of the prior contract year. For example, 12 months of 2014 complaints data will be used for the 2016 measures. Expansion of the data used for this measure will provide a more comprehensive evaluation of the plan. Currently, complaints filed in the second half of a year are not accounted for in a contract's performance rating when only the 6-month period is used. Also, this change addresses contracts' requests for CMS to allow adjustments to complaints' assigned categories, or contracts. There will now be an approximately 6-month "wash out" period to account for any adjustments per CMS's CTM Standard Operating Procedures. CMS's simulation of contracts' complaint rates found similar complaint rates when using either the first 6 months of CY2014, or the full CY2013 complaints data. There were also instances where contracts' complaint rates improved when using the full 12 month set of complaints, due to the "wash-out period" noted above. Because this change was announced prior to the expanded measurement period, and does not significantly change contracts' complaint rates, we will not move the measure to the display page for one year. However, the complaints measures will not be used in the calculation of the Improvement measures.

   A few commenters requested we use a 12 month snapshot of data by pulling complaints from the last 6 months of the prior contract year and the first 6 months of the current contract year. We do not support using data spanning two different contract years and potentially different formulary and benefit packages.

9. *Improvement measures (Part C & D).* Please refer to Appendix 4 for the measures to be used to calculate the 2016 improvement measures.

10. *Appeals Auto-forward and Upheld measures (Part D).* We appreciate the positive support received for these proposals. We are finalizing our proposal to modify the Part D Upheld measure to use the same 12-month measurement period as the Part D Appeals Auto-forward measure. For the 2016 Star Ratings Upheld measure, we will use the full 12 months of 2014 data. This change allows consistency across all four Part C and Part D appeals measures and provides a more comprehensive evaluation of plans' decisions. Because this change was announced prior to the expanded measurement period, we will not move the measure to the 2015 Display Page. However, the Part D Upheld measure will not be used in the calculation of the Part D Improvement measure. Additionally, this change allows CMS to include cases reopened by the IRE. Consistent with the Part C measure, if a reopened case is decided prior to April 1 of the following year, the decision for the reopened case is used in place of the reconsideration decision. Previously, contracts with fewer than 5 total cases were not rated in the Part D Upheld measure. We will re-evaluate and adjust the minimum number of cases as necessary.

    We will also modify the Part D Auto-Forward measure to exclude cases the IRE remands to the plan. Based on sponsor feedback and discussions with the IRE, plans may occasionally auto-forward cases to the IRE in error, when the plan hasn't exceeded the applicable coverage determination/redetermination timeframe. As described above, CMS's policy is to continue a measure in the Star Ratings if a specification change announced during the measurement year does not significantly impact the numerator or denominator. Exclusion of remanded cases will not significantly impact the numerator for this measure; therefore we will implement this change for the 2016 Star Ratings.

    Commenters requested that CMS exclude hospice-related appeal cases due to guidance changes during 2014 for sponsors' review of Part D coverage status of drugs for hospice beneficiaries. For the 2016 Star Rating Upheld measure, we will exclude appeal cases for beneficiaries enrolled in hospice at any point during 2014. This exclusion will only be necessary for the 2016 measure as it is based on 2014 data that may have been affected by policy changes. This exclusion will not be continued for the 2017 Star Rating Upheld measure.

11. *Medication Adherence (for Diabetes Medications and Hypertension (RAS antagonists)) (Part D).* PQA updated its 2014 specifications for these two measures to exclude End-Stage Renal Disease (ESRD) patients from the denominator of these measures based on the ICD-9 code 585.6 and/or by the RxHCC 121. We are finalizing our proposal to use the beneficiary ESRD coverage dates reported in the Medicare Enrollment Database (EDB) rather than the ICD-9 code or RxHCC, to identify beneficiaries with ESRD for

exclusion for the 2016 Star Ratings. Beneficiaries with ESRD will be excluded from the denominators of these measures for the entire calendar year.

EDB data are available for all Part D beneficiaries, and are also current (after considering data lag), whereas RxHCCs do not necessarily reflect current diagnoses. CMS's testing of these indicators found a very high level of overlap between the ESRD indicators in the EDB and ICD-9 codes in inpatient and outpatient claims when calculating the final rates for these measures. While there is some lag in data updates, we found the overlap between the two data sources was greater than 95%. Issues of data lag should be resolved by the time the final 2016 Star Ratings are calculated in July 2015.

See *Retirement of Measures* section for additional discussion regarding the Diabetes Treatment measure.

12. *Medication Adherence (Diabetes Medications, Hypertension (RAS antagonists), and for Cholesterol (Statins)) (Part D).* Currently, when calculating the Proportion of Days Covered (PDC) for the three Adherence measures, if a beneficiary disenrolls from his/her contract in the middle of the calendar year due to death or disenrollment, CMS uses the Common Medicare Environment (CME) enrollment table to obtain the beneficiary's disenrollment date and identify the end of the beneficiary's measurement period. The disenrollment date in the CME is always the last day of the month of disenrollment, regardless of the date of death or actual disenrollment. For example, if a beneficiary is enrolled in a contract starting January 1, 2013 and has a death date of May 10, 2013, CMS uses the May 31, 2013 CME disenrollment date as the end of the beneficiary's measurement period. In response to sponsor feedback, we investigated the feasibility and impact of using the exact death date when available in CME instead of the CME disenrollment date as the end of the beneficiary's measurement period.

    This change affects two aspects of the Adherence rate calculation. First, it may reduce the number of beneficiaries eligible for inclusion in the denominator due to the 91 days restriction. To be included in the denominator of the Adherence rate per the PQA specifications, the beneficiary must have at least two fills of the relevant medication(s) and the first fill must occur at least 91 days before the end of the beneficiary's measurement period. By using the death date instead of the month-end date as the end of the beneficiary's measurement period, some beneficiaries may no longer be eligible for the denominator.

    Secondly, for beneficiaries who have death dates that occur before the end of the month, the methodology change shortens the beneficiary measurement period in the PDC calculation. The PDC represents the proportion of days covered by the relevant

medication(s) between the date of the beneficiary's first fill and the last day of the measurement period.

Based on simulations with the data used for the 2015 Star Ratings, we found replacing the month-end date with the death date to generally have no effect on the majority of contracts' Adherence rates. This change could have an impact on a small number of individual beneficiaries' PDCs within a contract; therefore, some contracts may observe a small positive or negative impact on their Adherence rates. Simulations of this change using data from the 2015 Star Ratings found that a small number of contracts (less than 5%) may have small increases or decreases in their highest Star Rating (i.e., overall rating for MA-PDs and Part D rating for PDPs). We will use the exact death date (when available in CME) instead of the CME disenrollment date as the end of the beneficiary's measurement period beginning with the 2016 Star Ratings to improve the specificity of the PDC calculation. Comments from sponsors to the draft Call Letter strongly supported this change to improve the specificity of the measure. We also will implement this change in the Patient Safety monthly reports of 2014 PDE in early 2015. We note that there can be up to a three month delay for a beneficiary's death date to populate in the CME; therefore, the data may change in the monthly reports, but should stabilize by the time data are finalized for the 2016 Star Ratings in July 2015.

13. *Obsolete NDCs (Part D).* For the 2016 Star Ratings and display measures (using 2014 PDE data), we will implement PQA's 2014 obsolete date methodology.

    Specifically, the obsolete date methodology includes the following steps:

    - Query the MediSpan and First DataBank databases to develop an NDC list.
    - Cross-check the NDC list developed at step 1 against the FDA's Comprehensive NDC Structured Product Labeling (SPL) Data Elements File (NSDE) and its effective dates.
    - Include the NDC in the file if:
        - There is no obsolete date noted by MediSpan or First DataBank or NSDE; or
        - The obsolete date in any of the databases is within the measurement year; or
        - The obsolete date is within six months prior to the beginning of the measurement year.

    While most commenters supported the implementation of the PQA's updated obsolete NDC methodology for the 2016 Star Ratings, CMS received some suggestions for additional methodology changes (including increasing the frequency of updates to the NDC list and increasing the look back period). We will share these comments with PQA, as they maintain the NDC lists and methodology.

14. *CAHPS (Part C & D).* As announced in the 2015 Call Letter, and 2016 draft Call Letter, we will make minor modifications to the CAHPS methodology to permit contracts that have CAHPS scores that are imprecisely measured due to low-reliability to receive 1 or 5 stars, if evidence warrants such a designation. In the past we have not assigned contracts that had a score with low reliability 1 or 5 stars given the imprecision around the score. However, CMS has conducted additional analyses and some contracts with scores that have low reliability nonetheless have good evidence of performance that is well above the 4-star cut point or below the 2-star cut point. We will modify the CAHPS methodology to permit low-reliability contracts to be assigned 5 stars if the measure score exceeds the 5-star cut point and also exceeds the 4-star cut point by 1 standard error. Similarly, low-reliability contracts can be assigned 1 star if their score is below the 1-star cut point and also falls below the 2-star cut point by 1 standard error.

- *Retirement of Measures*

  CMS is proceeding with retiring the following measures for the 2016 Star Ratings:

  - Cardiovascular Care: Cholesterol Screening (Part C)
  - Diabetes Care: Cholesterol Screening (Part C)
  - Diabetes Care: Cholesterol Controlled (Part C)
  - Appropriate Treatment of Hypertension in Diabetes (Part D)

  Due to the release of the new American College of Cardiology (ACC)/American Heart Association (AHA) Guidelines on the Treatment of Blood Cholesterol, NCQA convened its Cardiovascular Measurement Advisory panel in order to address the question of whether changes were needed in their HEDIS measures related to LDL-C control.

  For HEDIS 2015, NCQA retired the three Part C measures listed above so the data from these measures will no longer be available to be included in the Star Ratings.

  PQA has elected to retire the measure Appropriate Treatment of Hypertension in Diabetes as a result of new guidelines from the eighth Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC-8) support several therapeutic categories, in addition to Angiotensin Converting Enzyme (ACE) Inhibitors and Angiotensin Receptor Blockers (ARBs), as first line treatment of hypertension for persons with diabetes (*JAMA. 2014; 311(5):507-520).* Most commenters disagreed with retaining this measure for the 2016 Star Ratings, because the new guidelines were published early in the data year (2014) which may bias the measurement. Consequently, CMS is moving forward with retiring this measure from the 2016 Star Ratings.

- *Temporary Removal from Star Ratings*

  Improving Bladder Control (Part C). This measure, collected through the Health Outcomes Survey (HOS), assesses the percentage of beneficiaries with a urine leakage problem who discussed this problem with their provider and received treatment for the problem. This is a cross-sectional (not a longitudinal) measure collected through HOS. NCQA is making three changes to this measure. First, NCQA changed the denominator of both indicators to include all adults with urinary incontinence, as opposed to limiting the denominator to those who consider urinary incontinence to be an issue. This will remove a potential bias toward only sampling patients who were treated unsuccessfully. Second, NCQA changed the treatment indicator to assess whether treatment was discussed, as opposed to 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 how much urinary incontinence impacts quality of life for beneficiaries. This outcome indicator will not be part of the Star Rating system until additional analyses have been done. These changes required revising the underlying survey questions in HOS. The revised questions will be first collected in 2015. As a result of these changes, there will be no data for this measure for the 2016 and 2017 Star Ratings. We will address the use of data from the revised measures for the 2018 Star Ratings in a subsequent Call Letter.

- *Contracts with Low Enrollment*

  Low enrollment contracts, as defined in §422.252, are those where enrollment is such that HEDIS and HOS data collections cannot be used to reliably measure the performance of the health plan. In the past, we have believed that contracts with less than 1,000 enrollees would meet that definition, but we have reevaluated whether that threshold is an appropriate implementation of the regulatory standard. Contracts with less than 1,000 enrollees first submitted HEDIS data to CMS in the summer of 2013. As a precursor to including low-enrollment contracts in the Star Ratings, CMS included HEDIS scores for low-enrollment contracts as part of the 2014 display measures. For the 2014 Star Ratings, 27 additional contracts would have received an overall rating if we used these data rather than merely posting the data as part of the display measures. Based on the data we received, CMS has determined that there are sufficient data to reliably measure and report on contracts in the Star Ratings with 500 or more enrollees in July of the HEDIS measurement year. (William T. Hoyt. 2010. “Interrater Reliability and Agreement” in Gregory R. Hancock and Ralph O. Mueller, The Review’s Guide to Quantitative Methods in the Social Sciences. NY: Routledge.)

  Last year CMS delayed including contracts with enrollment from 500 to 999 enrollees into the Star Ratings on Medicare Plan Finder to gain an additional year of experience with collecting and analyzing these data and to evaluate the reliability of the data. Beginning with

the 2016 Star Ratings, contracts with 500 or more enrollees as of July 2014 will not be considered low enrollment contracts; they will be included for Quality Bonus Payments to be made in CY 2017. Contracts with 500 or more enrollees in most cases will have sufficient data to produce both overall and Part C and D ratings. The HEDIS data for contracts with less than 500 enrollees will continue to be posted on the Display Page as these will continue to be considered low enrollment contracts.

CMS has provided low enrollment contracts (i.e., less than 500 enrollees) their simulated 2014 and 2015 Star Ratings data. It is important to note that only the measures where the contract meets the minimum denominator requirements are included in the Star Ratings. Thus, if a contract with 500 to 999 enrollees does not meet the minimum denominator requirements for a measure, the particular measure will not be included in its overall rating calculation. Contracts between 500 to 999 enrollees have always been included in the Star Ratings for all non-HEDIS measures when the contract met the measure denominator requirements. However, without the HEDIS data, the contracts did not have enough measures to obtain an overall rating. Starting with HEDIS 2013, contracts with less than 1,000 enrollees began submitting HEDIS data. For the HEDIS measures, we will exclude from the cut point determinations and the overall rating calculations any contract-specific measure scores that have low reliability. Specifically, any contracts with 500-999 enrollees that have a contract-level reliability of less than 0.7 for a measure will be excluded. The contract-level reliability measures the signal-to-noise ratio which is how much of what is being measured is "signal" (true variation in performance), rather than "noise" (measurement error). Reliability levels of 0.7 or greater are acceptably reliable.

- *Data Integrity*

  CMS's Star Ratings data must be accurate and reliable. CMS's policy is to reduce a contract's measure rating to 1 star if it is identified that biased or erroneous data have been submitted. This exclusion 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; 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. CMS may perform additional audits or reviews to assure the validity of data for specific contracts. Without independent validation of these data, CMS could reward contracts with falsely high ratings in these areas.

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 are interested in developing more comprehensive quality checks for measures using organization or sponsor-reported data, for example, the Part C and D appeals measures which use data that sponsors report to the IRE. Sponsors have commented in the past that they too are supportive of a comprehensive review of their processes, in lieu of focused or targeted sampling to determine if errors have been made, but at no additional costs to sponsors. Comments to the 2016 draft Call Letter again requested CMS differentiate between systemic and/or intentional errors from infrequent clerical errors.

CMS began using validated Part C and D plan reported data for the 2015 Star Ratings with the introduction of the SNP Care Management measure. In order to be evaluated in this measure, contracts must score at least 95% for the SNP Care Management reporting section, and also be found by the data validator to be compliant with data validation standards/sub-standards for the specific data elements used for the measure. Contracts that fail to meet this requirement are assigned 1 star in this measure, and shown as "CMS identified issues with this plan's data." With the addition of the new MTM CMR measure for 2016 Star Ratings, CMS will apply the same methodology for contracts' validation results of reported MTM data. Sponsors may appeal determination(s) it receives for either individual Part C and/or Part D reporting sections or for the overall combined Part C and Part D determination within 5 business days of receiving information from CMS about the threshold level. Sponsors should refer to the Data Validation Manual and other documents posted at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html for more information.

We continue to consider expanding the data integrity checks to use the Part C and D Data Validation results for associated measures as a viable option in the future. This would provide a new method of comprehensively reviewing sponsors' operational systems and verifying the validity of some data used for Star Ratings. Per the Part C and D reporting requirements, contracts submit various data such as their processing of organization determinations, coverage determinations, and appeals, including the timeliness of their processing. Independent data validators' assessments that these data were inaccurately processed and reported to CMS may have implications to the other data provided or reported for Star Ratings.

For example, contracts that fail data validation for specific data elements related to organization determination, coverage determination or redetermination timeliness (e.g., For the CY2014 Coverage Determinations and Redeterminations reporting section, elements 1.N – coverage determinations processed timely and 2.C – redeterminations processed timely) would be considered to have also biased the data reported to the IRE, and therefore should be reduced in the respective Part C or D appeals Star Rating measures. Similar applications could be determined for other reporting areas directly relevant to Star Rating

measures. CMS would not apply data validation results to measurement areas where other validation or audit activities exist, such as HEDIS measures.

We performed an analysis of Part D data reported by sponsors for CY 2013 which were independently validated in April-June 2014. A total of 62 contracts failed to meet CMS's passing thresholds for accurately reporting coverage determinations/exceptions or redeterminations data for CY2013 (4 of these 62 contracts failed to pass data validation in both sections' data) as outlined in the Part C and D Data Validation Standards. Of these 62, 8 contracts were also found by CMS 2014 program audits to have serious CDAG deficiencies and already reduced in the corresponding 2015 Star Ratings appeals measure. Therefore, if we had expanded the use of CMS's data validation results for the 2015 Star Ratings, approximately 50 additional contracts would have reduced Part D appeals Star Ratings. Since not all sponsors are audited by CMS each year, this method may more comprehensively capture evidence of biased data. Organizations continued to raise concerns regarding the data validation standards, CMS training for reviewers, and inter-rater reliability. CMS will provide additional guidance in response to these issues. We will not consider applying the data validation results until the CY2017 Star Ratings, at the earliest, until the concerns raised are explored and additional guidance is issued.

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 NQF, and the HRM rate is calculated using the PQA specifications and medication list based on American Geriatrics Society (AGS) recommendations.

We have received comments regarding the measure specifications with respect to Part D formulary and utilization management requirements. Sponsors may be required to include certain HRM medications on their formularies to meet certain formulary review requirements. The goal of this measure is to reduce potentially inappropriate use of these medications by beneficiaries over the age of 65, when there may be safer drug choices. We understand that the use of these medications may be medically necessary for some beneficiaries 65 and older, and the goal is not to achieve a zero percent HRM rate. Also, Part D sponsors generally serve some enrollees under age 65.

Sponsors may apply utilization management edits to reduce the inappropriate use of these medications. However, in the absence of specific age-related contraindications in the FDA-approved labeling, these edits must be submitted and approved by CMS through HPMS. Sponsors who implement unapproved edits for these medications may be found to have data integrity issues. CMS's policy is to reduce a contract's measure rating to 1 star if it is identified that biased or erroneous data have been submitted. Implementation of unapproved edits for HRM medications would be subject to this policy.

- *Duals/LIS*

  CMS is proud of the Star Ratings Program and the quality improvements it has generated. We believe MAOs and Part D sponsors have responded to this program because it employs a solid, reliable methodology. CMS continuously reviews the methodology and seeks to enhance the methodology to improve the Star Ratings process, incentivize plans, and provide information that is a true reflection of the performance and experience of the enrollees.

  Multiple MA organizations and PDP Sponsors believe that plans with a high percentage of dual eligible (Dual) and/or LIS enrollees are disadvantaged in the current Star Ratings Program. Similar claims have been made about other Medicare quality measurement programs such as readmission rates, Hospital Quality Reporting, Home Health Quality Initiative, ESRD Quality Incentive Program, and the Outpatient Quality Reporting Program. CMS is committed to exploring and examining whether the Star Ratings are sensitive to the percentage of Dual/LIS enrollees in the plan. Extensive internal and contract-supported research has been commissioned and continues to date. The IMPACT Act (P.L. 113-185) instructs ASPE (Assistant Secretary for Planning and Evaluation) to conduct a study that examines the effect of individuals' SES on quality measures and resource use and other measures for individuals under the Medicare program. All CMS components are in the process of coordinating their research with ASPE. The Star Ratings team will continue to work collaboratively with ASPE to examine the issue and its impact on the Star Ratings program. CMS will also continue to work diligently to explore this issue with the goal that all MA and Part D beneficiaries receive the highest quality care possible.

  In fall 2014, CMS issued a Request for Information (RFI) that provided the opportunity for the public and Medicare health and drug plans to submit their analyses and research that demonstrated that dual status causes lower MA and Part D quality measure scores. In the RFI, we also solicited examples of any research that demonstrated that high quality performance in MA or Part D plans can be achieved in plans serving Dual beneficiaries. The research conducted and information collected related to Dual/LIS status and Star Ratings measures is publically available at http://go.cms.gov/partcanddstarratings.

  There are a total of 46 Part C and D Star Rating measures for 2015. The current research conducted by CMS, both internally and in conjunction with our contractors, excluded measures that were already case-mix adjusted for SES, measured plan operations and performance not beneficiary-level issues, were being retired/revised, or were restricted to SNP only. After applying these exclusions, CMS's extensive review focused on 19 of the 46 individual Star Rating measures.

  The CMS research had the advantages of access to Star Ratings data across contracts and at different levels of measurement (e.g., beneficiary, plan-level, contract-level, and the ability

to link beneficiary-level datasets). Numerous advanced statistical methodologies were employed by CMS for its research. Regardless of the statistical methodology employed, statistically significant results do not necessarily imply practical significance. Given the large quantity of data available for internal research, the practical significance (i.e., the size of the effects) was evaluated in addition to the statistical significance.

CMS's research examined a number of issues including, but not limited, to the following: modelling the effect of Dual/LIS status on the measure outcomes of interest using contract effects both with and without controlling for individual characteristics of age, sex, and race/ethnicity; examining the effect of controlling for self-reported health status, education, and age; and exploring the possible existence of differences in performance of Dual/ LIS and non-Dual/LIS in terms of the percent of Dual/LIS enrollees in the contract.

Our research has found some differences in measure-level performance for Dual/LIS beneficiaries, although for the majority of measures the differences are small. Even for measures with larger observed differences, evidence of an association between higher Dual enrollment (and higher LIS beneficiary enrollment) and lower Star Ratings does not prove causality. For some measures, scores were higher for plans with higher Dual enrollment. Additionally, in some cases, the association between scores and Dual/LIS enrollment dissipated or reversed once the models included additional individual characteristics. For some Part D measures, the differential between LIS and non-LIS results was specific to whether the plan was an MA-PD or PDP. Further, findings suggest that certain beneficiary characteristics—namely, educational attainment, dual eligibility, self-rated general health status, and age—are strongly associated with better rates for several HEDIS measures within contracts. In addition, the preliminary analysis revealed that in general, contracts that have a high percentage of LIS enrollees have LIS group means on par with the non-LIS enrollees in the contract.

In response to the RFI, CMS received over 65 submissions. The majority of the submissions were from sponsors, plans, and associations representing them. The submissions varied in terms of content, evidence, and data source. Over half of the submissions employed quantitative methodologies and of those, approximately half included statistical significance testing. A number of the submissions used a mixed methodology. CMS is grateful for the time and effort put forth by the commenters to aid in the examination of the Dual/LIS concerns.

Some of the quantitative research used rich, detailed patient-level data that were readily available to plans employing a variety of methodologies. Other submissions relied on publically available data as the primary source for information. The unit of analysis varied based on the data employed. The definition of Dual and LIS varied across submissions. A number of the studies included Duals in Dual SNPs only, some analyzed Duals and excluded all beneficiaries enrolled in Dual SNPs, and others used a broader view and

included all Duals, regardless of whether the enrollee was enrolled in a Dual SNP, MA-PD, or PDP. A number of the submissions used a standard for evidence as association and not causation. Several cited their Acumen Medication Adherence reports that break out results by LIS and non-LIS; however, we note that these reports do not control for contract-level effects. Some of the research conducted reflected limited regional effects and thus, lacked generalizability of the results to the Star Ratings Program; nonetheless, it was valuable in its own right.

A comparison of the RFI quantitative, statistically-based submissions demonstrated varied results. Some research indicated that Duals (as a group) realized lower performance outcomes on measures, while other research on the same measure using a different subgroup of beneficiaries found no difference in performance outcomes for Duals or that Duals experienced better outcomes as compared to a non-Dual comparison group. Many of the studies found an association between performance rates and Dual status but did not control for demographic characteristics.

The qualitative submissions provided the opportunity for submitters to share their best practices. Many of the submissions referenced other studies and provided responses that reflected a strong commitment to continuous improvement in providing quality care. A number of plans provided insight to the challenges of addressing the needs of the Dual/LIS population and innovative ways to provide outstanding care to all of their beneficiaries. There were some sponsors that focus on Duals and LIS that were proud of their high quality performance in MA or Part D plans and provided proof that such results can be achieved.

NCQA responded to CMS's Request for Information with concerns that we may risk lowering the standard on measurement by applying case-mix adjustment to performance measures since this can mask disparities in care for lower SES patients. NCQA recommended working with providers to ensure they have the resources and skills to meet the patients' needs. In its communications to CMS, NCQA cited other work that demonstrates that good outcomes can be achieved despite challenges that may be present for subgroups of beneficiaries.

CMS believes additional research into what is driving the differential performance on a subset of measures is necessary before any permanent changes in the Star Ratings measurements can be developed and implemented.

In the long-term, it may be appropriate to adjust the Star Ratings in cases where there is scientific evidence that performance on certain measures is impacted by patient factors such as comorbidities, disability, or Dual/LIS status. Additionally, such adjustments may particularly be warranted when these unadjusted patient factors may influence patient ability to meet recommended clinical guidelines. These factors could include, for example, health literacy issues, transportation issues, comorbidities, and disabilities. Any changes would be

proposed and subject to comment through future Star Ratings Request for Comments and Call Letters.

In the draft Call Letter, we had proposed to take the interim step of reducing the weights on a subset of six Part C measures for MA (MA-only and MA-PD contracts) and 1876 contracts and one Part D measure for PDP contracts for the 2016 Star Ratings where our preliminary analyses revealed both practical and statistically significant evidence of differential outcomes for Dual/LIS beneficiaries. Five of the six MA measures were process measures already receiving a low weight in the Star Ratings system, and there was one outcome measure for PDPs. Many stakeholders provided comments about the proposed interim step, as well as general feedback about the possible sensitivity of socioeconomic factors on the Star Ratings Program.

CMS appreciates the views and opinions contained within the responses to the draft Call Letter, and we listened carefully to the multiple stakeholders in making our decision on treatment of these seven measures and further steps in our analysis. We are grateful for the positive feedback that commended our examination of the possible effect of individuals' SES on quality measures used in the Star Ratings Program. Many commenters applauded CMS for the transparency in our processes, as demonstrated by the dissemination of the RFI information regarding external and internal research and findings.

The vast majority of commenters did not support the reduction of the weights of a subset of measures. The few stakeholders that viewed the proposal somewhat positively stressed that it should only be implemented as a short term solution. Many respondents felt it was premature to make a modification to the Star Ratings methodology and that such changes threatened the integrity of the methodology and the Star Ratings program. Instead, many commenters believed we should continue our internal research, coordinate with ASPE, and work with measure developers. In addition, many commenters believed the proposed change would not provide immediate relief and posed numerous potential unintended consequences such as inflating ratings and signaling improvement in the quality of care that may not actually exist. Further, commenters expressed concern that some measures or groups of measures may now have greater emphasis due to the modified weights for the subset of measures. Commenters also warned that reducing the weight of the selected measures would de-incentivize plans to improve quality on important aspects of care and would not reward plans for their current efforts to improve on those measures. Some commenters believed that if a revision were implemented, it should be applied to only plans with a high percentage of LIS or Dual enrollees. Several respondents suggested modifying the thresholds for plans with a high proportion of LIS to allow like comparisons across all plans (apples-to-apples). A number of respondents focused on proposing financial solutions. Several commenters suggested ways to reward plans serving Dual/LIS enrollees and allow additional payment for the 2016 payment year. In addition, many sponsors suggested that if CMS moves forward with the modified weights for 2016 Star Ratings, we should implement a 'hold-

harmless' provision. All commenters did agree with retaining the original weights of all measures for the improvement measures.

After consideration of the information collected to-date and the comments received in response to the draft Call Letter, CMS has decided not to move forward with the proposed interim step to reduce the weights on a subset of measures for the 2016 Star Ratings Program. CMS is firmly committed to continuing to identify the issue more precisely (i.e., to identify the effect on specific measures) and to build the foundation for a solution that appropriately addresses the issue.

CMS believes the appropriate solution must focus on beneficiaries. The policies implemented must result in high quality of care and health outcomes for all of our beneficiaries. We cannot risk the potential for masking disparities in care or jeopardizing the integrity of the Star Ratings Program by implementing changes that are not grounded in scientific evidence. Beneficiaries must be provided information on Medicare Plan Finder that is a true reflection of the care and experience of the plan's members.

Given the uncertainty about what factors are driving the associations observed in the preliminary research, further in-depth examination by CMS, our HHS partners, MAOs, and Part D sponsors in quality measurement, as well as external measure developers, is warranted. The goal of the research is to provide the scientific evidence as to whether sponsors that enroll a disproportionate number of Dual/LIS beneficiaries are systematically disadvantaged by the Star Ratings and, if so, how such sponsors are disadvantaged (e.g. to identify specific quality measures) and to what extent they are disadvantaged.

We recognize that the solution must acknowledge the unique challenges of serving traditionally underserved subsets of the population. The original request from some industry representatives was that certain quality measures be adjusted for the SES of their enrollees. The nature of such a statistical adjustment is that some plans would benefit, while others would experience lower measured performance. We note that a number of proposals submitted by the industry during the comment period were not consistent with this approach and were not budget neutral. In addition, we must be cognizant that the policy response must adequately address the unique situations in the territories. Upon completion of additional research, adjustments for the 2017 Star Ratings or other appropriate adjustments would be proposed in the fall Request for Comments. Depending on the research findings, solutions could include case-mix adjustments, different weighting options, excluding certain measures, or payment solutions. As we continue to explore this important issue, we will continue to be transparent and welcome collaboration with all stakeholders.

- *Measures Posted on the CMS Display Page*

Display measures posted on www.cms.gov are not part of the Star Ratings. They include measures that have been transitioned from the Star Ratings, new measures that are tested

before inclusion into the Star Ratings, or measures displayed for informational purposes. Similar to the 2015 Display Page, organizations and sponsors will have the opportunity to preview their data on the display measures prior to release on CMS's website in fall 2015. Data on measures moved to the Display Page will continue to be collected and monitored, and poor scores on display measures are subject to compliance actions by CMS. During the Request for Comments, some commenters voiced concerns about CMS issuing compliance actions for display measures. We remind sponsors that many display measures evaluate compliance with contractual requirements, and that overall performance trends are considered when identifying poorly performing contracts. It is expected that all 2015 display measures will continue to be used for 2016, and remain posted on www.cms.gov. CMS will continue to provide advance notice regarding measures considered for implementation as future Star Ratings. Other display measures are provided as information only.

Regarding the Pharmacotherapy Management of COPD Exacerbation (PCE) display measures, NCQA staff has determined that changes to the PCE measure to incorporate intravenous corticosteroids administered during inpatient or ED visits is not possible at this time due to the significant technical challenges of capturing this information through a measure limited to administrative claims. The administration of these medications during treatment of the exacerbation is clinically appropriate to include in the measure numerator, and NCQA will continue to examine methods to re-specify the measure accordingly as data sources are made available for measurement.

- *Forecasting to 2017 and Beyond*

  The following describes potential changes to existing measures and new measures. All of the HEDIS changes and additions are tentative pending a final decision by the NCQA Committee on Performance Measurement and the Board of Directors in June 2015. We also describe potential changes to CAHPS measures to reflect AHRQ's CAHPS 5.0 Health Plan Survey.

  - Potential changes to existing measures:

    15. Medication Reconciliation Post Discharge: 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. NCQA is proposing two changes: 1) expand the coverage on this measure from Medicare Special Needs Plans only to all of MA; and 2) expand the age range from adults 65 years and older to adults 18 years and older. Both of these proposed changes for HEDIS 2016 are seen as an important step to measure the quality of care coordination post-discharge for MA beneficiaries as well as ensuring patient safety. If this measure is implemented for HEDIS 2016, CMS will include in the 2017 Display Page and will consider for the 2018 Star

Ratings. We have shared comments submitted to the draft Call Letter about this measure with NCQA.

16. CAHPS 5.0 changes: The current MA & PDP CAHPS Survey includes the core CAHPS 4.0 Health Plan Survey. CMS is interested in potentially updating the survey for future years to reflect AHRQ's CAHPS 5.0 Health Plan Survey. We will conduct an experiment in 2015 to understand if/how performance on CAHPS measures differs between 4.0 and 5.0. Based on these results we will consider whether changes or adjustments should be made to the MA & PDP CAHPS Surveys in the future. We will provide details on results as soon as they are available and provide opportunity for comment on any changes to the measures.

CMS reminds contracts that MA & PDP CAHPS Surveys are currently translated into Spanish and Chinese (Cantonese and Mandarin). We received a few suggestions for translations into additional languages and will consider these going forward.

17. MPF Price Accuracy: CMS is considering updating the MPF Price Accuracy measure in the future. The first proposed change is related to the method in which claims are excluded from the measure. Currently, the measure is limited to 30-day claims filled at pharmacies reported by sponsors as retail only or retail and limited access only in their Medicare Plan Finder (MPF) Pharmacy Cost files. That is, claims filled for near 30 days supplies, or claims filled for 60 and 90 days supplies are excluded. Additionally, claims filled by retail pharmacies who 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 propose to include claims with 28-34 days supplies, as we believe it would be appropriate to compare their PDE costs to MPF's fixed display of 1 month pricing. We also propose to include 60 and 90 day supply claims. Beginning with CY2015 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. While the majority of claims are for a 30 day supply, we found that claims with a 90 day supply account for almost one-fifth of available PDE data, thus allowing for a more comprehensive evaluation of PDE claims.

Additionally, we propose to use the PDE-reported Pharmacy Service Type code in conjunction with the MPF Pharmacy Cost data to identify retail claims. Prior to the availability of this PDE field, there was no way to determine whether a given claim was priced under the retail setting of the dispensing pharmacy when a pharmacy had multiple types. There may be incentives for sponsors to misreport pharmacy types in the MPF Pharmacy Cost files to reduce the number of claims eligible for inclusion in

the Price Accuracy Score. CMS began requiring pharmacies to populate the Pharmacy Service Type field on all PDEs at the end of February 2013. As of June 2014, the Pharmacy Service Type field was populated for 99.9 percent of CY2014 PDEs submitted. We recommend expanding the retail claims identification process to include all PDEs that are from at least 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.

These proposed changes can also be applied to mail order claims. Including mail order claims with 28-34, 60, and 90 days supplies would add another dimension to the Price Accuracy Scores and further increase the number of PDEs eligible for inclusion. CMS could take the following steps to include mail order pharmacy claims: 1) CMS uses the MPF Pharmacy Cost data to identify mail order pharmacies; 2) CMS identifies PDEs filled at those pharmacies, with the Pharmacy Service Type field reported as Mail Order; 3) CMS uses MPF Pricing File data for 30, 60, and 90 day supply mail order claims, and MPF Pharmacy Cost data for brand and generic dispensing fees to compare MPF and PDE costs for mail order claims.

We are also considering changes to the methodology by which price accuracy is calculated. Because the current methodology measures the magnitude of a contract's overpricing relative to its overall PDE costs, the Price Accuracy Scores do not reflect the frequency of accurate price reporting, and can be significantly impacted by high cost 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 also factor in how often PDE costs exceeded MPF costs. The frequency of inaccuracy by a contract would be the percent of claims where PDE cost is greater than MPF cost. The numerator is the number of claims where PDE cost is greater than MPF cost, 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 Medicare Plan Finder 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, there is the potential to harm beneficiaries by not changing the prices at the point of sale to lower prices, where warranted. We would note that PDEs priced lower than MPF displayed pricing does not lower a plan's score in this measure. CMS's simulation of this proposal found little change in the range of contracts' accuracy scores. Other options we explored included 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 cost and a $1.00 MPF cost would be considered equally overpriced as a claim with a $200.00 PDE cost and a $100.00 MPF cost.

We propose these changes are implemented for the 2018 Star Ratings (using 2016 PDE and MPF data). We believe the proposed changes will greatly improve the Price Accuracy Scores, making them a more comprehensive assessment of contracts' price reporting for Part D beneficiaries.

- Potential new measures:

Comments to the 2016 draft Call Letter about these measures have been shared with NCQA and PQA. CMS will also monitor any additional measures developed by NCQA and PQA for potential incorporation into the Star Ratings in future years (i.e., 2017 and beyond).

18. Care Coordination Measures: Effective care coordination contributes to improved health outcomes. CMS believes that 5-star plans perform well on our Star Ratings measures because they understand how to effectively coordinate care for their enrollees. Our assumption about plans, however, is based largely on anecdote and discussions with high-performing plans. To date, our ability to measure plans' care coordination efforts has largely been limited to data we collect from CAHPS surveys, which reflect enrollees' experience with the care they receive.

CMS is working to expand efforts in this area to measure the plans' coordination approaches. These efforts will focus on developing measures related to the patient assessment of their plans' care coordination, encounter data-based measures, and medical records-based measures. CMS is particularly interested in comments on measures that could be developed using MA encounter data. For example, measures that identify post-discharge utilization by plan enrollees in order to identify plans in which an unusually high number (proportion) of enrollees do not obtain expected follow-up care (follow-up physician visit within first week),

enrollees receiving Part A-covered skilled nursing facility care who do not receive information about receiving long-term services and supports in a community settling, or, if appropriate, for whom there are no changes to prescribed medications following discharge. In addition, CMS is interested in measuring the effectiveness, timeliness and clinical relevance of information shared electronically during transitions and referrals, and is seeking to identify measures of electronic exchange of health information that reflect improved care coordination. As measures are developed and tested, they will be added to the Display Page and Star Ratings.

19. Asthma Measure Suite: NCQA tested three asthma measures in fall 2014 to evaluate the effects of expanding the measure to include older adults. The age range for these measures is currently members 5 – 64 years of age. The three measures under consideration for inclusion of older adults include:

- Use of Appropriate Medications for People with Asthma: The percentage of members during the measurement year who were identified as having persistent asthma and who were appropriately prescribed medication during the measurement year.
- Medication Management for People with Asthma: The percentage of members 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).
- Asthma Medication Ratio: 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.

Testing results will be reviewed with NCQA's measurement advisory panels, including the Geriatric Measurement Advisory Panel. These panels will help NCQA determine whether expanding the age range of these measures to include the 65+ population is appropriate. The proposed changes, if approved, would be published in HEDIS 2016.

20. Depression: NCQA is developing a new set of HEDIS measures that would assess depression care along the continuum of care. These measures are intended for all individuals age 12 and older but may be particularly relevant to the population age 65 and older. The measures currently in testing include:

- Depression Screening and Follow-up: The percentage of individuals who were screened for depression using a standardized tool and received appropriate follow-up for a positive screen.

- Utilization of the PHQ-9 for Monitoring of Depressive Symptoms: The percentage of individuals with a diagnosis of major depression or dysthymia who were monitored using the Patient Health Questionnaire (PHQ-9).
- Depression Remission, Response or Treatment Adjustment at 6 Months: The percentage of individuals with a diagnosis of major depression or dysthymia and symptomatic depression at baseline who achieved either remission of depression symptoms, response (i.e., reduction) in symptoms or an adjustment in treatment at six months.

21. Hospitalizations for Potentially Preventable Complications: NCQA is finalizing testing of 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 will assess the rate of hospitalization for complications of chronic and acute ambulatory care sensitive conditions. The intent of the measure is to assess the quality of ambulatory care to prevent the complications of chronic and acute conditions that result in hospitalization. The new measure, if approved, would be published in HEDIS 2016.

22. Statin Therapy: NCQA is currently developing two statin therapy measures aligned with the 2013 ACC/AHA blood cholesterol guidelines. The 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. Measure development and field-testing are expected to continue through winter 2015. The new measures if approved would be published in HEDIS 2016.

PQA has developed a new measure to support ACC/AHA guidelines which recommend moderate- to high- intensity statin therapy for primary prevention for patients aged 40-75 years of age with diabetes. The measure calculates the percentage of patients in this age group who received a medication for diabetes that also received a statin medication during the measurement period. This measure was endorsed by the PQA in November 2014, and CMS will continue to test this measure, explore developing new reports to Part D sponsors via the Patient Safety Analysis website, and evaluate adding this measure as a future Part D Star Rating. For example, with PQA endorsement of this measure in 2014, this measure could be considered as a new 2017 display measure (using 2015 data) and a 2018 Star Rating (using 2016 data). Patient safety reports to sponsors may be released as early as spring 2015.

23. High Risk Medication (HRM): The American Geriatric Society (AGS) is currently considering revisions to the Beer's criteria which may precipitate future changes to the PQA measure specifications and medication list. CMS is closely following these activities. If changes are published by the AGS and measure

updates endorsed by the PQA with sufficient lead time ahead of the 2017 formulary and bid deadlines in May and June 2016, CMS may consider adoption for the 2019 Star Ratings (using 2017 data). Additionally, CMS will consider other stakeholder's suggestions for future measure specification changes.

24. Opioid Overutilization: PQA is currently developing three measures that examine multi-provider, high dosage opioid use among individuals 18 years and older without cancer. Patients enrolled in hospice are also excluded. The measures currently in development include:

- Measure 1 (Opioid High Dosage): The proportion (XX out of 1,000) of individuals without cancer or enrolled in hospice receiving a daily dosage of opioids greater than 120mg 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 enrolled in 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 enrolled in hospice receiving prescriptions for opioids greater than 120mg 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.

If these measures are endorsed by the PQA prior to the 2017 bid deadline in June 2016, CMS may adopt them as future display measures or alternatively use in the Overutilization Monitoring System (OMS). Due to concerns about the lack of consensus clinical guidelines for the use of opioids to treat chronic, non-cancer pain and potential exceptions due to medical necessity, CMS is not considering these measures for Star Ratings at this time. Commenters also expressed support of the PQA Triple Threat: Concomitant Use of Opioids, Benzodiazepines, and Muscle Relaxants measure concept currently under development.

- Measurement Concepts

CMS is committed to continuing to improve the Star Ratings by identifying new measures and methodological enhancements. We appreciate the comments received regarding alternative levels of evaluation for Star Ratings, new measures, organization-specific cut points, and the unique challenges of Puerto Rico and other territories. We will consider them as we continue to look at these measurement concepts. Feedback or recommendations help CMS's continuing analyses, as well as our collaboration with measurement development entities such as NCQA and PQA.

Audit & Oversight

Program & Compliance Plan Audit Performance

Since the fall of 2014, CMS has released four HPMS memos regarding best practices, improvement strategies and common findings from program audits, which are meant to be educational for plan sponsors. These memos discuss CMS audit findings related to common compliance violations that resulted in the improper denial of access to care for beneficiaries. Despite our release of these memos and various other outreach efforts, CMS has not found that program audit performance has improved. We strongly encourage plan sponsors to utilize the evaluation tools and information that we have made available to proactively verify that their organizations are compliant with CMS requirements. Organizations must confirm that necessary access to drugs and health services remains uninterrupted for beneficiaries. As a reminder, CMS can pursue enforcement actions including sanctions or civil money penalties for plan sponsors that substantially fail to meet this requirement.

New Program Audit Modules

As announced earlier this year via HPMS memo, CMS will pilot two new audit modules during 2015. These modules will test compliance with Medication Therapy Management (MTM) and Provider Network Adequacy requirements. As with previous pilot audit modules, sponsors will not receive an audit score for their performance, nor will the results appear in their audit report for audits conducted during the pilot phase. Organizations are on notice that the two modules will be revised based on our experience in 2015 and made permanent for contract year 2016, consistent with past piloted audit modules.

Integrated Dual-Eligible Special Needs Plans

We received a range of helpful and supportive responses from representatives of states, D-SNP sponsors, and beneficiary advocates to our request for comments regarding administrative flexibilities that would foster the offering of a more seamlessly integrated benefit for Medicare-Medicaid enrollees, facilitate Medicare-Medicaid integration through D-SNPs, and streamline regulation and oversight for MAOs offering highly integrated D-SNPs. We thank the responders for those comments.

In particular, we received broad support for the development of model notices and marketing materials that better communicate the integrated benefit to Medicare-Medicaid enrollees. We agree that, working with states, D-SNP sponsors, and beneficiary advocates to improve these materials, we can promote better understanding of their Medicare and Medicaid benefits and coverage options by Medicare-Medicaid enrollees. We will be reaching out to these stakeholders to prioritize materials for possible revision and to develop a process for crafting integrated materials. As an initial step in this effort, we will solicit state interest in adding state-specific

information to the model D-SNP non-renewal notice in order to provide a single notice that explains both their Medicare and Medicaid enrollment options.

We received a number of suggestions regarding other potential administrative improvements, including streamlining state and CMS approval processes for materials, coordinating Medicare and Medicaid beneficiary survey requirements, and establishing regular communication with states on D-SNP regulatory issues. We are grateful for these suggestions and will use them to inform our ongoing outreach to plans and states on implementing administrative flexibilities.

Seamless Conversion Enrollment Option

In the draft Call Letter we explained how entities that sponsor Medicaid managed care organizations (MCOs) and affiliated D-SNPs can promote coverage of an integrated Medicare and Medicaid benefit through existing authority for seamless conversion enrollment of Medicaid MCO members as they become eligible for Medicare. We further articulated the current policies for a seamless conversion enrollment option outlined in Chapter 2 of the Medicare Managed Care Manual. A number of commenters did not support this existing enrollment option, urging CMS to carefully evaluate MAO requests for CMS approval of the seamless conversion option, and to closely monitor implementation of any approved requests, in order to ensure beneficiaries are made fully aware of their rights and options, including their option to decline enrollment. We appreciate the concerns raised by these commenters and are committed to the careful review of proposals to ensure that MAOs requesting approval of this enrollment mechanism meet the parameters outlined in guidance and that beneficiaries' rights, including the freedom to choose coverage that best meets their needs, are not undermined as we seek to further Medicare-Medicaid integration.

Benefit Flexibility for Highly Integrated, High Performing D-SNPs

In the draft Call Letter, we sought recommendations on how to increase the number of highly integrated, high performing D-SNPs that take advantage of the flexibility that allows them to offer supplemental benefits beyond those permitted for MA plans, such as non-skilled in-home support services, assistive devices for home safety, and caregiver supports. We received comments recommending both more and less restrictive criteria for which SNPs should have this flexibility, as well as which subgroups of Medicare-Medicaid beneficiaries would most benefit from the benefits that highly integrated, high performing D-SNPs may offer. We note that some of the recommendations would require changes both to the underlying regulations at 422.102(e) as well as to the guidance in Chapter 16b of the Medicare Managed Care Manual. We appreciate these comments and will consider them as we determine appropriate steps that could expand the number of D-SNP enrollees who could benefit from this flexibility.

Value-Based Contracting to Reduce Costs and Improve Health Outcomes

Commercial organizations as well as CMS have increasingly taken steps to make certain that health care providers operate most efficiently, reduce costs, and improve the health outcomes of patients. Such programs often involve physician incentive programs and frequently include financial incentives paid to providers. The Affordable Care Act provides primary care incentive payments, for example, to physicians meeting specific qualifications designed to improve and encourage primary care and the Medicare Shared Savings Program, a new way for Medicare to support high quality, efficient care over time. Through the Innovation Center, CMS is testing on a large scale a wide variety of new payment models including different types of accountable care organizations, bundled payments for episodes of care or related health care services, and primary care medical homes. The overall goal of these payment models is to improve quality of care and reduce its cost. More specific goals include reducing hospital readmissions and improving performance on specific health care measures.

In order for these models to succeed in the long term, health care providers must make operational changes within their organizations. These changes will only be attractive if a critical mass of payers, including CMS, supports these new financial models for health care payment. Therefore, in order to test and evaluate new payment models effectively, CMS will be reaching out to and having conversations with MA organizations regarding how they are using physician incentive payments (e.g. payments based on quality of care, patient satisfaction) and value-based contracting of provider services to achieve these goals. Based on this input, we will also, this year, ask MAOs to share data regarding their adoption of alternative payment models. In the context of value-based contracting we are also interested in comments from MAOs regarding issues or concerns they may have regarding compliance with the physician incentive regulations at 422.208. We note that, under this regulation, MAOs must guarantee that stop-loss insurance is in place if their physicians are at risk for more than 25 percent of their potential income based on the use or cost of referrals they make. Recently, the Department of Health & Human Services (HHS) launched the Health Care Payment Learning and Action Network to help advance the work being done across sectors to increase the adoption of value-based payments and alternative payment models. Information about this initiative and how to participate can be found at http://innovation.cms.gov/initiatives/Health-Care-Payment-Learning-and-Action-Network/.

We received many comments on this section of the draft Call Letter supporting CMS's general goals. Commenters representing physician groups, beneficiary advocates, plans and other stakeholders expressed support and interest in CMS's efforts in this area. Many commenters asked that any new measures CMS develops be genuinely meaningful for achieving higher quality and lower costs. Many commenters pointed to their current efforts in this area or made specific suggestions for standards and measures. CMS looks forward to working with all interested parties to better understand the value-based contracting initiatives many already have in place as we work to support and accelerate the implementation of programs to improve efficiency and quality of care in the MA program.

In the draft Call Letter we solicited comments from MAOs regarding issues or concerns they may have in complying with the physician incentive regulations at §422.208, particularly the current stop loss requirements. We received several comments indicating that the current requirements and stop loss thresholds are outdated and should be updated because they could hamper development of value-based contracting processes. One commenter stated that value-based contracting has little to do with, and is outside the scope of the current physician incentive requirements.

CMS will consider all of the comments as we move forward in our efforts to encourage value-based contracting and to update the MA program regulations.

MAOs have great flexibility to include incentives in their physician contracts and many are employing methods to reduce costs, better coordinate care and promote better health outcomes. CMS looks forward to working with organizations and other key stakeholders, including hospitals and other providers, to explore and better understand possible means for achieving those goals with the idea of incorporating the most successful of these methods, more fundamentally, into MA program policies.

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 2015 Call Letter, CMS indicated its intention to partner with private payers to test innovations in health plan design for CMS beneficiaries, including but not limited to value-based arrangements, beneficiary engagement and incentives, and/or care coordination. Subsequently, in the fall of 2014, CMS issued a formal Request for Information (RFI), requesting public feedback on several potential approaches to models involving private payers. CMS received a robust response to this RFI, and based on this feedback has continued work on the development of potential Innovation Center models in this area.

Section II – Part C

Overview of CY 2016 Benefits and Bid Review

Portions of this guidance apply to cost-based plans and MA plans (including EGWPs, 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 cost-based plans are duplicative under §422.256(b)(4), also referred to as the "meaningful difference" evaluation. Similarly, employer group plans and cost-based plans are not evaluated for low enrollment under § 422.506(b)(1)(iv) and (b)(2). Please note: 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 1, 2015 deadline. Any organization whose bid fails the published Part C Service Category Cost Sharing, PMPM Actuarial Equivalent Cost Sharing, Meaningful Difference, Total Beneficiary Cost (TBC), and/or Optional Supplemental Benefit requirements will receive a compliance notice, even if the organization is allowed to correct the deficiency. The severity of compliance notice may depend on the type and/or severity of errors.

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

Table 1. Plan Types and Applicable Bid Review Criteria

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

[1] 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)).

We have made changes to service category cost sharing amounts, PMPM Actuarial Equivalence factors, and Total Beneficiary Cost (TBC) limits for CY 2016 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 plans that had fewer than 500 enrollees for non-SNP plans or fewer than 100 enrollees for SNP plans and had been in existence for three or more years as of March 2015 (three annual election periods). The notification represents CMS's 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 determined were located in service areas that did not have a sufficient number of competing options of the same plan type (such that the low enrollment plan still establishes a viable plan option for enrollees).

MAOs must either confirm, through return email, that each of the low enrollment plans identified by CMS will be eliminated or consolidated with another of the organization's plans for CY 2016, or they must provide a justification for renewal. If CMS does not find a unique or compelling reason that the plan is a viable independent option for enrollees in order to maintain the plan with low enrollment, 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 will be 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 the CY 2016 renewal/non-renewal guidance (see the Medicare Managed Care Manual: section 150 of Chapter 4, HPMS memo released November 7, 2014, and/or section 60.3 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.

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 2016, 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. Documentation and instructions for the OOPC

model are available at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/OOPCResources.html.

As stated in the draft Call Letter, CMS considers HMO and HMO-POS as one plan type, unless the HMO-POS plan covered all Parts A and B services outside the network, in which case the HMO-POS plan is considered meaningfully different from the HMO plan. This standard for evaluating meaningful difference will remain in effect for CY 2016.

As explained in the draft CY 2016 Call Letter, CMS is considering whether – for CY 2017 – to propose to consider HMO-POS plans meaningfully different only if the plans do not place geographic or provider limitations on the out-of-network benefits. CMS is also considering whether to apply the meaningful difference evaluation at the "legal entity"/MAO level and/or the "parent organization level" rather than the "contract" level as the evaluation is currently performed.

We received several comments recommending that CMS not move forward with either proposal due to the potential restrictions it could place on the benefits offered to the enrollees. CMS reviewed these comments and will take them into consideration for future years.

For CY 2016, we will apply the current plan type and SNP flexibilities discussed in the methodology below.

CMS will evaluate meaningful differences among CY 2016 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.

Note that plan characteristics such as premium, variations in provider networks, and/or serving different populations are not considered meaningfully different characteristics. Comments requested CMS to change its meaningful difference interpretation and analysis to allow provider network and/or premium differences to constitute a meaningful difference between similar plan offerings. While we considered these comments and other requests, CMS is maintaining its current interpretation that excludes premium differences from the criteria since the regulatory meaningful difference requirement is intended to be an objective measure of benefits between two plans and the inclusion of premium would introduce risk selection, costs, and margin into the evaluation and negate the evaluation's objectivity. 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.

CMS expects MAOs to submit CY 2016 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 and CMS will not approve plan bids that do not meet these standards. MAOs must follow the CY 2016 renewal/non-renewal guidance in the final Call Letter to determine if their plans may be consolidated with other plans.

NOTE: Please see policy updates below for changes to PBP that will impact the OOPC model and may 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).

We received comments describing the pressures MAOs have in complying with the TBC standard, given CMS payment-related changes. Comments suggested that CMS should account for changes in the CMS-HCC risk adjustment model as part of the TBC payment adjustment factor. Other comments expressed concerns about MAOs not being able to navigate both the

TBC and margin requirements. We also received comments about the proposed modifications to the TBC calculation for both CY 2016 and proposed CY 2017.

CMS has focused on sharing information and providing transparency as it relates to the TBC year-to-year evaluation. Consistent with past years, we will continue to incorporate the technical and payment adjustments described below and expect organizations to address other factors, such as risk adjustment model changes and health insurance provider's fee independently of our TBC requirement. As such, plans are expected to anticipate and manage changes in quality compensation, county benchmark, coding intensity, and other environmental factors to minimize changes in benefit and cost sharing over time. We also remind MAOs that the Office of the Actuary extends flexibility on margin requirements so MAOs can satisfy the TBC requirement.

In mid-April, as in past years, CMS will provide plan specific CY 2015 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 (no change for CY 2016).
- Payment Adjustments: (1) county benchmark, (2) coding intensity, and (3) quality bonus payment and/or rebate percentages.

CMS will maintain the TBC change threshold at $32.00 PMPM for CY 2016. 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, we are finalizing the following modifications to the TBC evaluation.

For CY 2016, 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. We remind MAOs that the Office of the Actuary extends flexibility on margin requirements so MAOs can meet the TBC standard. CMS will provide detailed operational guidance via an HPMS memo and will post TBC adjustment factors in HPMS in April.

Under §422.254, CMS will reserve 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. For organizations consolidating multiple CY 2015 plans into a single CY 2016 plan, CMS will use the enrollment-weighted average of the CY 2015 plan values to calculate the TBC. Otherwise, these plans will be treated as any other plan for the purpose of enforcing the TBC requirement. CMS had contemplated requiring each individual plan to be "crosswalked" into another plan to meet the TBC requirement on its own merit and discontinue the use of the enrollment-weighted average for multiple plans "crosswalked" into one plan to determine TBC for CY 2016. We will not move forward with this requirement for CY 2016, but will consider it in future years.

For CY 2017, CMS is considering an additional modification to the TBC evaluation and requested comments on this proposal in the draft Call Letter. We received several comments requesting further clarification about how this would affect the TBC calculation and concerns about additional pressures being placed on MAOs to satisfy TBC requirements. To clarify, our proposal would have the effect of "discounting" the plan-specific payment adjustment for both increases and decreases in payments experienced by each plan. For example, if CMS set the "discount amount" at ten percent (10%), each plan's net payment adjustment factor would be multiplied by 0.90 to establish the discounted adjustment factor. If a plan has a TBC net payment adjustment factor of $100 PMPM, the "discounted" payment adjustment factor used in the TBC calculation would be $90 PMPM (i.e., $100 × 0.90). This modification would be applied to all plans subject to the TBC evaluation. Since the ACA benchmark transition nears completion, it is our expectation that MAOs are better positioned to share payment changes and provide affordable and effective benefits for beneficiaries. We appreciate the concerns expressed in comments and will continue to evaluate this proposal. However, MAOs should expect and plan that CMS will move forward with implementing this proposal for CY 2017. Please note that the 10% "discount amount" used in the example above is for demonstration purposes only. Additional detail will be provided in the CY 2017 draft Call Letter.

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

Maximum Out-of-Pocket (MOOP) Limits

Table 2 below displays the CY 2016 mandatory and voluntary MOOP amounts and the combined (catastrophic) MOOP amount limits applicable to LPPOs and RPPOs. A plan's adoption of a MOOP limit that qualifies as a voluntary MOOP ($0 - $3,400) results in greater flexibility for individual service category cost sharing.

As codified at 42 CFR § 422.100(f)(4) 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. We chose to display the ranges of cost sharing within which plans may establish their MOOPs in order to illustrate that MOOP limits may be lower than the CMS-established maximum amounts and what MOOP amounts qualify as mandatory and voluntary MOOP limits.

Table 2. CY 2016 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 several comments requesting a description of how MOOP limits are established and suggestions that CMS consider increasing the MOOP limits each year to reflect the growth in health care costs. The CY 2012 Call Letter explained that 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 and CMS determines the proposed MOOP amount communicated through the Call Letter. 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 (e.g., between two and three years); this issue will be addressed in future years.

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

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

Total MA cost sharing for Parts A and B services must not exceed cost sharing for those services in Original Medicare on an actuarially equivalent basis. CMS will also apply this requirement separately to the following service categories for CY 2016: 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 2016.

CMS received comments on the removal of Home Health from the AE cost share limits. Since Home Health is covered at zero cost sharing in Original Medicare and CMS evaluates Home Health as part of the service category cost sharing requirements, we have removed Home Health from the AE evaluation.

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 facility and SNF services, the AE Original Medicare cost sharing values, unlike

plan cost sharing values, do not include Part B cost sharing; therefore, an adjustment factor is applied to these AE Original Medicare values to incorporate Part B cost sharing and to make the comparison valid.

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

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

	#1	**#2**	**#3**	**#4**	**#5**	**#6**	**#7**
BPT Benefit Category	PMPM Plan Cost Sharing (Parts A&B) *(BPT Col. l)*	Original Medicare Allowed *(BPT Col. m)*	Original Medicare AE Cost sharing *(BPT Col. n)* [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	1.397	$35.34	$0.00	Pass
SNF	$10.83	$58.19	$9.89	1.068	$10.56	$0.27	Fail
DME	$3.00	$11.37	$2.65	1.000	$2.65	$0.35	Fail
Part B-Rx	$0.06	$1.42	$0.33	1.000	$0.33	$0.00	Pass

[1] 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

We will continue our current policy of affording MA plans greater flexibility in establishing Parts A and B cost sharing by adopting a lower voluntary MOOP limit than is available to plans that adopt a higher, mandatory MOOP limit. Table 4 below summarizes the standards and cost sharing amounts by MOOP type (e.g., mandatory or voluntary) for local and regional MA plans that we will not consider discriminatory or in violation of the applicable standards. CY 2016 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 and Emergency standards have been updated to reflect estimated changes in Original Medicare cost for CY 2016.

Table 4. CY 2016 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	$4,209
Inpatient - 10 days	1a	$2,444	$1,955
Inpatient - 6 days	1a	$2,218	$1,774
Mental Health Inpatient - 60 days	1b	$2,599	$2,079
Mental Health Inpatient - 15 days	1b	$1,953	$1,562
Skilled Nursing Facility – First 20 Days[1]	2a	$40/day	$0/day
Skilled Nursing Facility – Days 21 through 100[2]	2a	$160.00/day	$160.00/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
Renal Dialysis	12	20% or $30	20% or $30
Part B Drugs-Chemotherapy[4]	15	20% or $75	20% or $75
Part B Drugs-Other	15	20% or $50	20% or $50

[1] MA plans and 1876 Cost Plans may not charge enrollees higher cost sharing than is charged under Original Medicare for chemotherapy administration, skilled nursing care and renal dialysis services (42 CFR §§417.454(e) and 422.100(j)).
[2] MA plans may have cost sharing for the first 20 days of a SNF stay. The per-day cost sharing for days 21 through 100 must not be greater than the Original Medicare SNF amount. Total cost sharing for the overall SNF benefit must be no higher than the actuarially equivalent cost sharing in Original Medicare, pursuant to §1852(a)(1)(B).
[3] Emergency Care and Urgently Needed Care benefits are not subject to 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. Please note that MAOs with benefit designs which 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 as part of supporting documentation for the Bid Pricing Tool as described in the Instructions for Completing the Medicare Advantage Bid Pricing Tools for Contract Year 2016, Appendix B-Supporting Documentation.

We received comments about the cost sharing requirements for certain service categories. CMS annually evaluates available Medicare data and other information to establish our requirements in accordance with applicable law. Organizations are afforded the flexibility to design their benefits as they see fit as long as they satisfy Medicare coverage requirements. In regards to emergency care, we received comments that suggested increasing the cost share limit and providing more flexibility for plans offering a voluntary MOOP. CMS appreciates these comments and will consider these suggestions for future years.

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 2015, we consider a plan to be not discriminatory when the total value of all optional supplemental benefits offered to non-employer plans under each contract 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%.

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

PBP Updates and Guidance

Medical Services Performed in Multiple Health Care Settings

As stated in the draft Call Letter, the same medical service may be entered in multiple PBP service categories, since a single service can be performed in different health care settings (e.g., physician office, outpatient hospital, and free standing facility). CMS is clarifying how to place these services in the appropriate service category and correctly complete data entry within the PBP.

The outpatient 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 variety 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 cost sharing preventive services must be included in PBP Service Category 14a and must not be included in any other service category. 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.

This is a change from what we have allowed in the past and may impact benefit design and estimated OOPC. Further, these changes may have an impact on the TBC and meaningful difference evaluation for some plans. As a result, we intend to implement these changes over time and provide organizations with our expected changes for CY 2016 and future years for bid planning purposes. For CY 2016, we expect the service categories listed in the table below to reflect cost sharing for these services within each designated service category.

CMS received many comments and suggestions concerning the CY 2016 changes. CMS chose the service categories below since they are currently more defined and changes for CY 2016 will be less disruptive than the changes we are contemplating for future years. Please keep in mind we are only implementing the service categories in the table below for CY 2016. As stated earlier, there should not be any reference to these services in any other service category other than their own 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	End-Stage Renal Disease
14a	Medicare-Covered Zero Cost-Sharing Preventive Services
15	Medicare Part B Rx Drugs and Home Infusion Drugs

We received comments regarding End-Stage Renal Disease requesting clarification on what services are included in this service category. End-Stage Renal Disease (section B-12) includes dialysis medications, laboratory tests, home dialysis training, and related equipment and supplies. To accurately determine the cost sharing associated with specific benefits, organizations should refer to the service category and benefit descriptions in HPMS and the PBP software. We also received comments expressing concern that our PBP changes may affect TBC and Meaningful Difference evaluations as a result of potential changes to the estimated beneficiary out-of-pocket cost (OOPC) model. By making these changes over time, CMS provides plans the opportunity to proactively prepare benefit strategies as well as anticipate and mitigate potential concerns related to satisfying TBC, meaningful difference and other cost sharing requirements.

For CY 2017 and perhaps CY 2018, we intend to refine the service categories listed in the table below to reflect cost sharing for services provided in a variety of healthcare settings. We are also considering removing "Outpatient" from the titles of service categories for PBP Section B-8a and 8b, as well as either removing or disabling 9a entirely and renaming 9b. We anticipate these changes will improve transparency and streamline the data entry so the cost sharing associated with those PBP service categories below reflect 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)

We appreciate the comments and suggestions provided to our proposal in the draft Call Letter. While we are moving forward with the changes for CY 2016, we will continue to evaluate our approach to making service category changes for future years and intend to address this in future Call Letters.

Service Category Titles

The following Plan Benefit package (PBP) service category titles and data entry guidance will be changed for CY 2016 to align with Medicare Managed Care Manual, Chapter 4 terminology and to further refine benefit descriptions:

- "Web/Phone Technology" name has been changed to "Remote Access Technologies"
- "Membership in Health Club/Fitness Classes" has been changed to "Fitness Benefit"
- "Weight Management Programs and Alternative Therapies" will be listed with the other defined supplemental benefits in 14C.

- "Readmission Prevention" will have a drop down of the services that are included within the benefit, such as medication reconciliation, bathroom safety and meals (this is separate from the 13c meals service category)
- "Worldwide Emergency/Urgent Coverage" in 4c will specify the benefit covers both emergent and urgent care.
- "Nursing Hotline" will be removed and will now be considered "Remote Access Technologies"

CMS will be moving forward with the changes above; and we remind organizations that marketing materials provide the flexibility to describe benefits to beneficiaries.

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.

We revised the PBP so MAOs can more clearly describe their tiered benefit structure using data entry. The PBP will incorporate a new screen that includes a pick list of service categories that may have tiered cost sharing. The MAO must indicate which medical benefit service categories are subject to tiered cost sharing on this screen. The MAO must then complete the minimum and maximum data entry fields in each service category selected along with providing a note describing the tiering structure within that benefit.

CMS received comments expressing concern about transparency, how tiers are selected, and enrollee's access to and the availability of benefits. CMS has permitted the tiering of medical benefits for several years. CMS will continue to require that organizations submit tiering documentation prior to bid submission. For CY 2016, MAOs will be submitting tiering requests to CMS through an electronic mailbox and will no longer need to contact the Regional Office Account Manager. Details regarding the process will be provided in an HPMS memo in April.

Policy Updates

Part C Emergency/Urgently Needed Services Deductible Guidance

In the CY 2015 Final Call Letter, CMS stated enrollees utilizing the Emergency Care/Urgently Needed Service benefits are not subject to a plan level deductible amount; however, enrollee cost sharing associated with Emergency and Urgently Needed Service visits always applies toward a plan level deductible. CMS received comments from multiple organizations about this proposed change and the difficulty it creates in administering these benefits and the potential for enrollee

confusion. As a result, we proposed in the draft Call Letter to eliminate the stipulation that all cost sharing associated with Emergency/Urgently Needed Services apply toward any plan-level deductible.

We received comments supporting our proposal, as well as comments concerned that enrollees would not satisfy their plan-level deductible with this change in policy. In addition, we received comments that enrollees obtaining MA coverage through employers need flexibility in how this cost sharing is administered. To balance concerns expressed in comments, we are finalizing our guidance as follows. Plans cannot charge enrollees the plan-level deductible prior to receiving Emergency Care/Urgently Needed Services and the cost sharing for those services must always contribute to satisfying the MOOP. Plans may count the Emergency Care/Urgently Needed Services cost sharing towards the plan-level deductible or plans may choose to not have enrollee cost sharing count towards the plan-level deductible. However, plans must apply this policy uniformly across the entire plan and marketing materials provided to enrollees must be transparent regarding whether or not cost sharing applies toward the plan-level deductible.

Annual Physical Exam Supplemental Benefit

Under our current rules, MA plans may choose to offer benefits to enrollees in addition to the covered Medicare Parts A, B, or D benefits as supplemental benefits. Guidance on the criteria CMS applies in determining whether or not specific additional items and services qualify for inclusion in a plan's benefit package are described in Chapter 4 of the Medicare Managed Care Manual, titled "Benefits and Beneficiary Protections." Subject to CMS approval under 42 CFR § 422.102(a)(3), MA plans may offer Annual Physical Exams as mandatory supplemental benefits for all enrollees in the plan. (SNPs are expected to provide higher levels of enrollee assessment than non-SNP MA plans and therefore, may not offer Annual Physical Exams as supplemental benefits (Final Call Letter, April 2, 2012).)

Currently, about 65 percent of MA plans choose to provide an Annual Physical Exam as a supplemental benefit to their enrollees; however, the components of the exam benefit offered vary across plans. We believe that an Annual Physical Exam could be useful to MA enrollees because it engages them with their providers, helps screen for diseases, promotes preventative care, including vaccination(s), encourages a healthy lifestyle and assesses risk for future medical problems. We strongly believe that providing clarification regarding the Annual Physical Exam, will improve enrollees' (and MAOs') understanding of what comprises an Annual Physical Exam and help differentiate the Exam from Medicare Annual Wellness Visits (AWV).

Beginning for CY 2016, an Annual Physical Exam will qualify as a supplemental benefit if it is provided by a qualified physician or qualified non-physician practitioner, hereafter referred to as a practitioner. At a minimum, the exam must include a detailed medical/family history and the performance of a detailed head to toe assessment with hands-on examination of all the body systems. For example, the practitioner must use visual inspection, palpation, auscultation and

manual examination in his/her full examination of the enrollee to assess overall general health and detect abnormalities or signs that could indicate a disease process that should be addressed. CMS wants to clarify, however, that these components are the minimum elements and not meant to be an exhaustive list.

Other aspects of the Annual Physical Exam may include, as appropriate, follow-up orders for referral to other practitioners, lab tests, clinical screenings, EKG, etc. The Annual Physical Exam also should emphasize prevention, i.e., the recommendations for preventive screenings, vaccination(s), and counseling about healthy behaviors. We emphasize that providers have the ability to exercise clinical judgment when determining the additional components necessary for an Annual Physical Exam to meet the individual needs of the enrollee.

We received a few comments regarding our description of the Annual Physical Exam that will qualify as a supplemental benefit. Based on the comments received, there is strong support for defining what constitutes an Annual Physical Exam, and, for promoting consistency should MAOs choose to offer this as a supplemental benefit. One commenter suggested that CMS consult with trade organizations to further refine the components of the Annual Physical Exam Supplemental Benefit. We believe that the components we have defined in the draft Call Letter help to appropriately screen for diseases, promote preventive care, encourage a healthy lifestyle, and assess risk for future medical problems. We believe that further refinement of the components could lead to CMS being overly prescriptive.

We appreciate the comments received on this topic in the draft Call Letter. Note that CMS will not provide Annual Physical Exam CPT Code specific information as requested by one commenter. Any additional information regarding the Annual Physical Exam Supplemental benefit will be provided as part of the Contract Year 2016 Bid Review and Operations Guidance HPMS memo that will be issued April 2015.

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

As codified at 42 CFR §422.100(l)(2), MA organizations may, within specific categories of durable medical equipment (DME), limit coverage of DME to certain brands or manufacturers. The categories of DME that may be limited are those that are essentially interchangeable. DME items that are specifically tailored to individual needs may not be limited to certain brands or manufacturers. 42 CFR §422.100(l)(2)(vii) codifies the requirement that MA plans provide full coverage, without limitation on brand and manufacturer, to all DME categories or subcategories determined annually by CMS to require full coverage. Details regarding applicable items for CY 2016 are provided below; the items identified remain unchanged from CY 2015.

We have identified one category of DME that may not be subject to full limitation based on brand/manufacturer for CY 2016: Speech-Generating Devices. People who require speech-generating devices frequently have other disabilities; the speech-generating device is generally

tailored to meet the individual's needs. For example, a child with cerebral palsy (CP) could accidentally change a setting on some devices and therefore, should be furnished with a device that is sensitive to the movements of a child with CP. Consequently, MA plans may not limit coverage to a specific brand or type of device; rather, they must furnish any medically-necessary speech-generating device purchased by an enrollee.

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

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

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

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

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

Contract Consolidations

CMS encourages MAOs operating more than one MA-PD contract of the same product type under the same legal entity to consolidate these contracts under a single contract ID for contract year CY 2016. Please note this is separate from an MAO's request to consolidate individual plans, leaving one plan under a single contract ID. MAOs are not permitted to consolidate contracts of different product types.

MAOs can offer the following product types:

- MA-PD Health Maintenance Organization (HMO)/Health Maintenance Organization Point of Service (HMOPOS)
- MA-PD Local Preferred Provider Organization (PPO)
- MA-PD Regional PPO
- MA-PD Provider Sponsored Organization (PSO)
- MA-PD Private Fee-For-Service (PFFS) (with Part D)
- Medicare Advantage (MA) Only – PFFS

- MA Only – Medical Savings Account (MSA)
- Prescription Drug Plan (PDP)
- Employer/Union Direct Contract PFFS no Part D
- Employer/Union Direct Contract PFFS with Part D
- Employer/Union Direct Contract MA-PD Local Preferred Provider Organization (LPPO)
- Employer/Union Direct Contract PDP

CMS requests that an MAO seeking to consolidate multiple contracts under the same legal entity submit a formal request to CMS on plan letterhead in PDF format which includes the following:

- How the MAO came to operate more than one contract of the same plan type (e.g. different service areas, acquisitions, etc.);
- The contract(s) to be consolidated, and the contract ID into which the MAO wishes to consolidate the contract(s);
- The service area covered by the contracts;
- The plan types under the contracts (e.g. employer group waiver plans, SNP plans); and
- Any pending applications under the contracts.

CMS provided specific guidance on the content of consolidation requests via an HPMS memo dated February 6, 2015. CMS requires that all contract consolidation requests be submitted by **April 15, 2015** at https://dmao.lmi.org. CMS will notify MAOs regarding the approval or denial of their request by May 2015.

Limiting Applications

CMS has received inquiries from organizations wishing to apply for a separate contract for the same product type that they are already operating under an existing contract. Organizations can request a new contract ID for the following product types that they do not already operate:

- MA-PD Health Maintenance Organization (HMO)/Health Maintenance Organization Point of Service (HMOPOS)
- MA-PD Local Preferred Provider Organization (PPO)
- MA-PD Regional PPO
- MA-PD Provider Sponsored Organization (PSO)
- MA-PD Private Fee-For-Service (PFFS) (with Part D)
- Medicare Advantage (MA) Only – PFFS
- MA Only – Medical Savings Account (MSA)
- Prescription Drug Plan (PDP)
- Employer/Union Direct Contract PFFS no Part D
- Employer/Union Direct Contract PFFS with Part D
- Employer/Union Direct Contract MA-PD Local Preferred Provider Organization (LPPO)
- Employer/Union Direct Contract PDP

CMS would like to remind existing organizations that CMS will not assign a new contract ID to existing legal entities for product types they currently contract with CMS. If a legal entity would like to broaden its service area (or add Employer Group Waiver Plans or individual plans), that legal entity should complete a Service Area Expansion (SAE) request for its existing contract ID. Please note that Non-network PFFS products transitioning to a full network are exempt from this requirement. If a legal entity would like to offer a SNP as one of their HMO offerings and the entity already holds an HMO/HMOPOS contract, the entity will need to submit a SNP Proposal in order to offer that plan type under their existing HMO contract. CMS will not permit the organization to operate a SNP as a separate HMO contract from their existing HMO contract.

MA/MA-PD Application Change

An organization must meet certain requirements in order to hold an MA contract with CMS (see 42 CFR §§ 422.502 and 422.503) and meet minimum enrollment thresholds (see § 422.514). For example, the organization applying for an MA contract should be able to handle risk and capitated payments. In addition, CMS expects that an organization is able to effectively manage a health care delivery system, including:

- The enrollment and disenrollment of members,
- Timely payment of claims,
- Providing quality assurances, and
- Having systems to handle grievances and appeals.

CMS recognizes that new applicants may believe they are capable of administering and managing an MA contract even when they do not meet the minimum enrollment requirement. CMS also recognizes that there may be reasonable factors, such as specific populations served or geographic location, which might result in a plan having low enrollment. For example, SNPs may legitimately have low enrollment because they focus on a subset of enrollees with certain medical conditions. Such organizations and new applicants may submit a request to waive the enrollment requirement. CMS regulations at 42 CFR §422.514(b) provide for a transition period allowing CMS to waive the minimum enrollment requirement during an organization's first three years of operation.

CMS has developed a minimum enrollment waiver request attestation and a minimum enrollment waiver request template as a part of the CY 2016 Part C (Medicare Advantage) and 1876 Cost Plan Expansion Application. CMS will require applicants to complete and upload into HPMS the minimum enrollment waiver request attestations and template. Applicants should complete these attestations and the template with detailed explanations (and supporting documentation, as necessary) of the applicant's previous experiences, including that of the parent organization and management, in managing and providing health care services under a risk-based payment arrangement to at least as many individuals as the applicable minimum enrollment for the entity as described in 42 CFR §422.514.

The attestations, template, and supporting documentation must demonstrate to CMS's satisfaction that the organization is capable of administering and managing an MA contract and is able to manage the level of risk required under the contract. Please see 42 CFR §422.514(b) for factors that CMS may consider in evaluating any waiver request. If CMS determines the applicant is not able to meet the minimum enrollment requirements to be an MA organization, CMS will notify the applicant of these deficiencies only in a Notice of Intent to Deny (NOID). Applicants that receive the NOID are allowed ten (10) days from the date of the notice to respond in writing to CMS's preliminary findings and to revise their application remedying any defects that CMS has identified. If an applicant fails to submit a revised application within ten (10) days from the date of the notice, or a revised application fails to meet the necessary requirements, CMS will deny the application.

Two-Year Prohibition

Section 1857(c)(4)(A) of the Act prohibits organizations from re-entering the MA program in the event that a previous contract with the organization was terminated at the request of the organization within the preceding two-year period. Under section 1857(c)(4) and various regulations, CMS may provide an exception to this prohibition where circumstances warrant special consideration as determined by CMS. In the Contract Year (CY) 2016 Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Program Final Rule, 80 FR 7945, CMS adopted a final rule to amend the regulations, expanding application of the two-year prohibition (found at 42 CFR §§422.502, 422.503, 422.506, 422.508, and 422.512) to avoid (1) unnecessarily narrowing the scope of the two-year prohibition, or (2) precluding CMS from preventing poor performing MA organizations from reentering the MA program.

Once the new regulation is effective in CY 2015 and moving forward, CMS interprets §§ 422.503(b)(6) and 422.503(b)(7) as authorizing denials of new contracts and service area expansions, consistent with the proposed text for §§ 422.503, 422.506 and 422.512, regardless of the contract type, product type, or service area of the previous nonrenewal. CMS will apply this new interpretation to all organizations that mutually terminate or non-renew a contract starting April 2015, and moving forward.

In the preamble to the Final Rule, CMS also clarified that (1) the two-year prohibition, for purposes of §§ 422.502, 422.506, 422.507, 422.508, and 422.512, is applied at the legal entity level, and that (2) the two-year ban is applicable for the two (2) contract years following the year in which the non-renewal or termination of an organization's contract is effective. For example, if an organization does not renew its contract for an effective date of January 1, 2016, CMS would not enter into a contract with the organization for CYs 2016 and 2017, unless there are circumstances that warrant special consideration, as determined by CMS. The organization can apply to contract with CMS in 2017 to operate in CY 2018. Likewise, if an organization enters a mutual termination for a contract with CMS midyear during 2015, then CMS will not enter into a

contract with the organization for CYs 2016 and 2017 absent circumstances warranting special consideration. An organization can, however, apply to contract with CMS in 2017 to operate in CY 2018. CMS understands that there are a variety of reasons that an organization may decide to terminate or to non-renew a contract, and subsequently want to re-enter the program. CMS will consider when circumstances warrant special consideration on a case-by-case basis.

CMS encourages organizations with questions about the applicability of the two-year prohibition to submit them to CMS's Non-Renew/Terminations mailbox located at: https://dmao.lmi.org.

Guidance to Verify that Networks are Adequate and Provider Directories are Current

42 CFR § 422.111 requires MAOs to disclose the provider directory; § 422.112 requires MAOs maintain and monitor the network of providers and to provide adequate access to covered services. Providers whose practices are closed or who are otherwise unavailable cannot be used to successfully meet our network adequacy standards. CMS has become aware of a range of issues with online provider directories. Recent provider and beneficiary complaints have highlighted problems with the accuracy of some MAO online provider directory information. For example, there have been complaints of directories including providers who are no longer contracting with the MAO, have retired from practice, have moved locations, or are deceased. Additionally, some provider directories contain the names of providers who, while still in the MAO's network, are not open and available to new patients, but are not identified as such. Therefore, CMS may view inaccurate provider directories as an indication that the MAO may be failing established CMS access standards.

In the draft Call Letter, we proposed new guidance on our regulatory requirements to ameliorate these issues. We received a number of comments from beneficiary advocacy organizations, professional associations and from the industry on these proposals, which are discussed below.

Beneficiary advocacy and some provider professional organizations were highly supportive of CMS efforts to redress problems with online provider directories and network adequacy standards. Overall, most commenters supported CMS's three-pronged approach to monitor compliance, and intent to consider instituting a requirement for MAOs to submit, and regularly update, network information to CMS in a standardized, electronic format for eventual inclusion in a nationwide provider database.

Most industry stakeholders who commented objected to the proposed guidance regarding online provider directories, stating that the requirements were unnecessary because they believe clear guidance currently exists in the Medicare Marketing Guidelines and there is no need to expand the guidance. These commenters stated that these requirements would result in undue added burden and administrative costs. A few commenters suggested that requirements for online directory updates should conform to those established for the Qualified Health Plans (QHPs) in the Marketplace. Additionally, they suggested that CMS take action to compel providers to notify MAOs of their status.

We firmly believe the provision of accurate provider information and verifying adequate access to covered services are essential protections for enrollees and help enrollees make educated decisions about their MA plan choices. We have carefully considered the comments and are finalizing the provisions as proposed with clarifications.

Over time, CMS will harmonize these policies with the requirements for QHPs to provide health plans with consistent rules across programs. As indicated in the preamble to the recent QHP final rule (80 FR 10830), QHPs in the Marketplace are required to update provider directories monthly. Consistent with those requirements, we clarify that MAOs are expected to update their online provider directories in real-time, which means MAOs are to make updates when they are notified of changes in a provider's status, or when the MAO itself makes contracting changes to its network of providers. Additionally, MAOs are expected to communicate with providers monthly regarding their network status.

CMS does not have the authority to require providers to notify MAOs of their current status. However, we strongly encourage providers to be responsive to MAO inquiries and to notify MAOs of changes in their status in a timely manner.

Consistent with the requirement of § 422.1(b) to maintain and monitor an adequate network, MAOs are expected to establish and maintain a proactive, structured process that enables them to assess, on a timely basis, the true availability of contracted providers which includes, as needed, an analysis to verify that the provider network is sufficient to provide adequate access to covered services for all enrollees. An effective process would include:

- Regular, ongoing communications/contacts (at least monthly) with providers to ascertain their availability and, specifically, whether they are accepting new patients, in addition to requiring contracted providers to inform the plan of any changes to street address, phone number, and office hours or other changes that affect availability; and
- Developing and implementing a protocol to effectively address inquiries/complaints related to enrollees being denied access to a contracted provider with follow through to make corrections to the online directory.

We are reinforcing that, in order for us to consider the MAO compliant with §§ 422.111 and 422.112, MAOs must include in their online provider directories all active contracted providers, with specific notations to highlight those providers who are closed or not accepting new patients.

We will initiate a three-pronged approach to monitor compliance with the regulations, including:

1) Direct monitoring. We have secured additional contractor funding to verify the accuracy of MAOs' online provider directories.
2) Development of a new audit protocol. A new audit protocol will be tested in CY 2015 to further enhance our oversight of the validity and accuracy of MAOs' online directories as well as the availability and accessibility of network providers and whether the lack of

availability and accessibility may impact a plan's ability to meet provider network adequacy standards.

3) Compliance and/or enforcement actions. MAOs that fail to maintain complete and accurate directories may be subject to compliance and/or enforcement actions, including civil money penalties or enrollment sanctions. MAOs whose network adequacy is not met because of failure to have a sufficient number of providers open and accepting new patients may also be subject to such actions.

In addition, CMS is considering, beginning on or after CY 2017, instituting a new regulatory requirement for MAOs to provide, and regularly update, network information in a standardized, electronic format for eventual inclusion in a nationwide provider database. This approach would build upon other Departmental efforts, including pursuit of similar requirements for QHPs in the Health Insurance Marketplace. CMS's goal in this effort would be to make provider network data readily available to beneficiaries, stakeholders, and the public in a uniform format, based on the best available consensus-based standards that would be required by CMS. CMS anticipates that a common format and standard would enable greater interoperability across provider directories and more up-to-date information in provider directories maintained by health plans, at a state level, and in national databases such as the National Plan and Provider Enumeration System. Standardized provider directories would serve as a useful tool to search for individual providers and determine, on a readily-accessible, provider-specific basis, every MA plan for which a specific provider is currently contracted. We believe this approach could also be leveraged by application developers to create user-friendly search applications that will be more accessible, up-to-date, and useful for consumers than the current, non-standardized websites or printed provider directories. This approach would enhance the transparency of provider networks, and enable beneficiaries to make informed decisions about their health care coverage.

Guidance for Off-cycle Submission of Summaries of MOC Changes

CMS continues to emphasize the importance of the SNP MOC as a fundamental component of the SNP quality improvement framework. See §§ 422.101 and 422.152(g). In order to more effectively address the specific needs of its enrollees, a SNP may need to modify its processes and strategies for providing care during the course of its MOC approval timeframe. CMS indicated in the CY 2015 Call Letter that it would establish a mechanism by which SNPs could notify CMS when they make revisions to their approved MOC.

Based on our experience, we expect that such submissions will be relatively rare. During each of the past few years, very few SNPs have contacted CMS about the need to make MOC changes during an approval cycle and we do not anticipate this new process will result in a higher incidence of such MOC changes. Only relatively unusual circumstances require SNPs to make changes to their MOCs that are so significant that notification of CMS is warranted.

Below, we describe MOC changes requiring CMS notification and how SNPs should submit their MOC changes to CMS.

SNPs that make significant changes to their MOCs must submit a summary of the pertinent modifications to the approved MOC in HPMS. The SNP must also submit a redlined version of the approved MOC with the revisions highlighted.

The HPMS module for submitting the MOC changes will be available later in 2015. Additional details and guidance regarding the new module will be provided via an HPMS memo. Until the module is live in HPMS, SNPs should document any changes to their MOCs and notify CMS of those revisions as they do now.

NCQA will review the summary of changes submitted in HPMS to verify that the revisions are consistent with acceptable, high-quality standards, as included in the original, approved MOC. The revised MOCs will not be rescored and the MOC's original approval period (i.e., 1-year or multi-year) will not change as a result of NCQA's review of the changes. Therefore, changes made to MOC cannot be used to improve a low score.

SNPs should only notify CMS of substantive modifications, particularly those that include fundamental organizational changes and changes that are essential to MOC processes and functions. Examples of process changes that need to be submitted include, but are not limited to:

- Changes in legal entity, parent organization, and oversight (novation/mergers, changes to corporate structure);
- Target population changes;
- New benefit inclusion or benefit exclusions, especially for a SNP's most vulnerable members;
- Changes in level of authority/oversight (medical provider to non-medical provider/clinical vs. non-clinical personnel conducting care coordination activities);
- Changes to delegated providers and agreements; and
- Changes in policies and/or procedures pertinent to: the health risk assessment process, development and ongoing updates to the individualized care plan, changes to risk stratification methodology, care transitions protocols, communication and frequency of meetings with ICT members, beneficiaries, and caregivers.

Changes that do **not** need to be submitted include:

- Changes in administrative staff, types/level of staff;
- Updates on demographic data about the target population;
- Updates to quality improvement metric results;
- Additions/deletions of specific named providers; and
- Grammatical and/or non-substantive language changes;

NCQA reviewers will designate the summary as "***Acceptable"*** or **"*Non-Acceptable"*** and will enter the findings in the HPMS character text box. A system-generated email will be sent to the designated SNP Application Contact, the MA Quality Contact, as well as the individual who submitted the revised MOC summary.

SNPs have one opportunity to correct ("cure") deficiencies to confirm that the revised MOC is consistent with the standards outlined in the original MOC. If NCQA determines that revisions to the MOC, as delineated in the MOC summary, do not reflect the quality standards as demonstrated by the original MOC and its associated score/approval period, the SNP will be notified via email with a "***Non-Acceptable"*** determination and a list of all deficiencies. If the summary and redlined version is non-acceptable after the second review, the SNP must continue implementing its approved MOC (without any revisions) for the remainder of its MOC approval period.

We believe that these proposed processes and procedures will: make certain that CMS and NCQA are apprised of up-to–date information regarding the MOC; strengthen our ability to adequately monitor the approved MOCs; and guarantee that SNPs continue to provide high quality care to enrollees.

Waiver of the Three Day Qualifying Inpatient Hospital Stay

Consistent with the current regulation at 42 CFR 409.30(b)(2), MAOs may cover SNF care that is not preceded by a three day inpatient hospital stay. Waiver of the qualifying hospital stay is based on CMS's determination that SNF stays provided by MAOs without a three day inpatient hospital stay meets the two tests in section 1812(f) of the Act, namely that the inclusion of such services will not result in any increase in the total of payments made under this title and will not alter the acute care nature of the benefit. Currently, ninety-five percent of non-employer MA plans have elected to waive the three day inpatient stay as a condition for SNF coverage. Although longstanding practice has been to allow MA organizations to price the waiver of the three day hospital stay as either a mandatory supplemental or as a basic benefit in the BPT, consistent with current regulation at 42 CFR 422.101(c), we are clarifying that the waiver of the three day hospital stay and the associated SNF stay are basic benefits and must be entered as such in both the PBP and BPT.

Our clarification makes certain that our terminology related to an MA plan's waiver of the three day inpatient stay and bid pricing guidelines are consistent with our regulations and has no effect on how plans present the waived days to enrollees and potential enrollees in marketing material.

Standardizing the Health Risk Assessment (HRA)

All MAOs are to make a best effort to conduct an initial assessment of each enrollee's health care needs within 90 days of the effective date of enrollment (§422.112(b)(4)(i)). SNPs are required to perform a comprehensive initial HRA that includes assessment of each enrollee's

physical, psychosocial, and functional needs within the first 90 days of enrollment and conduct reassessments annually thereafter (§422.101(f)(1)(i)). Beginning in CY 2014, CMS included SNPs' timeliness and completion rates as factors in the Star Ratings methodology.

To date, CMS has not required MAOs to use a standardized set of basic components for those assessments. In 2012, we reviewed the HRAs in use by SNPs, as submitted in the Health Plan Management System, and found more than 300 different versions were in use at that time. We found that the most common questions addressed chronic conditions, health care utilization, and activities of daily living and that the Center for Disease Control and Preventions' (CDC) Model HRA presented in the appendix to "A Framework for Patient-Centered Risk Assessments, Providing Health Promotion and Disease Prevention Services to Medicare Beneficiaries" (http://www.cdc.gov/policy/ohsc/HRA/FrameworkForHRA.pdf), in combination with the other elements of the AWV captured all of the most common components of the HRAs that were in use at the time of review.

We believe the CDC Model HRA and the other components of the AWV are sufficiently comprehensive to identify the medical, functional, cognitive, psychosocial and mental health care needs of enrollees, including those in SNPs. CMS believes that adoption of a standardized framework would provide consistency in CMS' and MAOs' data collection across all plans, provide uniform and comprehensive information to support care planning, health promotion and promote a proactive approach for initiating preventive and other appropriate care.

CMS strongly encourages MAOs to adopt the components in the CDC Model HRA beginning in CY 2016. In addition to those components, MA plans are free to include other components or elements that may appropriately assess the needs of enrollees, including components and elements designed to meet the care coordination and long term care goals of states that contract with D-SNPs to deliver integrated benefits to Medicare-Medicaid enrollees. CMS may consider developing and requiring a standardized HRA for use by all SNPs in the future through the notice and comment rulemaking process.

We received many comments regarding MAO adoption of these components as minimum elements for HRAs beginning in CY 2016. Some commenters questioned why CMS is pursuing the adoption of standard components, while allowing some customization to the HRA, while other commenters sought assurance that CMS would afford plans the flexibility to incorporate additional elements to meet the needs of the populations they serve and the programs they offer. CMS seeks to clarify that we are not mandating the implementation of the CDC Model HRA. However, CMS encourages MAOs to validate that their current HRAs are comprehensive and appropriately assess each enrollee's physical, psychosocial, and functional needs. CMS believes the elements contained in the CDC Model HRA serve as an adequate guide for these assessments. In addition, MAOs have the flexibility to tailor their HRAs for the populations they serve, and, CMS strongly encourages MAOs to include other elements to address the needs of their enrollees

Some commenters indicated that making changes to their current HRA, processes, methods, as well as data collection efforts would be costly, overly burdensome, and would not meet the needs of their enrollees. To clarify, CMS is not suggesting that MAOs modify their current IT applications in order to accommodate the CDC Model HRA. CMS believes that many MAOs, already have comprehensive HRAs, systems, and processes in place to effectively assess enrollee needs and we do not believe our recommendations contained herein are unduly burdensome or require MAOs' to make wholesale changes to their current processes.

Guidance for In-Home Enrollee Risk Assessments

In this section of the draft Call Letter we encouraged plans to adopt, as a best practice, a core set of components for the in-home assessments they perform, and track subsequent provided care. The MA and home care industry are generally supportive of our approach to in-home assessments and the best practices we articulated. We appreciate the comments submitted to CMS that providers should be afforded the flexibility to adapt the in-home assessment to appropriately meet each enrollee's needs and the recommendation that we add flexibility to enable D-SNPs working toward integration with states to align their in-home visits and related assessment functions to State Medicaid requirements to avoid duplication and confusion for plans and enrollees. However, we are finalizing this proposal, and encourage plans to use these best practices to provide in-home assessments and provide the necessary follow-up care.

Annual health risk assessments under MA are usually questionnaires sent to enrollees for self-completion and ask for basic information about physical, psychosocial, and functional needs. Special needs plans are required to verify all enrollees are assessed within 90 days of enrolling and annually thereafter whereas other MA plans need only make a "best effort" to assess their enrollees.

Over the past few years, CMS has observed an increase in in-home visits to assess MA enrollees.

These in-home assessment visits are usually performed by non-physician practitioners employed by downstream contractors and the comprehensiveness of the assessments and resulting care planning and care coordination appear to vary across plans.

For CY 2014, CMS proposed in the Advance Notice to exclude, for payment purposes, diagnoses collected from enrollee risk assessments that were not confirmed by a subsequent clinical encounter. For CY 2015, CMS again proposed to exclude, for payment purposes, diagnoses that were not confirmed by a subsequent clinical encounter but modified the proposal to include all home visits, not just in-home enrollee risk assessments. Neither of these proposals was finalized; however, beginning CY 2014, MAOs are required to flag diagnoses resulting from in-home assessments when reporting diagnoses to CMS for risk adjusted payments.

Our concerns related to the in-home enrollees risk assessments were two-fold. First, we were concerned that in-home assessments were merely a strategy by MA plans to find and report more

diagnosis codes to CMS, generating higher levels of coding and, therefore, payment than assumed under our risk adjustment methodologies. Second, we were concerned that, while there is potential for the home assessments to improve care, we want to be sure that providers who regularly care for these enrollees actually receive and use the information collected in these assessments and that the care subsequently provided to enrollees is substantially changed or improved as a result of the assessments.

The coverage criteria for home health visits and physician in-home visits are established under original Medicare. (MA plans may have less restrictive coverage terms for covering home health and/or in-home visits as a supplemental benefit.) Medicare coverage for home health visits require, among other things, that the enrollee be homebound and require skilled nursing and/or rehabilitation services in the home. Physician or non-physician practitioners may furnish the visits, depending on the treatment program set out in the plan of care. Original Medicare also covers in-home visits by a physician or non-physician practitioner when care is medically reasonable and necessary.

We believe that in-home assessments can have significant value as care planning and care coordination tools. In the home setting, the provider has access to more information than is available in a clinical setting. For example, the provider is able to evaluate the enrollee's home for potential risks, the need for supports to enable an enrollee to continue living in the community, and other relevant aspects of the enrollee's living situation. We expect plans to take advantage of the opportunities afforded by performance of in-home assessments to obtain and use that full spectrum of information to revise, develop, or implement comprehensive care plans for affected enrollees.

In support of that goal, we are strongly encouraging plans to adopt, as a best practice, a core set of components for the in-home assessments they perform. Our intention in providing guidance on best practices related to in-home assessments is promote their primary use as tools for improving care for MA enrollees and not just as a process to collect diagnoses that increase risk adjusted payments. In-home assessments that incorporate the components listed below, could have significant value as care planning and care coordination tools. At the same time, we remain concerned that in-home risk assessments may continue to be used as a tool to identify diagnoses primarily for reimbursement purposes.

We also will, in CY 2015, track and analyze care provision following in-home visits. We believe this two-pronged approach—providing guidance on best practices for conducting in-home assessments and tracking subsequently provided care—will provide CMS with some evidence that in-home assessments are a means to provide enrollees with all appropriate care and not solely for purposes of collecting diagnoses without providing follow-up care. We also think this approach will provide plans an incentive to adopt comprehensive in-home assessments consistent with the components we have identified as best practices.

As a best practice, we propose that in-home assessments be performed by physicians, or qualified non-physician practitioners[3], specifically advanced practice registered nurses, nurse practitioners, physician assistants or certified clinical nurse specialists. Other best practices as part of the in-home assessments and the MAO's program for such assessments include:

- All components of the annual wellness visit, including a health risk assessment such as the model health risk assessment developed by the CDC;
- Medication review and reconciliation;
- Scheduling appointments with appropriate providers and making referrals and/or connections for the enrollee to appropriate community resources;
- Conducting an environmental scan of the enrollee's home for safety risks, and need for adaptive equipment;
- A process to verify that needed follow-up care is provided;
- A process to verify that information obtained during the assessment is provided to the appropriate plan provider(s);
- Provision to the enrollee of a summary of the information, including diagnoses, medications, scheduled follow-up appointments, plan for care coordination, and contact information for appropriate community resources; and
- Enrollment of assessed enrollees into the plan's disease management/case management programs, as appropriate.

Plans' adoption of such comprehensive in-home assessments should provide additional information to support care planning and care coordination; and could lead to improved enrollee health outcomes.

Section 1876 Cost Contract Provisions

Cost Plan Application

We want to remind organizations that CMS will not accept any new cost plan applications but will continue to accept applications to modify cost plan contracts in order to expand service areas in accordance with 42 CFR §417.402. In addition, for CY 2016, CMS will apply the cost plan competition requirements in the review and evaluation of any applications to expand a cost plan's existing service area. CMS will deny any cost plan's application for a service area expansion to the extent that the application is for a service area or portions of service areas in which two or more competing MA local or regional coordinated care plans that meet specified enrollment thresholds are available.

[3] Note that only diagnoses from risk adjustment acceptable physician specialty types may be submitted for payment purposes.

Closing Cost Plans to New Enrollment when a Related Entity is Operating in the Same Service Area

CMS wants to remind MAOs that we revised the cost plan enrollment requirements at 42 CFR §422.503(b)(vi)(G)(5) so that the regulation now says that MA organizations "[n]ot accept, or share a corporate parent organization with an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan," and that they "[n]ot accept, as either the parent organization owning a controlling interest of or subsidiary of an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan." We revised the requirements because, contrary to our intent, they previously permitted legal entities that are related to each other under a common parent organization to offer a cost contract and MA plan in the same service area, creating the same potential for the entities to move higher risk enrollees from one plan to another in order to take advantage of the differing Medicare payment rules for the two plan types or for other reasons that are not related to the enrollees' best interests.

Cost Contract Plan Competition Requirements

In accordance with the Protecting Access to Medicare Act of 2014, beginning CY 2016, CMS will non-renew cost plans in service areas or portions of service areas in which at least two competing MA local or two MA regional coordinated care plans that meet specified enrollment thresholds are available. Affected cost contractors will not be able to operate in impacted service areas in 2017.

We will non-renew any portion of a cost plan's service area if there are also two or more MA local or regional coordinated care plans with a minimum of 5,000 enrollees (urban areas) or 1,500 enrollees (non-urban) for the entire year prior to the non-renewal, operating in the same service area. In CY 2016, we will use 2015 enrollment data to identify the cost plans that are subject to non-renewal and will notify them in time to make necessary arrangements, that they will be non-renewed for CY 2017.

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

Cost plans that offer Part D as cost-PD plans also may not expand into service areas served by at least two competing MA local or two MA regional coordinated care plans.

Section III – Part D

Improving Drug Utilization Review Controls in Medicare Part D

In this section, we describe the results of sponsors' implementation of improved drug utilization controls to prevent overutilization of medications in Part D, and our additional expectations for further reductions of opioid overutilization in the Medicare Part D program. We appreciate the comments and suggestions submitted by sponsors, patient advocates, and other organizations about the proposals to strengthen the overutilization policy in order to reduce the unsafe overutilization of medications by Part D beneficiaries.

Background

In the Final 2013 Call Letter, published April 2012, and supplemental guidance, published September 2012, CMS described several methods for Part D sponsors to prevent overutilization of prescribed medications.[4] CMS's expectations beginning January 1, 2013 generally were outlined as follows: 1) Sponsors were to improve their safety controls at the point-of-sale (POS), in particular with respect to acetaminophen (APAP), and their formulary utilization management designs; 2) Sponsors were to implement improved retrospective drug utilization review to detect egregious cases of opioid overutilization and apply case management principles to targeted cases in accordance with CMS guidance. After case management, sponsors would implement beneficiary-level POS claim edits if necessary to prevent continued overutilization of opioids. Lastly, sponsors that implemented such POS claim edits would share certain data with a new sponsor when the beneficiary moves to another plan in accordance with applicable law.

Since the general overutilization policy was announced, CMS has taken several steps to make sure that sponsors were implementing it effectively and appropriately, beginning with the launch of the Overutilization Monitoring System (OMS). The OMS provides quarterly reports to sponsors on beneficiaries with potential opioid or APAP overutilization issues identified through analyses of PDE data from the previous 12 months and through CMS program integrity investigations; sponsors should respond to the OMS within 30 days on the status of their review for each beneficiary case. In January 2014, the OMS was enhanced to collect potential opioid overutilization issues and the status of each beneficiary case that was identified through Part D sponsors' own internal criteria and reviewed by the sponsors, but not previously identified by CMS. In February 2014, CMS enhanced the MARx system to accept beneficiary-level opioid POS edit data and to alert sponsors when a newly-enrolled beneficiary was subject to a

[4] 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 (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html).

beneficiary-level opioid POS edit in their prior plan.[5] For CY 2015, CMS announced its expectation that sponsors use the 120 mg morphine equivalent dose (MED) and 90 consecutive day threshold as the basis for their internal opioid criteria for improved drug utilization review and case management.[6]

Results

We believe the Part D overutilization policy has played a key role in reducing opioid and APAP overutilization in the program. A comparison of overutilization in 2011, 2013, and 2014 shows a significant reduction of opioid and APAP overutilization in Part D since the overutilization policy went into effect. Although the total number of Part D enrollees and the count of beneficiaries who used opioids increased from 2011 through 2014, the number of potential opioid overutilizers, based on the CMS definition in the OMS, decreased from 29,404 in 2011 to 21,838 in 2014 (see Table 1).

Table 1. OMS Part D Potential Opioid Overutilization Rates, 2011 - 2014 YOS (Comparable OPIOID Methodology)

YOS	Total Part D Enrollees	Total Part D Enrollees Utilizing Opioids	% Part D Enrollees Utilizing Opioids	Total Beneficiaries with at least 90 Consecutive Days >120mg MED Daily AND > 3 Prescribers & > 3 Pharmacies for Opioid Claims	Difference Year-to-Year	Share of Opioid Utilizers Flagged as Outliers
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	0.21%
2014‡	39,982,962	12,308,735	30.8%	21,838	−3,509	0.18%

Table 1 includes partial year inactive contracts, and hospice and cancer patients are excluded from utilizer and potential overutilizer counts. Results slightly differ from prior analyses due to these methodological changes.

*2011 PDE TAP Data (PDEs processed through 7JAN2012). For this comparison, CMS applied the revised 2013 opioid methodology, including the expanded drug list from CDC, and comparable PDE cut-off dates to 2011 data.

†2013 PDE TAP Data (PDEs processed through 4JAN2014)

‡2014 PDE TAP Data (PDEs processed through 3JAN2015)

In addition, from 2011 through 2014, the number of beneficiaries identified as potential APAP overutilizers, based on the CMS definition in the OMS, notably decreased from 76,581 in 2011 to 6,286 in 2014 (see Table 2).

---

[5] The Medicare Advantage and Prescription Drug Plan Communications User Guide (PCUG): http://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-technology/mapdhelpdesk/Plan_Communications_User_Guide.html

[6] Sponsors may lower the MED or number of consecutive days threshold and may vary other factors, such as the number of prescribers and pharmacies as described in the CY 2015 Call Letter.

Table 2. OMS Part D Potential APAP Overutilization Rates, 2011 - 2014 YOS (Comparable APAP Methodology)

YOS	Total Part D Enrollees	Total Part D Enrollees Utilizing APAP	% Part D Enrollees Utilizing APAP	Total Beneficiaries with daily APAP dose exceeding 4g for 30 or more days within any six-month period with at least one day exceeding 4g within the most recent calendar quarter.	Difference Year-to-Year	Share of APAP Utilizers Flagged as Outliers
2011*	31,483,841	9,449,693	30.0%	76,581		0.81%
2013†	37,842,632	10,591,651	28.0%	26,122	−50,549	0.25%
2014‡	39,982,962	10,845,499	27.1%	6,286	−19,836	0.06%

*2011 PDE TAP Data (PDEs processed through 13AUG2012). For this comparison, CMS applied the 2014 OMS APAP methodology, including the 6-month measurement period, which reduced the potential APAP overutilization counts as compared to the prior 2011 analysis

†2013 PDE TAP Data (PDEs processed through 04JAN2014)

‡2014 PDE TAP Data (PDEs processed through 03JAN2015)

Acetaminophen (APAP)

As described in the 2015 Call Letter, sponsors are expected to implement soft formulary-level edits in 2015 to reduce overutilization of APAP. However, we stated that if the soft formulary-level POS edits did not significantly reduce overutilization of APAP, we would consider announcing an expectation that Part D sponsors use hard edits for CY 2016. We are pleased that there has been a significant reduction in APAP overutilization observed through 2014 in the Part D program, as noted above. Therefore, CMS is not expecting sponsors to implement hard APAP formulary edits in CY 2016, but we still encourage sponsors to implement hard APAP formulary edits to prevent doses at egregious levels for which there would be no reasonable medical or dispensing explanation.[7]

Opioids

Although the use of improved drug utilization review, case management, and beneficiary-level POS edits have reduced overutilization of opioids in the Part D program, CMS believes that Part D sponsors should take additional steps to further reduce opioid overutilization, and suggested that sponsors implement a soft, formulary-level POS edit based on cumulative daily MED. CMS recommended potential specifications for the POS edit, including options for the MED and number of prescribers thresholds, and methods to minimize false positives to reduce the impact on beneficiaries at POS.

---

[7] More information about soft and hard rejects and edits is available from the National Council for Prescription Drug Programs: "Telecommunication Version D and Above Questions, Answers and Editorial Updates," *NCPDP*, February 2014, http://www.ncpdp.org/NCPDP/media/pdf/VersionD-Editorial.pdf (accessed 1/22/2015).

Although several commenters supported the proposed soft opioid POS edit, few offered recommendations on the edit specifications, and many raised concerns such as difficulties developing the edit as specified in time for the formulary submission and implementing it by CY 2016, as well as the potential impact on beneficiaries at the pharmacy. We will delay specifying the parameters for the POS edit until additional testing can be completed, but we continue to encourage sponsors to implement a soft, formulary-level cumulative MED POS edit and build the capacity for a more sophisticated POS edit in preparation for CY 2017. Sponsors who are interested in pilot testing the soft formulary-level POS edit should send an email to the new Part D Overutilization Management mailbox (PartD_OM@cms.hhs.gov).

Revisions to the Overutilization Monitoring System Methodology

The OMS has proven to be a valuable tool to make certain that sponsors have established reasonable and appropriate drug utilization management programs to monitor beneficiaries who are at-risk for adverse events due to potential overutilization of opioids and APAP as described above. With input from Part D sponsors and other stakeholders, CMS has revised the OMS and related systems (e.g., MARx). In the draft version of this Call Letter, CMS described potential enhancements to the OMS, including two new metrics and four new measures:

- Opioid Daily Dose rate: # opioid days > 120mg MED/1000 Opioid utilization days
- APAP Daily Dose rate: # APAP days > 4g/1000 APAP utilization days
- High-dose opioids in opioid naïve patients
- More than 90mg cumulative MED daily of short-acting opioids for greater than 90 consecutive days
- Concurrent buprenorphine and opioid use for more than 90 consecutive days
- Concurrent opioid and other CNS depressant use from multiple prescribers

Several entities submitted comments and questions about the proposed rates and measures, including what action CMS expected from sponsors in response to the new rates, requests for more details of the measure specifications, and suggestions for measure specifications. While there was support for the two concurrent opioid use measures as useful indicators of potentially unsafe practices, some commenters recommended a measure based on the concurrent use of benzodiazepines, opioids and skeletal muscle relaxants rather than concurrent use of opioids and CNS depressants. Therefore, for CY 2016, the new Opioid and APAP Daily Dose rates will be added to the OMS for informational purposes only. CMS will also investigate the concurrent use of buprenorphine and opioids in Part D as a potential new measure for the OMS as information only for CY 2016.

See additional discussion regarding opioid overutilization measures in Enhancements to the 2016 Star Ratings and Beyond, Potential new measures, Opioid Overutilization section of the Call Letter.

Improved Drug Utilization Controls for Other Drug Classes

Now that sponsors have more experience in implementing the overutilization policy, and CMS has more experience in overseeing compliance with the policy, we solicited feedback on expanding the Part D overutilization policy to other drugs or classes of drugs. The comments submitted were mixed concerning expansion of the Part D overutilization policy to other drugs or classes of drugs. A few commenters offered suggestions regarding other drugs and classes, such as the concomitant use of opioids, benzodiazepines, and muscle relaxants, which we will investigate or pilot test for future expansion of the policy. For CY 2016, we will not expand our overutilization policy beyond the opioid class. We note that current CMS guidance is that sponsors may adapt Part D overutilization policy to non-opioid medications, including HIV drugs, as long as they use the same level of diligence and documentation that CMS expects with respect to opioids, including written notice to the beneficiary when implementing POS claim edits.

Research, Guidelines, and Training Materials

CMS encourages Part D sponsors and members of their P&T committees to keep abreast of current research, guidelines, and training materials related to the appropriate use of opioids, such as the following information:

- *Common Elements in Guidelines for Prescribing Opioids for Chronic Pain*, published by the Centers for Disease Control and Prevention (CDC) at CDC.gov (http://www.cdc.gov/HomeandRecreationalSafety/overdose/guidelines.html)
- *The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain*, Publication No. 14-E005-EF, September 2014, published by the Agency for Healthcare Research and Quality (AHRQ) at AHRQ.gov (http://www.ahrq.gov/research/findings/evidence-based-reports/opoidstp.html)
- *Opioids for chronic noncancer pain*, A position paper of the American Academy of Neurology, published in the September 30, 2014 issue of the journal *Neurology*, and available at AAN.com (https://www.aan.com/uploadedFiles/Website_Library_Assets/Documents/6.Public_Policy/1.Stay_Informed/2.Position_Statements/3.PDFs_of_all_Position_Statements/Position%20and%20Policy%20Documents.pdf)
- *NIDAMED: Medical & Health Professionals* provides tools, resources, continuing education and training for medical and health professions through the website of the National Institute on Drug Abuse (http://www.drugabuse.gov/nidamed-medical-health-professionals)

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 2015 MTM program annual cost threshold is $3,138. The MTM program annual cost threshold is updated for 2016 using the annual percentage increase of 11.76%, as specified in the Calendar Year (CY) 2016 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies. Therefore, the 2016 MTM program annual cost threshold is $3,507.

A memo containing MTM program guidance and submission instructions is released each year by CMS and is available on the CMS.gov MTM page at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html. The guidance memo for CY 2016 will be released approximately one month before the 2016 MTM program submission deadline in May 2015. Questions regarding the MTM submission process or policy may be sent via email to partd_mtm@cms.hhs.gov.

We remind sponsors that our expectations for their MTM webpages are included in the MTM program guidance and submission instructions. During a recent assessment of beneficiary experience using sponsors' MTM webpages, beneficiaries found that it was often difficult for them to navigate to the MTM webpage using the search options and hyperlinks, sometimes requiring more than two clicks. Increasing font sizes and using lay language will help beneficiaries to read and understand the content of the MTM webpage.

Access to Preferred Cost-Sharing Pharmacies

In the CY 2015 Call Letter, CMS announced that we had received complaints from interested parties that some Part D plan sponsors were not providing their enrollees with reasonable access to network pharmacies that offered preferred cost sharing. CMS noted that we were concerned that beneficiaries might be misled into selecting plans based on advertised low preferred cost sharing only to find later that no preferred cost sharing pharmacies (PCSPs) were located within a reasonable distance from their residence. We stated that we had engaged a contractor to study the issue and, based on the results of the study, would consider whether to adopt network adequacy standards for PCSPs.

Currently, CMS evaluates Part D sponsor retail networks against TRICARE standards[8] as established for the Part D program by Congress; no distinction is made between standard cost sharing and preferred cost sharing pharmacies. In the spring of 2014, CMS initiated a new study, using Medicare Plan Finder (MPF) data to calculate plan-level beneficiary access to PCSPs. The MPF data was selected as the source of the plans' PCSP networks because it is the updated snap-shot of the plans' pharmacy networks, is the basis for beneficiaries' plan selections, and is provided to CMS directly from the plans. If plans submit erroneous pharmacy network data to CMS, then those errors are reflected in the findings for that plan.

In October 2014, CMS received findings from the analysis of beneficiaries' access to PCSPs offered under Part D. The analysis indicates that some beneficiaries residing in all types of geographic areas, but particularly in urban areas, face limited or, in some instances, no access to PCSPs. For instance, the study showed that, of the 641 plans with PCSP networks that do not meet the urban access standard (constituting 54% of all plans), 103 provide access to a PCSP within 2 miles of a beneficiary's urban residence to less than 30% of beneficiaries (33 of those plans provide such access to less than 10% of beneficiaries). The remaining 538 plans in this category provided PCSP access within 2 miles of their residence to between 31% and 89% of urban beneficiaries in their service area.

Overall, 46% of plans provide a level of access to PCSPs in urban areas equivalent to the convenient access standard in 42 C.F.R. §423.120(a)(1) for all (i.e., preferred and non-preferred) retail pharmacies; 87% have PCSP networks that meet the suburban, retail convenient access standard; and 95% have PCSP networks that meet the rural, retail convenient access standard. Though the great majority of Part D plans provide access to PCSPs at rates consistent with the regulatory convenient access standards in suburban and rural areas, there are some outliers in those areas as well.

Based on this analysis, we are concerned that beneficiaries residing in areas of low access to PCSPs may be unable to obtain the lower cost sharing as advertised in plan materials. We believe this may make marketing material misleading or otherwise misrepresent available cost sharing to beneficiaries in violation of our marketing requirements at 42 C.F.R. §423.2264(d). While we are not proposing to establish access standards for PCSPs at this time, we do plan to take a three-pronged approach to ensuring that beneficiaries are clearly informed of their options with respect to plans offering preferred cost sharing and increasing access to preferred cost sharing in areas where access is now low.

---

[8] The minimum standard for pharmacy [preferred or non-preferred] network access, based on the TRICARE standard, is as follows – urban areas: at least 90 percent of beneficiaries reside within 2 miles of a network retail pharmacy; suburban areas: at least 90 percent of beneficiaries reside within 5 miles of a network retail pharmacy; rural areas: at least 70 of beneficiaries reside within 15 miles of a network retail pharmacy.

First, CMS will publish information on PCSP access levels for each plan offering a preferred cost sharing benefit structure. This approach will offer more transparency to beneficiaries about their drug plan options. Information on 2016 access levels will be published on cms.gov in the fall. Posted data will be based on an analysis of PCSP pharmacies in 2016 networks that plans submit in their initial Medicare Plan Finder files in September 2015. In the future, we intend to publish information on PCSP access levels on Medicare Plan Finder.

Second, CMS will require plans whose PCSP networks are outliers in 2016 to disclose in marketing materials, including websites, that their plan's PCSP network offers lower access. If possible, CMS will also indicate which plans are outliers on Medicare Plan Finder. Outliers will be set at the bottom 10th percentile compared to all Part D plans in given geographic type, using 2014 data. For urban areas, using 2014 Plan Finder data, outliers based on the 10th percentile would consist of plans offering access to a PCSP within 2 miles of fewer than 40% of beneficiaries' residences. For suburban areas, this would be plans offering access to a PCSP within 5 miles of fewer than 87% of beneficiaries' residences. For rural areas, where the bottom 10th percentile is currently at 77%, plans that offer access to PCSP at a rate lower than the current convenient access standard would be considered outliers. So that Part D sponsors have time to implement this, CMS will not set outlier thresholds for 2016 higher than the 2014 thresholds. Plans will be reminded in April 2015 that their 2014 PCSP networks were outliers. CMS expects that Plans will analyze their own 2015 and 2016 networks to determine whether they are below the outlier thresholds. Plans whose 2016 networks are outliers based on the published 2014 thresholds should be prepared to make affirmative disclosures in 2016 marketing materials about their lower access to PCSPs. CMS will provide more guidance about the disclosures in the coming months.

Third, CMS will work with plans that were extreme outliers in 2014 to address concerns about beneficiary access and marketing representations relating to preferred cost sharing. CMS will notify these plans in or around April 2015 that we intend to address 2016 PCSP access issues with them during bid negotiation. CMS is opting to focus on extreme outliers in 2014 because 2016 data for all plans will not be available to CMS for analysis until after bid negotiations are complete.

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.

Threshold Calculations and Inflation Factor

The benefit parameters for CY 2016 are set forth in Table 1 below. Consistent with previous years, these thresholds are based on the 95th percentile of the CY 2015 Bid Data. For CY 2016, we will be implementing an inflation factor of 5.5% to the copayment cost sharing thresholds, consistent with the inflation value that is used in the out-of-pocket cost (OOPC) model for 2015, to account for the rising cost in drug prices. The inflation factor will not apply to the generic tiers given that the cost sharing thresholds for these tiers are already changing for CY 2016 based on the 95th percentile, as well as in consideration of the other changes that we intend to implement for the generic tiers as noted below. In the draft Call Letter, we proposed a $15 cost share threshold for the Generic drug tier for 2016. The proposed $15 threshold was based on the 95th percentile of all generic tiers combined. We received a number of industry comments expressing concern over the rising costs of generic drugs and the need for additional flexibility in managing benefit costs. Therefore we are increasing the Generic drug tier copayment threshold to $20, as reflected in Table 1 Benefit Parameters. This threshold aligns with the 95th percentile of CY 2015 bid data for the non-preferred generic tier.

Tier Labeling and Composition

A growing number of stakeholders are expressing concerns over the increasing cost sharing being applied to generic drugs, pointing to the significant copay differentials that exist between the cost sharing thresholds for preferred and non-preferred generic tiers, as well as the perception that certain generic drugs are "non-preferred" based on current tier labeling and hierarchy. Therefore, the tier labeling for generic tiers will change in CY 2016. This change merges the generic and non-preferred generic tiers into one standard "Generic" Tier, with the option of having a "Preferred Generic" tier with lower cost sharing for a subset of generic drugs. While the tier labeling requirements are changing for CY 2016, the Plan Benefit Package (PBP) software will not reflect the new naming convention. Global hard copy changes will be available for the Summary of Benefits (SB). Based on comments we received, we may consider additional tiering options for CY 2017.

While sponsors are not prohibited from having a mix of both brand and generic drugs on each tier, we remind sponsors that it is our expectation that a Drug Tier Label should be representative of the drugs that largely make up that tier. We are seeing a growing trend of generic drug products being shifted to non-preferred brand tiers resulting in significant increases in cost sharing and beneficiary out of pocket costs. Moving forward, we will be evaluating this trend as part of the bid review process and will communicate any outliers.

For purposes of determining whether coverage gap cost-sharing thresholds specified in Table 1 have been met, we will continue to rely on the FDA marketing status to identify formulary drugs

as applicable or non-applicable. The maximum coinsurance of 65% 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 38% 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 for the Select Care/Diabetic Drug Tiers, although the maximum allowable coinsurance value is less than 25%, we will conduct the same cost-sharing analysis for these tiers.) We will also continue to disallow incentives such as $0 or very low cost-sharing for 30-day supplies at mail service, unless offering the same cost sharing at the retail network.

Despite ACIP recommendations and Healthy People 2020 targets, adult immunization rates, while increasing, still remain quite low. We encourage Part D sponsors to consider offering $0 or low cost sharing for vaccines, if not doing so already, 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 2015.

The methodology for developing the CY 2016 out-of-pocket costs (OOPC) model is consistent with last year's methodology except for the following enhanced modifications: 1) how plan deductible and category level deductibles interact in the OOPC calculations; and 2) how average drug prices in Part D formulary tiers are calculated. For more information, please reference the HPMS memorandum dated January 7, 2015 titled "Medicare Plan Finder (MPF) Plan Version (V1) of Out-of-Pocket Cost (OOPC) Model for CY 2015 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 2016 bid submissions, are also included in the 2016 model. Using this model, the minimum monthly cost-sharing OOPC difference between basic and enhanced PDP offerings will be $18. The minimum monthly cost-sharing OOPC difference between enhanced PDP offerings will be $30. The methodology to determine the meaningful difference thresholds remains consistent with last year's methodology. These meaningful difference requirements apply to all stand-alone PDPs, including those belonging to sponsors under a consolidation plan. We will continue to expect that the additional EA PDPs within a service area

will have a higher value than the first EA plan and will include additional gap cost-sharing reductions for at least 10 percent of their formulary brand drugs.

In the draft Call Letter we proposed to change our approach with respect to cost-sharing and premiums by instituting a Total Beneficiary Cost (TBC) measure for PDPs, similar to what has been in place for MAOs. We believe this will meet CMS's goals of establishing a more transparent and predictable process so that beneficiaries can select a plan that best meets their health care needs, while also being protected from high or unexpected cost sharing that could discourage enrollment by certain beneficiaries. More specifically, we are considering using 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. We received a number of comments and requests for additional information on this policy. As we consider the implementation of this TBC measure for CY 2017, we will look to engage stakeholders to better understand industry perspective.

Table 1: Benefit Parameters

	CY 2016 Threshold Values
Minimum Meaningful Differences (PDP Cost-Sharing OOPC)[1]	
Enhanced Alternative Plan vs. Basic Plan	$18
Enhanced Alternative Plan vs. Enhanced Alternative Plan	$30
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 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 Brand Tier	50%

	CY 2016 Threshold Values
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	38%
Generic Tier	38%
Preferred Brand/Brand Tier	65%
Non-Preferred Brand Tier	65%
Injectable Tier	65%
Select Care/Diabetic Tiers[5]	65%
Minimum Specialty Tier Eligibility	
1-month supply at in-network retail pharmacy	$600

[1]The Enhanced Alternative Plan to Basic Plan meaningful difference minimum threshold is based on the 95th percentile of the October CY 2015 Bid Data run through the CY 2015 OOPC MPF model which incorporates CY 2015 Formulary Data, 2009/10 MCBS Data, and FDA data for brand/generic determinations related to coverage gap cost-sharing estimates. For each parent organization, any cost-sharing OOPC comparison between a basic plan and EA plan in the same region must meet the minimum Enhanced Alternative Plan vs. Basic Plan threshold. For each parent organization, any cost-sharing OOPC comparison between two EA plans in the same region must meet the threshold established annually by CMS.

[2] These thresholds are based on the 95th percentile of the CY 2015 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 38% 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 & Deductible

This year the minimum specialty tier eligibility threshold remains $600 (refer to Table 1). To make the Specialty Tier methodology transparent, we will post it at the following site upon the release of the Final CY 2016 Call Letter: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/ProgramReports.html. While the methodology continues to support the $600 threshold for CY 2016, we will consider the comments received and will be evaluating options for future guidance related to specialty products for CY 2017.

By placing these drugs on a specialty tier, plan sponsors are restricted to charging cost sharing no greater than that permitted under the defined standard benefit. In return Part D sponsors are shielded from tier exceptions for the most expensive drugs, and need not increase their bids and all Part D premiums to maintain actuarial equivalence for an estimate of increased plan liabilities arising from approved tier exceptions.

Also, Part D sponsors are permitted under 42 CFR § 423.578(a)(7) to exempt a specialty tier, in which it places very high cost and unique items, from tiered cost-sharing exceptions. 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 comply with the following in accordance with Chapter 6 Section 30.2.4 of the Prescription Drug Benefit Manual:

- Only one tier is designated a specialty tier exempt from cost-sharing exceptions.
- Cost-sharing associated with the specialty tier is limited to 25% after the deductible and before the initial coverage limit (or an actuarially equivalent for sponsors with decreased or no deductible under alternative prescription drug coverage designs).

- Only Part D drugs with sponsor negotiated prices that exceed the dollar-per-month amount established by CMS in the annual Call Letter may be placed in the specialty tier. CMS will apply an upfront evaluation across all plans for drugs that exceed the dollar-per-month threshold and are intended for inclusion in the specialty tier.
- If not all drugs (including all strengths) within a category or class meet the criteria for inclusion in the specialty tier, the sponsor must make sure that placement of the remaining drugs among the other tiers of the formulary does not substantially discourage enrollment.

Thus, in accordance with the second bullet above and annual Call Letter guidance, 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 to 33% cost-sharing if no deductible is required, or some percentage in-between dependent on a decreased deductible. (Example: a $360 deductible and 25% cost-sharing of an initial coverage limit of $3310 is essentially the equivalent of $1097.50 in out-of-pocket expenses, whereas no deductible and 33% cost-sharing of the same initial coverage limit is essentially the equivalent of $1092.30 in out-of-pocket expenses.)

CMS understands that some Part D sponsors are offering alternative prescription drug benefit plans that include Specialty Tiers when the plans also feature a decreased deductible or no deductible, but only for certain tiers, and in some cases only for the Specialty Tier. This is contrary to what we intended. Moreover, we believe it is misleading to beneficiaries who may choose these plans without realizing that the reduced or no deductible feature only applies to certain tiers and not all tiers. Therefore, we are clarifying our guidance in Chapter 6 Section 30.2.4 that the cost-sharing associated with the specialty tier is limited to 25% after the deductible and before the initial coverage limit, or to the benefit parameters established in the annual Call Letter, when there is decreased or no deductible for <u>all</u> tiers under alternative prescription drug coverage designs.

Maximum Allowable Cost (MAC) Pricing

Effective January 1, 2016, drug pricing based on maximum allowable cost (MAC) is subject to the regulations governing the disclosure and updating of prescription drug pricing standards at 42 CFR §§423.501; 423.505(b)(21); and 423.505(i)(3)(vii). When updating MAC prices, the regulations will also require Part D sponsors to disclose the drug prices to the applicable pharmacies in advance of their use for reimbursement, if the source for any prescription drug pricing standard is not publicly available. We explained in the preamble to the final rule (4159-F) that these changes mean that Part D sponsors will have to convey to network pharmacies the actual MAC prices to be updated in advance (70 Fed. Reg. 29883, May 24, 2014). We also stated in the preamble that final rule does not specify any particular time period for advance notice of MAC prices to network pharmacies.

In the final rule, we declined to require a certain format layout and delivery method for disclosure of maximum allowable cost prices. However, we stated in the preamble that an option could be a secure internet site that allowed network pharmacies to look up their drug prices. We further stated that the site or other delivery method to convey MAC prices would have to enable the pharmacies to connect a claim to the correct drug price at the appropriate point in time in order to validate the price (70 Fed. Reg. 29884, May 24, 2014).

We are concerned that some Part D sponsors may be planning to send applicable network pharmacies constant updates of MAC prices, whether electronically, or by facsimile, or by some other method, and with no particular organization, other than perhaps in time order of update. We caution Part D sponsors that updates of MAC prices must be disclosed to network pharmacies in a manner that is usable by pharmacies because, as noted above, the manner of updating MAC prices must enable pharmacies to validate prices.

Mail Order and Changes to Applying for Exceptions to the Auto-Ship Policy

The auto-ship policy (Auto-Ship Refill Programs in Part D) announced in the 2014 Call Letter has two exceptions available to sponsors (announced in memoranda dated 10/28/2013 and 12/12/2013), which have been widely applied since 01/01/2014. The exceptions address automatic shipments of mail order prescriptions without obtaining prior beneficiary consent, provided that refunds are available to beneficiaries who receive unneeded or unwanted medications, and the other conditions described below are met.

Starting in 2016, Part D sponsors interested in offering automatic deliveries of <u>new</u> prescriptions (as described in the 12/12/2013 memo) will no longer need to request an exception to the auto-ship policy by emailing CMS. Instead, the exception will remain available to all Part D plans, without the need to specifically submit a request. Plans are permitted to start or continue automatic shipments, provided they meet the conditions listed in the authorizing memoranda and also listed below. Similarly, starting in 2016, Employer Group Waiver Plan (EGWP) sponsors interested in offering automatic deliveries of <u>refill</u> prescriptions (as described in the 10/28/2013 memo) will no longer need to separately request an exception to the Auto-Ship policy by emailing CMS.

Current Policy:

The current process for requesting one or both exceptions is that the sponsor should send an e-mail request to CMS providing the sponsor name, contract number(s) affected, and an acknowledgement that the automatic delivery arrangement meets all of the conditions detailed for the exception. As a reminder, the exception to automatically send <u>refill</u> medications without obtaining prior beneficiary consent (provided that refunds are available and all other exception terms are met) is only available to EGWP sponsors.

As stated in previous guidance, medications coordinated and shipped or delivered by Programs of All-Inclusive Care for the Elderly, do not need to obtain beneficiary consent prior to coordinating new or refill prescriptions for their enrollees.

2016 Policy:

For Contract Year 2016, any Part D sponsors interested in automatically sending new prescriptions not directly initiated by the beneficiary under the 12/12/2013 exception may do so without submitting a specific request to CMS, but are still expected to meet all of the conditions listed in the applicable memoranda.

CMS will continue to monitor mail order and auto-ship practices, including related complaints submitted by beneficiaries. As a reminder, under the Part D program, choice of pharmacy, including use of mail-order, home delivery, or other automatic shipment must be voluntary.

This change only eliminates the need for a sponsor to submit the request and contract number(s) to CMS. It does not change the exception conditions; including the condition to verify a beneficiary's interest in continuing automatic shipments at least annually (either by obtaining consent from the beneficiary directly or by citing mail order use under the same plan, as noted in the Review of Exception Requirements).

Review of Exception Requirements:

The conditions listed for the 10/28/2013 and 12/12/2013 exceptions are included below. As noted in a clarifying memo issued 03/21/2014, if a beneficiary has experience using mail-order or other automatic delivery programs under the plan, sponsors and their network pharmacies do not need to establish an additional opt-in procedure for obtaining consent to participate in automatic delivery programs. In line with this clarification, sponsors may also cite history of mail order use under the plan to meet the annual consent condition. However, if a beneficiary has had no previous mail-order, home delivery, or other automatic shipment experience under the plan, a new prescription submitted by anyone other than the beneficiary (or authorized representative) should not be automatically shipped under an exception. In these cases, a sponsor should have its mail order pharmacy contact the beneficiary (or authorized representative) to obtain consent prior to shipping, as described in the Auto-Ship policy.

Further, for plans applying either exception, beneficiaries should be able to easily opt-out of automatic deliveries at any time. The sponsor should respond in a timely fashion to all opt-out requests, and any automatic shipments sent without obtaining prior consent should be eligible for a full refund. Additionally, once a plan receives notification that a member is deceased, automatic shipments should be cancelled and any medications that are automatically shipped to deceased beneficiaries should be refunded and deleted from the PDE data. A beneficiary who chooses to opt-out of automatic deliveries should still be permitted to use mail order services if they choose. If opted-out out of automatic deliveries, the pharmacy would obtain consent prior to

shipping any new or refill medication orders not directly initiated by the beneficiary (or authorized representative), as detailed in the original policy in the 2014 Call Letter.

12/12/2013 Exception Conditions for New Prescription Automatic Delivery (Available to all Part D plan sponsors)

1. Enrollee participation in the automatic delivery program is voluntary and opt-in only. (Per 03/21/2014 guidance, plans may cite recent mail order use.)

2. After the initial fill of a new prescription, any shipments of authorized refills not initiated by the beneficiary should conform with the policy described in the 2014 Call Letter, with the pharmacy obtaining beneficiary or authorized representative consent prior to each delivery.

3. Printed and online beneficiary materials should have easy to locate and easy to understand information on how to dis-enroll from automatic delivery programs. Plans will respond within 30 days to any dis-enrollment requests.

4. The plan will provide a refund to the beneficiary for the full amount of the cost-sharing and will delete the prescription drug event (PDE) for any new prescription sent to a beneficiary in an automatic delivery program that the beneficiary reports as unneeded or otherwise unwanted. Beneficiary materials related to refunds must be easy to locate and easy to understand. Plans providing no-fee return of unneeded or unwanted drugs do not need to provide a full refund or delete the PDE when the prescription has been fully or partially used or consumed.

5. The plan will confirm at least annually with the beneficiary if he/she wants to continue in the automatic delivery program. (Per 03/21/2014 guidance, plans may cite recent mail order use.)

6. The plan will promptly discontinue automatic delivery after notification that a beneficiary entered a skilled nursing facility, or elected Medicare hospice coverage.

7. The plan agrees to monitor all grievances and complaints related to mail order and to determine if concerns with unwanted initial fills have decreased to a minimal level. If not, plans will identify processes to correct the delivery program accordingly. The format and schedule for defining and determining such decreases will be announced by CMS at a later time.

10/28/2013 Exception Condition for Refill Prescription Automatic Delivery (Available to EGWP sponsors only)

1. Enrollee participation in the automatic delivery program is voluntary and opt-in only.

2. The automatic delivery program only applies to prescription refills and does not apply to new prescriptions that are e-prescribed, faxed, mailed, or phoned-in directly to the pharmacy, even if the new prescription is a continuation of existing therapy.

3. The EGWP has easy to locate and easy to understand beneficiary materials on how to dis-enroll from automatic delivery programs, and the EGWP responds promptly to all dis-enrollment requests.

4. The EGWP will provide a refund to the beneficiary and delete the PDE for any auto-shipped refill that the beneficiary reports as unneeded or otherwise unwanted. Beneficiary materials related to refunds must be easy to locate and easy to understand. Plans providing no-fee return of unneeded or unwanted drugs do not need to provide a full refund or delete the PDE when the prescription has been fully or partially used or consumed.

5. The EGWP will confirm whether the beneficiary wants to continue in the automatic delivery program at least annually and upon receipt of a new prescription from a provider, even if the new prescription is a continuation of existing therapy

6. The EGWP will promptly discontinue automatic delivery after notification that a beneficiary entered a skilled nursing facility, or elected Medicare hospice coverage.

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 2016 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 2016 bids.

In contract year 2016, 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 (MARx) system 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: http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/index.html to determine if any of their plans meet this criterion. By April 2015, we will notify plans with less than 1,000 enrollees of available consolidation/withdrawal options. We reserve the right to require low enrollment plans to consolidate/withdraw in the future based on the marketplace at that time to verify 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.

Appendix 1 – Contract Year 2016 Guidance for Prescription Drug Plan (PDP) Renewals and Non-Renewals

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

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

Conversely, a PDP sponsor may reduce its service area by electing not to submit bids for those regions from which it expects to withdraw. A PDP sponsor must notify CMS in writing (by sending an email to nonrenewals@cms.hhs.gov) of its intent to non-renew one or more plans under a contract by the first Monday in June (June 1, 2015). 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 2016 is summarized below and defined in Appendix 2. All but one of these actions can be effectuated by PDP sponsors in the HPMS Plan Crosswalk.

1. New Plan Added

A PDP sponsor may create a new PBP for the following contract year with no link to a PBP it offers in the current contract year in the HPMS Plan Crosswalk. In this situation, beneficiaries electing to enroll in the new PBP must complete enrollment requests, and the PDP sponsor offering the PBP must submit enrollment transactions to MARx. No beneficiary notice is

required in this case beyond receipt of the Evidence of Coverage (EOC), and other documents as required by current CMS guidance, following enrollment.

2. Renewal Plan

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

3. Consolidated Renewal Plan

PDP sponsors are permitted to merge two or more entire PBPs offered in the current contract year into a single renewal plan in the HPMS Plan Crosswalk. A PDP sponsor may not split a current PBP among more than one PBP for the following contract year. A PDP sponsor consolidating two or more entire PBPs must 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 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 1, 2015. 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. In this situation, the sponsor will not submit disenrollment transactions to MARx for affected enrollees. When a sponsor terminates a PBP, plan enrollees must make a new election for their Medicare coverage in the following contract year. To the extent that a current enrollee of a terminated PBP elects to enroll in another plan offered by the current or another PDP sponsor – or, alternatively, elects to enroll in an MA plan – he/she must complete an enrollment request, and the enrolling organization or sponsor must submit enrollment transactions to MARx so that those individuals are enrolled. Enrollees of terminated PBPs will be sent a model termination notice that includes notification of a special election period, as well as information about alternative options.

6. Consolidated Plans under a Parent Organization

For purposes of ensuring compliance with transition requirements following an acquisition or merger under our significant differences policy, or to make plan transitions following a novation, CMS may elect to 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 2016 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 2016 that is not linked to a 2015 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 2015 PBP in CY 2016. 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 2016 plan that links to a 2015 plan and retains all of its plan service area from 2015. The 2016 plan must retain the same plan ID as the 2015 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 2016. 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 2015 into a single renewal PBP for CY 2016. 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 2015 plans that merge into one 2016 plan. The 2016 plan ID must be the same as one of the consolidating 2015 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 2016.	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 2015 prescription drug PBP in CY 2016 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 2016.	HPMS Plan Crosswalk Definition: A 2016 800-series plan that links to a 2015 800-series plan and retains all of its plan service area from 2015, but also adds one or more new regions. The 2016 plan must retain the same plan ID as the 2015 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 2016. 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 2015 PBP.	HPMS Plan Crosswalk Definition: A 2015 plan that is no longer offered in 2016. HPMS Plan Crosswalk Designation: Terminated Plan	CMS expects the sponsor to crosswalk the affected enrollees into the most comparable plan. The PDP sponsor does not submit disenrollment transactions. If the terminated enrollee elects to enroll in another PBP with the same or another PDP sponsor or MAO, the enrolling PDP sponsor or organization must submit enrollment transactions to enroll the terminated enrollees.	Terminated enrollees must complete an enrollment request if they choose to enroll in another PBP, even a PBP offered by the same PDP sponsor.	Terminated enrollees are sent a CMS model termination notice including SEP information and receive a written description of options for obtaining prescription drug coverage in the service area.

	Activity	Definitions	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
6	Consolidated Plans across Contracts under the Same Parent Organization	A parent organization merges two or more whole PBPs under different contracts (the contracts may be the same legal entity or represent different legal entities) as a result of a merger, acquisition, or novation. A PDP sponsor cannot complete this renewal option in the HPMS Plan Crosswalk.	Exceptions Crosswalk Request: Sponsors must submit an exceptions request to CMS, which will complete the crosswalk on behalf of the sponsor HPMS Plan Crosswalk Designation: The plan being crosswalked must be marked as a terminated plan in the HPMS crosswalk. The remaining 2016 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 2016. New enrollees must complete enrollment request.	Current enrollees are sent a standard ANOC.

Appendix 3

Measure – Beneficiary Access and Performance Problems (Revised Methodology)

Labels for Stars: Problems Medicare Found in Members' Access to Services and in the Plan's Performance (more stars are better because it means fewer serious problems)

Label for Data: Problems Medicare Found in Members' Access to Services and in the Plan's Performance (on a scale from 0 to 100, **higher numbers** are better because it means fewer serious problems)

Description: To check on whether members are having problems getting access to services and to be sure that plans are following all of Medicare's rules, Medicare conducts several different types of reviews. Medicare gives the plan a ***lower*** score (from 0 to 100) when it finds problems. The score combines ***how severe*** the problems were, ***how many*** there were, and ***how much*** they affect plan members directly. A higher score is better, as it means Medicare found fewer problems.

Metric: This measure is based on CMS's sanctions, civil monetary penalties (CMP) as well as Compliance Activity Module (CAM) data (this includes: notices of non-compliance, warning letters {with or without business plan}, and ad-hoc corrective action plans (CAP) and the CAP severity).

- Contracts' scores are based on a scale of 0 -100 points.
- The starting score for each contract works as follows:
  - Contracts with an effective date of 1/1/2014 or later are marked as "Plan too new to be measured".
  - All contracts with an effective date prior to 1/1/2014 begin with a score of 100.
- Contracts placed under sanction anytime during the data time frame are reduced to a score of 0. This is separate from the deduction applied at the overall score level for contracts with more recent sanctions.
- The following deductions are taken from contracts whose score is above:
- For each CMP, Contracts that received a CMP with beneficiary impact related to access: 40 points.
- Contracts that have a CAM score (CAM score calculation is discussed below) are reduced as follows:
  - 0– 2 CAM Score – 0 points
  - 3 – 9 CAM Score – 20 points
  - 10 – 19 CAM Score – 40 points
  - 20 – 29 CAM Score – 60 points
  - ≥ 30 CAM Score – 80 points

Calculation of the CAM Score combines the notices of noncompliance, warning letters (with or without business plan) and ad-hoc CAPs and their severity. The formula used is as follows:

CAM Score = (NC × 1) + (woBP × 3) + (wBP × 4) + (6 × CAP Severity)

Where: NC = Number of Notices of Non Compliance
woBP = Number of Warning Letters without Business Plan
wBP = Number of Warning Letters with Business Plan
CAP Severity = Sum of the severity of each individual ad-hoc CAP given to a contract during the measurement period. Each CAP is rated as one of the following:
3 – ad-hoc CAP with beneficiary access impact
2 – ad-hoc CAP with beneficiary non-access impact
1 – ad-hoc CAP no beneficiary impact

Data Source: CMS Administrative Data

Data Source Description: Findings of CMS compliance actions that occurred during the 12 month past performance review period between January 1, 2014 and December 31, 2014. For compliance actions, the date the action was issued is used when pulling the data from HPMS.

CMS Framework Area: Population/Community Health

NQF#: None

Data Time Frame: 01/01/2014 – 12/31/2014

General Trend: Higher is better

Statistical Method: Relative Distribution and Clustering

Improvement Measure: Not Included

Weighting Category: 1.5

Data Display: Rate with no decimal point

Reporting Requirements:

1876 Cost	Demo	Local, E-local, RPPO, CCP w/o SNP	Local, E-local, RPPO, CCP w/ SNP	MSA	E-PDP & PDP	E-PFFS, PFFS
Yes	Yes	Yes	Yes	Yes	No	Yes

4- Star threshold: Not predetermined

Appendix 4 - Improvement measures (Part C & D)

Part	Measure	Improvement Measure
C	Breast Cancer Screening	No
C	Colorectal Cancer Screening	Yes
C	Annual Flu Vaccine	Yes
C	Improving or Maintaining Physical Health	No
C	Improving or Maintaining Mental Health	No
C	Monitoring Physical Activity	Yes
C	Adult BMI Assessment	Yes
C	Special Needs Plan (SNP) Care Management	Yes
C	Care for Older Adults – Medication Review	Yes
C	Care for Older Adults – Functional Status Assessment	Yes
C	Care for Older Adults – Pain Assessment	Yes
C	Osteoporosis Management in Women who had a Fracture	Yes
C	Diabetes Care – Eye Exam	Yes
C	Diabetes Care – Kidney Disease Monitoring	Yes
C	Diabetes Care – Blood Sugar Controlled	Yes
C	Controlling Blood Pressure	Yes
C	Rheumatoid Arthritis Management	Yes
C	Reducing the Risk of Falling	Yes
C	Plan All-Cause Readmissions	Yes
C	Getting Needed Care	Yes
C	Getting Appointments and Care Quickly	Yes
C	Customer Service	Yes
C	Rating of Health Care Quality	Yes
C	Rating of Health Plan	Yes
C	Care Coordination	Yes
C	Complaints about the Health Plan	No
C	Members Choosing to Leave the Plan	Yes
C	Beneficiary Access and Performance Problems	No
C	Health Plan Quality Improvement	No
C	Plan Makes Timely Decisions about Appeals	No
C	Reviewing Appeals Decisions	Yes
C	Call Center – Foreign Language Interpreter and TTY Availability	No
D	Call Center – Foreign Language Interpreter and TTY Availability	No
D	Appeals Auto–Forward	Yes
D	Appeals Upheld	No
D	Complaints about the Drug Plan	No
D	Members Choosing to Leave the Plan	Yes
D	Beneficiary Access and Performance Problems	No
D	Drug Plan Quality Improvement	No
D	Rating of Drug Plan	Yes
D	Getting Needed Prescription Drugs	Yes
D	MPF Price Accuracy	No
D	High Risk Medication	Yes
D	Medication Adherence for Diabetes Medications	Yes
D	Medication Adherence for Hypertension (RAS antagonists)	Yes
D	Medication Adherence for Cholesterol (Statins)	Yes
D	Medication Therapy Management Program Completion Rate for Comprehensive Medication Reviews	No

Appendix 5 - 2016 Draft Call Letter Star Ratings Summary of Comments and Responses

Call Letter Section	Summary of Comments	CMS Final Course of Action
Changes to the Calculation of the Overall Rating and the Part C and D Summary Ratings	The associations and most sponsors would like to retain pre-determined 4-star thresholds to help set expectations and performance goals in particular for value-based contracting with providers. A number suggest setting prospective cut points. A few sponsors support the removal of pre-determined 4-star thresholds. One advocacy group strongly supports the removal of pre-determined 4-star thresholds to ensure accuracy of rating system. They say it is vital to public confidence. A pharmacy advocacy group supports the removal of thresholds as well. One organization strongly supports the removal of pre-determined 4-star thresholds.	The goal of removing pre-determined thresholds was to reduce misclassification in the rating system. We will proceed as planned since it is critical to measure performance as accurately as possible. Some of the suggested alternatives such as setting prospective cut points would introduce additional misclassification into the Star Rating system. Sponsors can set their own benchmarks to help drive higher levels of performance.
New 2016 Measure: MTM CMR	Patient advocates and pharmacists are supportive of inclusion of the MTM CMR measure into the Star Ratings for 2016 and the potential value of MTM programs in general. Nearly all organizations supported the inclusion of this measure. One does not feel that this measure reflects plan performance (beneficiary choices, circumstances outside of plan control, access to other programs, or cannot reach members) and that plans with restrictive eligibility criteria are advantaged. One sponsor and one PBM support the inclusion of this measure, and the remaining sponsors and PBMs are opposed. They have concerns that this was an activity/process (not outcomes) measure, and that plans may have varying eligibility criteria to determine who must be offered the CMR. Some suggest different cut points for ranges of eligibility criteria or other qualifiers. Others suggest revising the measure to include all MTM enrollees (based on plan-specific expanded criteria versus mandated) or excluding LTC.	Proceed as planned to include measure in 2016 Star Ratings.
Returning Measures for 2016		
Breast Cancer Screening (Part C)	Overall sponsors support the proposed change. Organizations support bringing it back to the Star Ratings and changes to the measure.	Proceed as planned.

Call Letter Section	Summary of Comments	CMS Final Course of Action
Call Center – Foreign Language Interpreter and TTY Availability measures (Part C & D)	Most commenters support the return of this measure. Many sponsors ask for further details about 2015 Stars' data issues, or submitted technical questions. One organization requests the measure be removed due to historical data accuracy issues. One sponsor opposes the change, because they feel the measurement period beginning in March is a material retrospective change prior to the final Call Letter.	Proceed as planned. The proposed measurement period is in line with prior years. Technical questions about sampling size and other methodology concerns are being reviewed by the appropriate team for follow-up. Last year's data issues were related to both the Accuracy and Accessibility and the Timeliness surveys conducted by CMS' contractor. For example, there were disconnection issues that could not be resolved until July, when it was determined that a change made to the contractor's phone system did not provide backward compatibility with plans using older phone technology. Other issues included incorrect contractor training and call documentation. Some sponsors' calls were incompletely documented by the contractor; therefore retrospective corrections could not be made. CMS has taken corrective steps, such as increasing the quality assurance procedures used by the contractor to proactively validate the data as the surveys progress. Any findings will be reported to CMS immediately. We have also increased the frequency of checks performed so that any issues identified can be corrected while the contractor verifies past results. Sponsors are encouraged to alert CMS of any issues, comments or questions about the Call Center Monitoring project by email to CallCenterMonitoring@cms.hhs.gov .

Call Letter Section	Summary of Comments	CMS Final Course of Action
Beneficiary Access and Performance Problems (Part C & D)	Most commenters support the return of this measure. A few want to reshape the measure to benefit their own score. One sponsor feels that this measure duplicates Past Performance evaluation.	Proceed as planned.
Changes to Measures for 2016		
Controlling Blood Pressure (Part C)	Most sponsors and organizations support the proposed change. One organization has serious concerns about the expanded blood pressure measure and is strongly against any change. Another organization recommends that the measure metric be changed to less than or equal to rather than just less than.	Proceed as planned.
Plan Makes Timely Decisions about Appeals (Part C)	Sponsors and organizations support proposed change.	Proceed as planned.
Plan All-Cause Readmissions (Part C)	All sponsors support proposed change. One inquired if CMS will count two readmissions if they remove the current exclusion from the denominator for hospitalizations with a discharge date in the 30 days prior to the Index Admissions. One asked the impact of the change on scores. Most organizations support the proposed change, and one association expresses support for the proposed change as well.	Proceed as planned.
Osteoporosis Management in Women who had a Fracture (Part C)	Organizations and sponsors are mixed on the proposed changes, with several commenting on specific exclusions or requesting additional exclusions. One organization and several sponsors dislike the measure in general.	Proceed as planned. CMS will provide comments to NCQA.
Complaints about the Health/Drug Plan (CTM) (Part C & D)	One organization agrees that expansion of the data for this measure will provide a more comprehensive evaluation of the plan. All sponsors support use of one full year of CTM data, but request the measure be moved to the display page since 2014 complaints were used for two years of Star Ratings. Several sponsors recommend using July 1, 2014 through June 30, 2015 for the 2016 Star Ratings.	Proceed as planned. We do not recommend using complaint data spanning across contract and benefit years.

Call Letter Section	Summary of Comments	CMS Final Course of Action
Improvement measures (Part C & D)	A Puerto Rico association and a sponsor from Puerto Rico recommend including medication adherence measures only within the improvement measure, but not the separate adherence measures to avoid the disproportionate impact of the benefit disparity. One sponsor recommends including the CTM measure. Nearly half of sponsors request removing some measures including Members Choosing to Leave the Plan, Osteoporosis Management, Flu Vaccine, CAHPS, HOS, SNP measures, HRM, Diabetes Treatment. One expresses concern that high performing plans can in effect be penalized with the high weighting of these two improvement measures in the current system. A couple sponsors request to modify the methodology for including the Part C or D improvement measure, as well as the application of the i-Factor.	Proceed as planned.

Call Letter Section	Summary of Comments	CMS Final Course of Action
Appeals Upheld and Auto-forward (Part D)	An association generally agrees with adjustment to the measurement period for the upheld measure, but also recommends delaying the change to include re-openings until contractor-based issues are resolved. For sponsors, the feedback regarding changing the collection period for the upheld measure varied. The majority agree with the change from Jan 1 – Dec 31, but suggest it be a display measure in 2016 to avoid double counting. Also for sponsors, the feedback regarding changing the minimum case threshold for the upheld measure varied. Comments range from leaving the minimum threshold at 5 cases, adjusting the threshold, setting a threshold to be a proportion of each contract's membership, and giving contracts with less than 5 cases 5 stars. Sponsors agree that reopened cases should be included in the upheld measure. Similarly, remanded cases should be excluded from the auto-forward measure. There were several additional comments from sponsors such as: the auto-forward measure is biased towards large health plans with the ability to enroll a diversified population, reopened cases for the first 6-8 months should be included in the upheld measure, sponsors should have similar timeframes as the IRE, removing appeals related to Part D vs. Part A – Hospice, change the calculation to account for the volume of cases appealed to the Independent Review Entity (IRE) as a percentage of a plan's total coverage determination and re-determination cases, account for different data submitted by the doctor to the plan compared to what is submitted to the IRE, and explicitly exclude both withdrawn and dismissed cases from the appeals metrics.	Proceed as planned. For the 2016 Star Rating upheld measure, we will exclude appeal cases for beneficiaries enrolled in hospice at any point during 2014. This exclusion will only be necessary for the 2016 measure as it is based on 2014 data that may have been affected by policy changes.
Medication Adherence (for Diabetes Medications and Hypertension (RAS antagonists)) and Diabetes Treatment (Part D)	Less than half of the commenters support one or both of the proposed changes. However, more than half, including the majority of sponsors, opposed the recommendation to retire the Diabetes Treatment (DT) measure for the 2017 Star Ratings. Instead, they propose retiring as of the 2016 Star Ratings because the JNC 8 guidelines were published in the beginning of 2014. Several organizations are mixed about retiring the measure for 2016 or 2017 Star Ratings.	We will finalize the ESRD exclusion as planned. We will retire the DT measure for the 2016 Star Ratings, instead of the 2017 Star Ratings as initially proposed.

Call Letter Section	Summary of Comments	CMS Final Course of Action
Medication Adherence (Diabetes Medications, Hypertension (RAS antagonists), and for Cholesterol (Statins)) (Part D)	Most commenters support using the exact death date when available in CME instead of the month-end CME disenrollment date as the end of the beneficiary's measurement period. Only a few sponsors and one PBM oppose this proposal, citing concerns with availability or timeliness of the data element and inconsistency with current business systems.	Proceed as planned to use the exact death date beginning with the 2016 Star Ratings. There can be up to a three month delay for a beneficiary's death date to populate in the CME, but 2014 death dates should stabilize by the time data are finalized for the 2016 Star Ratings in July 2015.
Obsolete NDCs	A couple sponsors and one organization support the proposal to implement the PQA's revised obsolete NDC date methodology, while one organization opposes. We also received some technical comments (such as expanding the look back period to 24 months) which we will share with the measure developer for future consideration.	Proceed as planned to implement the revised PQA methodology for the 2016 Star Ratings.
CAHPS (Part C & D)	One organization suggests all CAHPS measures should be display only; however, they approve of change for low reliability measure scores. Most sponsors support the minor modifications to the methodology. One sponsor requests documentation on how reliability is calculated, and another expresses concern that data for low reliability contracts is too limited. Another provider expresses support for this proposal.	Proceed as planned.
Retirement of Measures: For 2016 Stars: Part C: Cardiovascular Care: Cholesterol Screening; Diabetes Care: Cholesterol Screening; Diabetes Care: Cholesterol Controlled For 2017 Stars, Part D: Appropriate Treatment of Hypertension in Diabetes	Generally there is support for retirement of these measures, but some are concerned that there would be a measurement gap and/or an unintended message would be conveyed that cardiovascular care is less important. See Call Letter section above, Medication Adherence (for Diabetes Medications and Hypertension (RAS antagonists)) and Diabetes Treatment (Part D), for discussion on the retirement of the Diabetes Treatment measure.	Proceed as planned. We will retire the DT measure for the 2016 Star Ratings, instead of the 2017 Star Ratings as initially proposed.

Call Letter Section	Summary of Comments	CMS Final Course of Action
Temporary Removal of Measures: Improving Bladder Control (Part C)	All sponsors agree with removing this measure, but would prefer the removal to be permanent. At least one sponsor mistook this cross-sectional measure as a longitudinal one (as a two year change score, rather than as a single-point in time measure) and thought we had misstated when data would allow it to return to Star Ratings.	Proceed as planned.
Contracts with Low Enrollment	A few sponsors ask for clarifications or give suggestions. There is some confusion on whether scores would be shown if not included in clustering and suggestions to only report statistically valid measures. A beneficiary advocate strongly supports including contracts with 500-999 enrollees in the 2016 Star Ratings.	Proceed as planned.

Call Letter Section	Summary of Comments	CMS Final Course of Action
Data Integrity	General: Sponsors request changes from the current policy – 1) distinguish between the knowing and willful submission of inaccurate data and the unintentional submission of minor errors and mistakes and/or 2) ensure parity if CMS or its contractors are responsible for data issues, either automatically assign a 5 star rating or offer the sponsor the chance to reuse the prior year's data. One sponsor raises concerns about measure datasets. Use of Data Validation (DV) results to apply for related measure datasets: Organizations are divided – One supports the wider use of independent DV to ensure accuracy and thus fairness to all plans, and another organization states at a minimum, Part C and D plans' internal process should include the use of multiple reviewers and audits. A few organizations are opposed, due to inconsistent validation audits. Among sponsors, many request clarifying information or that the DV timeframe is adjusted so plans can resubmit erroneous data. Others ask if CMS vendors undergo data validation exercises. There is concern that Star Ratings and compliance/audit activities may lead to double penalties. Most commenters ask for more detail about the process for how the data integrity checks would be conducted in order to provide more specific feedback. HRM: Comments focused on CMS's formulary requirements for HRM drugs or measure specifications.	General: We cannot automatically assign a measure Star Rating of high performance, or assume a plan's performance has not changed from last year. We will share technical questions with the appropriate staff. Use of DV results: No changes to final Call Letter, and we will continue examining DV issues for future application to Stars. HRM: No changes necessary to CMS's direction.

Call Letter Section	Summary of Comments	CMS Final Course of Action
Duals/LIS	Organizations believe the proposed change is premature. In addition, they are concerned that the change diminishes the importance of clinical quality measures and has the potential to reward plans without improving care. The vast majority of associations do not support the proposed change. Some associations express concern that the implementation of the proposed change has the potential of undermining the Star Ratings. In addition, some commenters discussed the impact of the down weighted measures on the weight of all Star Rating measures. Further, there is concern that D-SNPS would not receive any relief. Overall, sponsors are not supportive of the proposed change for reducing the weights for the subset of measure. Many sponsors believe that the proposed change was a one-size-fits-all response that would not adequately address the Dual/LIS issue. Further, sponsors state that it would provide minimal (if any) relief and has the potential for numerous unintended consequences such as inflating ratings without increasing the quality of care. If CMS were to move forward with the change, many sponsors request a 'hold-harmless' clause. Sponsors offer alternative options such as implementing an adjustment factor or modifying thresholds for plans with high percentage of Dual/LIS beneficiaries. All commenters agree with retaining the original weights of all measures for the improvement measures.	We are removing the proposal to reduce the weights for a subset of measures and will make no changes to the 2016 Star Ratings for Dual/LIS effects. We will continue to perform additional internal analyses, coordinate with ASPE on analyses related to the IMPACT Act, and strongly recommend that the measure developers concurrently begin their research.
Measures On the CMS Display Page: COPD	One organization supports, while a couple recommend that CMS move it from a display measure to an active measure. One sponsor supports it on display page but suggests modifying "active prescription" definition and count patients with the appropriate medicines at home. Another sponsor urges CMS to reassess its approach to enforcement of issuing non-compliance letters on measures and also requests that CMS provide further clarification on whether and when CMS plans to transition display measures to the Star Ratings system.	Proceed as planned.

Call Letter Section	Summary of Comments	CMS Final Course of Action
Potential changes to existing measures – 2017 and Beyond		
Medication Reconciliation Post Discharge	Plans and associations think reconciling drugs across multiple settings could be hard to measure, resource intensive, and not helpful; perhaps reconciliation from acute care to nursing homes would be sufficient. Some are concerned about unfair comparisons and suggested only including enrollees aged 65 and older or only enrollees with behavioral health and other chronic conditions.	Proceed as planned: provide comments to NCQA.
CAHPS 5.0 changes	A few organizations support CAHPS 5.0 testing and suggest CMS translate for any language representing 5% or more enrollees. One organization requests the opportunity to provide comment on potential updates, and one supports translation into additional languages. Most sponsors support CAHPS 5.0 testing, but a few request more information about CAHPS 5.0 before supporting any changes. Requests for translations include Hmong, Somali, Russian, and Vietnamese. One plan suggests CMS use 5% threshold for translation. A few plans express their dislike of CAHPS in general.	Proceed as planned.
MPF Price Accuracy	There is mixed feedback from commenters, and most sponsors continued to oppose the proposals. The major concerns are that market changes and frequency of real time price changes hinder accuracy of submitted MPF pricing and that the addition of measuring the accurate claims will further lower scores. Suggestions include using the Patient Residence code on the PDE to identify pharmacy type, moving this measure to Display, revisiting the rounding of pricing to determine if there is more impact on scoring, or creating larger thresholds of difference when comparing the pricing. Some request CMS leave the calculation in its current state.	Proceed as planned. Technical specifications will continue to be evaluated for 2017 R4C, for implementation for 2018.
Potential new measures and measurement concepts – 2017 and Beyond		
Care Coordination Measures	Commenters support moving beyond patient assessment (survey) measures and believe encounter data will help, but NOT eliminate challenges. Some aspects of care coordination will not be captured and this may particularly impact SNPs (their Model of Care does not fit measure). A number of commenters suggest CMS needs to clarify which facets of care coordination are of specific interest before moving forward.	Proceed as planned: provide comments to NCQA.

Call Letter Section	Summary of Comments	CMS Final Course of Action
Asthma Measure Suite	Comments caution that diagnosis of asthma is challenging in the elderly, especially those 80 and older or in nursing homes. Some suggest PDPs be excluded from measurement since they do not have a good source for determining an asthma diagnosis. Within the asthma measure suite, comments include concerns about measures not being aligned with NIH recommendations (Medication Management for People with Asthma) or with measures being retired by NCQA (Use of Appropriate Medications for People with Asthma).	Proceed as planned: provide comments to NCQA.
Depression	Commenters express concerns about the measures and suggested further stakeholder input about measures used. Some suggested PHQ-9 is not appropriate for screening or monitoring symptoms, but that PHQ-2 be used for screening. Some suggested that in a primary care setting the PHQ instruments would not be billed for, so medical record review would be needed to gather data, which could be burdensome. Others suggested simply measuring Depression screening rates with the instruments as a first step (before other Depression measures are implemented).	Proceed as planned: provide comments to NCQA.
Hospitalizations for Potentially Preventable Complications	Commenters suggest this measure may need to be risk adjusted or that it be delayed so that 2016 HEDIS data will not be used for measurement (i.e., avoid using data for measure that were collected before measure adopted by CMS).	Proceed as planned: provide comments to NCQA.
Statin Therapy	All commenters, except one sponsor, support future implementation of the PQA Statin Use in Persons with Diabetes measure. The sponsor requests more time for uptake of new treatment guidelines as standard of care. Also, some commenters provide additional comments about measure specifications which will be shared with the developer (addition of new class, diagnosis codes, and supplemental data).	Proceed as planned.
High Risk Medication (HRM)	There is a split between Organizations, PBMs, and Sponsors, four commenters supported the proposal to revise the HRM measure after AGS and PQA modifications are endorsed. A couple organizations and one PBM express opposition to this proposal or in general, inclusion of this measure in the Star Ratings. Others commented that any changes will necessitate sufficient lead time ahead of formulary and bid submission deadlines.	Proceed as planned. Any changes will be announced with sufficient lead time. Other technical specification comments will be shared with the developer.

Call Letter Section	Summary of Comments	CMS Final Course of Action
Opioid Overutilization	There is support for adoption of these measures as a future display measure, and more support for using these measures in Overutilization Monitoring System (OMS). Commenters also express support of the PQA Triple Threat: Concomitant Use of Opioids, Benzodiazepines, and Muscle Relaxants measure concept currently under development.	Proceed as planned. Any changes will be announced with sufficient lead time.
Measurement Concepts	There is support to expand the measurement period for the Complaints about the Health Plan/Drug Plan measures and the Appeals Upheld (Part D) measure to 12 months to increase the number of enrollees included in these measures. The feedback from associations includes one commenter that supports reporting at the PBP level and another encouraging alignment of quality measures across programs. Comments on areas for additional measures included care transition, medication possession ratio, heart failure at hospital admission and mortality rates, access, directory and network accuracy, access to specialists and subspecialists, and development of measures for all Advisory Committee for Immunization Practice (ACIP) recommended immunizations. The feedback from sponsors includes support for: contract-level reporting, the change in the reporting period for complaints and appeals, and retaining separate thresholds for MA-PD and PDP measures. Other measure-related comments include concern due to the number of measures in the Star Ratings Program, support for inclusion of the HEDIS advance directive measure, and support for an increased focus on outcome measures.	CMS will take this feedback into consideration as we make future changes to the Star Ratings system.
Duals/LIS in Puerto Rico (PR)	Due to the lack of LIS in PR, we received many comments recommending that CMS make an additional adjustment for Star Ratings to reflect the lack of Part D LIS funding. Additionally, for the 2016 payment year, commenters want CMS to apply an interim upward star adjustment for plans with higher than average concentrations of low income beneficiaries.	We appreciate the comments received and will consider them as we continue to look at measurement concepts.