April 3, 2017

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

SUBJECT:

Announcement of Calendar Year (CY) 2018 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter and Request for Information

CMS received many submissions in response to our request for comments on the Advance Notice/Draft Call Letter, published on February 1, 2017. Comments were received from professional organizations, Medicare Advantage (MA) and Part D sponsors, advocacy groups, the pharmaceutical industry, pharmacy benefit managers, pharmacies, and concerned citizens. In response to the comments, we made a number of changes in the Rate Announcement and Call Letter that reflect CMS' continued commitment to providing Medicare Advantage Organizations and Part D Plan Sponsors with the flexibility to develop and implement innovative approaches for providing Medicare benefits to enrollees and empowering enrollees. CMS expects the additional flexibility will result in additional and more affordable plan choices for Medicare beneficiaries. CMS is committed to exploring other avenues for simplifying and transforming the MA and Part D programs in order to encourage innovation and expand beneficiary choice, and is looking forward to working with stakeholders to achieve those shared goals. To facilitate this new approach, CMS is requesting that stakeholders and the public share their ideas for changes to the program's regulations, sub-regulatory guidance, and practices and procedures. Additional information regarding the timeline and process for sharing these ideas with CMS is in Attachment I.

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 2018 and the risk and other factors to be used in adjusting such rates. The capitation rate tables for 2018 and supporting data 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, qualifying counties, and each county's applicable percentage are also posted at this website.

Attachment II shows the final estimates of the National Per Capita MA Growth Percentage for 2018 and the National Medicare Fee-for-Service (FFS) Growth Percentage for 2018. These growth rates will be used to calculate the 2018 capitation rates. As discussed in Attachment II, the final estimate of the National Per Capita MA Growth Percentage for combined aged and disabled beneficiaries is 2.53 percent, and the final estimate of the FFS Growth Percentage is

2.73 percent. Attachment III 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 2015 are being posted on the above website.

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

Attachment IV presents responses to Part C payment related comments on the Advance Notice of Methodological Changes for CY 2018 MA Capitation Rates and Part C and Part D Payment Policies (Advance Notice).

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

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

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

Attachment VIII presents the final Call Letter.

Key Changes from the Advance Notice:

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

MA Benchmark, Quality Bonus Payments and Rebate: Regarding the qualifying county determination for Puerto Rico, we have reevaluated our interpretation of Section 1853(o)(3)(B) and §1853(c)(1)(B) of the Act as a result of the reasoning provided by commenters. This reinterpretation of the law will, for PY2018, identify those counties in Puerto Rico that would have had an urban floor county rate, but for the cap established under §1853(c)(1)(B)(iii)(II), to meet the criteria of having an MA capitation rate that, in 2004, was based on the amount specified in subsection (c)(1)(B) for a Metropolitan Statistical Area with a population of more than 250,000.

Calculation of FFS Cost: We will not apply the VA and DoD adjustments concurrently, given that we were unable to obtain the necessary data in sufficient time to develop the adjustment factors. The VA and DoD adjustment factors will remain the same as those used in the 2017 ratebook development. The Secretary has directed the Office of the Actuary to adjust the fee-for-service experience for beneficiaries enrolled in Puerto Rico to reflect the 2018 GPCIs included in the 2017 Medicare Physician Fee Schedule Final Rule. The Secretary has directed the Office of the Actuary to adjust the fee-for-service experience for beneficiaries enrolled in Puerto Rico to reflect the propensity of zero dollar beneficiaries nationwide.

MA Employer Group Waiver Plans: For 2018, CMS will use the methodology and ratios, described in the 2018 Advance Notice to calculate the EGWP county payment rates that were applied in calculating the 2017 MA EGWP payment rates. That is, the ratio used to set MA EGWP payment rates will continue to reflect a blend of individual market plan bids from 2016 and EGWP bids from 2016, with individual market plan bids weighted by 50 percent and EGWP bids weighted by 50 percent.

Normalization Factor for the CMS-HCC ESRD Dialysis Model: The normalization factor for the ESRD dialysis model is being updated to 1.015.

Encounter Data as a Diagnosis Source for 2018 (non-PACE): CMS will calculate 2018 risk scores by adding 15% of the risk score calculated using encounter data and FFS diagnoses with 85% of the risk score calculated using RAPS and FFS diagnoses without an adjuster.

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 and prior Rate Announcements.

IME Phase Out: For 2018, CMS will continue phasing out indirect medical education amounts from the MA capitation rates.

ESRD State Rates: We will continue to determine the 2018 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 Determination (NCD) for Routine Costs in Clinical Trials (Medicare NCD Manual, Pub. 100-3, Part 4, Section 310.1), as described in the Advance Notice.

Location of Network Areas for PFFS Plans in Plan Year 2019: The list of network areas for plan year 2019 is available on the CMS website at https://www.cms.gov/PrivateFeeforServicePlans/, under PFFS Plan Network Requirements.

Adjustment for MA Coding Pattern Differences: We will implement an MA coding pattern difference adjustment of 5.91 percent for payment year 2018.

Final 2018 Normalization Factors (other than the CMS-HCC ESRD dialysis model):

CMS-HCC model used for MA plans is 1.017.
CMS-HCC model used for PACE organizations is 1.082.
Functioning Graft Segment of the ESRD dialysis model is 1.082.
RxHCC model is 1.005.

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

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

Encounter Data as a Diagnosis Source for 2018 (PACE): As proposed, we will continue to calculate risk scores for PACE organizations by pooling risk adjustment-eligible diagnoses from encounter data, RAPS and FFS claims (with no weighting) to calculate a single risk score.

Part D Risk Sharing: The 2018 threshold risk percentages and payment adjustments for Part D risk sharing will be finalized as stated in the Advance Notice.

Part D Benefit Parameters: Attachment VI provides the 2018 Part D benefit parameters for the defined standard benefit, low-income subsidy, and retiree drug subsidy.

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

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Attachments

2018 ANNOUNCEMENT
TABLE OF CONTENTS

Attachment I. Request for Information

CMS is committed to maintaining benefit flexibility and efficiency throughout the MA and Part D programs. The MA and Part D programs have been successful in allowing for innovative approaches for providing Medicare and Part D benefits to millions of Americans. We wish to continue this trend by using transparency, flexibility, program simplification and innovation to transform the MA and Part D programs for Medicare enrollees to have options that fit their individual health needs.

We would like to take this opportunity to invite you to submit your ideas for regulatory, sub-regulatory, policy, practice and procedural changes to better accomplish these goals. Ideas could include recommendations regarding benefit design, operational or network composition flexibility, supporting the doctor-patient relationship in care delivery, and facilitating individual preferences. They could also include recommendations regarding changes to the way plans are paid and monitored and measured. For example, ideas regarding Stars and their alignment to quality of care in terms of measure inclusion and exclusion or timing of changes and the method of assessment are welcome. They could also include recommendations regarding when and how CMS issues regulations and policies and how CMS can simplify rules and policies for beneficiaries, providers and plans.

Please provide CMS with clear and concise proposals that include data and specific examples that could be implemented within the law to increase benefit flexibility, innovation and more affordable plan choices for beneficiaries. If the proposals involve novel legal questions, analysis regarding CMS' authority is welcome for CMS' consideration. Language illustrating the suggested approach is also welcome so that CMS may understand more precisely the parameters of the suggestion.

Please note that this is a request for information (RFI) only. As previously stated, respondents are encouraged to provide complete but concise responses. This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does not commit the Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. Not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. Please note that CMS will not respond to questions about the policy issues raised in this RFI. CMS may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to this notice are not offers and cannot be accepted by the Government to form a

binding contract or issue a grant. Information obtained as a result of this RFI may be used by the Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become Government property and will not be returned. CMS may publically post the comments received, or a summary thereof.

We are accepting feedback through April 24, 2017 at PartCDcomments@cms.hhs.gov. Please include "2017 Transformation Ideas" in the subject line.

Attachment II. Final Estimates of the National Per Capita Growth Percentage and the National Medicare Fee-for-Service Growth Percentage for Calendar Year 2018

The Table II-1 below shows the National Per Capita MA Growth Percentage (NPCMAGP) for 2018. An adjustment of −0.226 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 II-1. Increase in the National Per Capita MA Growth Percentages for 2018

	Prior increases	Current increases			NPCMAGP for 2018 with §1853(c)(6)(C) adjustment[1]
	2003 to 2017	2003 to 2017	2017 to 2018	2003 to 2018	
Aged + Disabled	54.84%	54.49%	2.76%	58.76%	2.53%

[1]Current increases for 2003-2018 divided by the prior increases for 2003-2017

The Affordable Care Act of 2010 requires the Medicare Advantage benchmark amounts be tied to a percentage of the county FFS amounts. Table II-2 below provides the change in the FFS USPCC which was used in the development of the county benchmark. The percentage change in the FFS USPCC is shown as the current projected FFS USPCC for 2018 divided by projected FFS USPCC for 2017 as estimated in the 2017 Rate Announcement released on April 4, 2016.

Table II-2 – FFS USPCC Growth Percentage for CY 2018

	Aged + Disabled	Dialysis–only ESRD
Current projected 2018 FFS USPCC	$847.73	$7,133.42
Prior projected 2017 FFS USPCC	825.20	7,023.24
Percent change	2.73%	1.57%

Table II-3 below shows the monthly actuarial value of the Medicare deductible and coinsurance for 2017 and 2018. In addition, for 2018, the actuarial value of deductibles and coinsurance is being shown for non-ESRD only, since the plan bids will not include ESRD benefits in 2018. These data were furnished by the Office of the Actuary.

Table II-3 - Monthly Actuarial Value of Medicare Deductible and Coinsurance for 2017 and 2018

	2017	2018	Change	2018 non-ESRD
Part A Benefits	$39.43	$37.16	−5.8%	$35.33
Part B Benefits[1]	125.73	126.88	0.9	117.43
Total Medicare	165.16	164.04	−0.7	152.76

[1]Includes the amounts for outpatient psychiatric charges.

Medical Savings Account (MSA) Plans. The maximum deductible for current law MSA plans for 2018 is $11,950.

Attachment III. 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 2019. In addition, this table shows the current projections of the USPCCs through 2020. 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 2020.

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

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

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

	Part A		Part B		Part A & Part B		
Calendar year	Current estimate	Last year's estimate	Current estimate	Last year's estimate	Current estimate	Last year's estimate	Ratio
2003	$296.18	$296.18	$247.66	$247.66	$543.84	$543.84	1.000
2004	314.08	314.08	271.06	271.06	585.14	585.14	1.000
2005	334.83	334.83	292.86	292.86	627.69	627.69	1.000
2006	345.30	345.30	313.70	313.70	659.00	659.00	1.000
2007	355.44	355.44	330.68	330.68	686.12	686.12	1.000
2008	371.90	371.90	351.04	351.04	722.94	722.94	1.000
2009	383.91	383.93	367.93	367.93	751.84	751.86	1.000
2010	383.94	382.99	376.82	376.82	760.76	759.81	1.001
2011	386.94	389.78	386.24	386.31	773.18	776.09	0.996
2012	378.95	379.28	392.77	392.90	771.72	772.18	0.999
2013	381.19	381.32	399.56	399.73	780.75	781.05	1.000
2014	371.71	371.80	418.73	418.58	790.44	790.38	1.000
2015	374.40	372.10	436.25	432.53	810.65	804.63	1.007
2016	374.68	375.95	447.60	441.72	822.28	817.67	1.006
2017	378.11	386.02	462.05	456.04	840.16	842.06	0.998
2018	382.86	397.89	480.53	473.50	863.39	871.39	0.991
2019	396.50	410.97	511.10	503.55	907.60	914.52	0.992
2020	412.63		538.17		950.80		

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	$371.17	$369.90	$374.91	$374.91	$746.08	$744.81	1.002
2011	370.01	373.81	384.39	384.47	754.40	758.28	0.995
2012	359.17	359.57	391.94	392.07	751.11	751.64	0.999
2013	365.50	365.58	395.85	395.99	761.35	761.57	1.000
2014	365.80	365.88	409.16	408.86	774.96	774.74	1.000
2015	370.14	368.23	430.15	426.30	800.29	794.53	1.007
2016	367.52	370.33	439.16	431.08	806.68	801.41	1.007
2017	369.28	378.95	455.72	446.25	825.00	825.20	1.000
2018	377.28	390.23	470.45	462.98	847.73	853.21	0.994
2019	390.42	402.64	498.55	491.86	888.97	894.50	0.994
2020	405.85		524.10		929.95		

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	6,882.85	6,779.61	1.015
2014	6,900.22	6,762.22	1.020
2015	6,836.71	6,815.23	1.003
2016	6,796.37	6,862.30	0.990
2017	6,933.11	7,023.24	0.987
2018	7,133.42	7,213.94	0.989
2019	7,434.24	7,455.35	0.997
2020	7,745.31		

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
2016	0.9979	0.9962	0.9941
2017	1.0216	0.9926	1.0141
2018	1.0549	0.9891	1.0434
2019	1.1034	0.9855	1.0874
2020	1.1536	0.9821	1.1329

Summary of Key Projections

Part A[1]

Year	Calendar year CPI percent change	Fiscal year PPS update factor	FY Part A total reimbursement (incurred)
2003	2.2%	3.0%	3.5%
2004	2.6	3.4	8.4
2005	3.5	3.3	8.8
2006	3.2	3.7	5.9
2007	2.9	3.4	5.7
2008	4.1	2.7	7.6
2009	−0.7	2.7	6.7
2010	2.1	1.9	3.0
2011	3.6	−0.6	4.6
2012	2.1	−0.1	0.8
2013	1.4	2.8	4.6
2014	1.5	0.9	0.6
2015	−0.4	1.4	3.0
2016	1.0	0.9	2.7
2017	2.2	0.15	3.7
2018	3.0	2.91	4.3
2019	2.6	2.75	6.2
2020	2.6	3.5	7.3

Part B[2]

Calendar year	Physician fee schedule		Outpatient hospital	Total
	Fees[3]	Residual[4]		
2003	1.4%	4.5%	4.4%	6.8%
2004	3.8	5.9	11.1	9.8
2005	2.1	3.2	10.8	7.0
2006	0.2	4.6	5.1	6.1
2007	−1.4	3.5	8.3	4.3
2008	−0.3	4.0	6.3	4.8
2009	1.4	1.6	5.7	4.0
2010	2.3	1.6	6.6	2.4
2011	0.8	2.3	7.1	2.3
2012	−1.2	1.0	7.2	1.7
2013	−0.1	0.2	7.3	0.8
2014	0.5	0.6	12.5	3.4
2015	−0.5	0.7	7.4	2.8
2016	−0.4	−0.2	5.0	2.1
2017	0.1	1.5	6.9	2.8
2018	−0.5	2.0	8.3	3.3
2019	0.9	4.0	8.2	6.1
2020	0.3	3.1	8.7	5.2

[1] Percent change over prior year

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

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

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

Medicare Enrollment Projections (In millions)

Non-ESRD Total

	Part A		Part B	
Calendar year	Aged	Disabled	Aged	Disabled
2003	34.437	5.961	33.038	5.215
2004	34.849	6.283	33.294	5.486
2005	35.257	6.610	33.621	5.776
2006	35.795	6.889	33.975	6.017
2007	36.447	7.167	34.465	6.245
2008	37.378	7.362	35.140	6.438
2009	38.257	7.574	35.832	6.664
2010	39.091	7.832	36.516	6.938
2011	39.930	8.162	37.228	7.247
2012	41.665	8.402	38.525	7.495
2013	43.065	8.619	39.758	7.725
2014	44.512	8.767	41.043	7.887
2015	45.892	8.806	42.288	7.964
2016	47.249	8.699	43.660	7.929
2017	49.114	8.649	45.154	7.862
2018	50.759	8.705	46.610	7.908
2019	52.461	8.830	48.106	8.010
2020	54.233	8.927	49.684	8.096

Non-ESRD Fee-for-Service

	Part A		Part B	
Calendar year	Aged	Disabled	Aged	Disabled
2003	29.593	5.628	28.097	4.875
2004	29.946	5.931	28.300	5.128
2005	30.014	6.178	28.287	5.339
2006	29.365	6.146	27.462	5.267
2007	28.838	6.226	26.782	5.297
2008	28.613	6.241	26.301	5.311
2009	28.563	6.288	26.071	5.374
2010	28.903	6.455	26.261	5.556
2011	29.190	6.650	26.421	5.729
2012	29.939	6.684	26.723	5.772
2013	30.308	6.682	26.927	5.783
2014	30.582	6.610	27.040	5.726
2015	30.929	6.443	27.252	5.597
2016	31.508	6.219	27.850	5.445
2017	32.162	6.016	28.121	5.223
2018	32.932	5.955	28.697	5.153
2019	33.837	5.971	29.391	5.146
2020	34.940	6.044	30.297	5.209

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	0.442	0.428	0.388	0.373
2011	0.457	0.442	0.399	0.384
2012	0.472	0.457	0.410	0.394
2013	0.485	0.470	0.416	0.400
2014	0.498	0.482	0.420	0.404
2015	0.507	0.492	0.418	0.402
2016	0.515	0.500	0.419	0.403
2017	0.524	0.509	0.418	0.402
2018	0.536	0.520	0.424	0.409
2019	0.548	0.533	0.432	0.416
2020	0.561	0.545	0.444	0.428

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

Calendar year	Inpatient hospital	SNF	Home health agency	Managed care	Hospice: Total reimbursement (in millions)
2003	$2,594.78	$370.63	$124.28	$457.87	$5,733
2004	2,714.57	413.44	133.89	500.73	6,832
2005	2,818.21	450.54	140.87	602.29	8,016
2006	2,764.82	475.07	141.30	757.20	9,368
2007	2,707.49	504.24	143.72	905.77	10,518
2008	2,695.88	536.68	151.00	1,075.01	11,404
2009	2,651.47	551.67	153.86	1,246.03	12,274
2010	2,626.79	571.72	155.17	1,250.01	13,126
2011	2,570.79	622.60	143.35	1,300.63	13,986
2012	2,501.26	543.27	136.04	1,360.33	15,026
2013	2,492.83	542.09	133.67	1,399.32	15,407
2014	2,431.03	535.10	128.88	1,359.28	15,515
2015	2,406.52	532.30	131.22	1,417.15	16,250
2016	2,368.70	514.83	129.65	1,479.12	17,282
2017	2,319.14	521.34	129.23	1,563.77	18,475
2018	2,340.61	531.30	131.65	1,586.83	19,679
2019	2,398.56	552.29	137.44	1,665.72	21,237
2020	2,483.56	580.68	144.21	1,738.85	22,956

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

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

Calendar year	Physician fee schedule	Outpatient hospital	Durable medical equipment
2003	$1,226.49	$364.77	$196.96
2004	1,343.99	418.85	195.61
2005	1,397.41	477.65	196.83
2006	1,396.39	497.47	197.78
2007	1,368.35	526.92	195.68
2008	1,367.83	555.09	200.92
2009	1,375.29	592.77	183.61
2010	1,413.77	628.54	183.76
2011	1,440.59	668.02	175.58
2012	1,396.66	703.06	173.43
2013	1,353.85	741.10	152.26
2014	1,334.72	821.77	128.39
2015	1,341.13	876.23	134.26
2016	1,323.88	912.50	124.63
2017	1,322.68	950.12	112.97
2018	1,346.07	1,014.46	116.75
2019	1,403.92	1,087.13	128.80
2020	1,446.28	1,175.37	135.19

Calendar year	Carrier lab	Other carrier	Intermediary lab
2003	$73.73	$329.81	$75.18
2004	78.48	354.00	80.47
2005	82.71	362.81	84.16
2006	85.59	361.08	84.51
2007	90.65	363.52	84.38
2008	94.50	366.62	85.78
2009	101.80	385.20	79.19
2010	101.08	393.78	80.23
2011	102.10	406.80	83.17
2012	109.63	409.80	84.51
2013	109.49	409.20	81.60
2014	115.00	410.93	55.31
2015	116.23	424.57	55.27
2016	108.78	452.75	56.27
2017	112.05	459.20	56.41
2018	109.58	466.82	53.78
2019	113.95	481.11	54.60
2020	119.35	500.98	55.94

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	Home health agency	Managed care
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	1,104.26
2009	187.44	282.09	1,203.81
2010	193.08	283.25	1,221.62
2011	198.30	262.37	1,277.63
2012	205.36	246.85	1,368.48
2013	195.03	241.37	1,497.22
2014	200.87	234.77	1,708.59
2015	211.58	232.61	1,828.86
2016	218.81	228.83	1,932.14
2017	225.22	228.97	2,064.04
2018	194.37	233.48	2,217.52
2019	201.54	243.93	2,403.89
2020	211.06	255.91	2,542.78

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

2018 Projections by Service Category for non-ESRD (Aged+Disabled)*

Service type	Current estimate	Last year's estimate	Ratio
Part A			
Inpatient hospital	$2,340.61	$2,416.83	0.968
SNF	531.30	594.39	0.894
Home health agency	131.65	128.29	1.026
Managed care	1,586.83	1,630.61	0.973
Part B			
Physician fee schedule	1,346.07	1,356.84	0.992
Outpatient hospital	1,014.46	982.07	1.033
Durable medical equipment	116.75	129.93	0.899
Carrier lab	109.58	121.55	0.902
Other carrier	466.82	437.75	1.066
Intermediary lab	53.78	56.36	0.954
Other intermediary	194.37	193.46	1.005
Home health agency	233.48	233.49	1.000
Managed care	2,217.52	2,155.04	1.029

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

Claims Processing Costs as a Fraction of Benefits

Calendar year	Part A	Part B
2003	0.001849	0.011194
2004	0.001676	0.010542
2005	0.001515	0.009540
2006	0.001245	0.007126
2007	0.000968	0.006067
2008	0.000944	0.006414
2009	0.000844	0.005455
2010	0.000773	0.005055
2011	0.000749	0.004396
2012	0.001008	0.003288
2013	0.000994	0.002846
2014	0.001003	0.002884
2015	0.000952	0.002730
2016	0.000852	0.002348
2017	0.000852	0.002348
2018	0.000852	0.002348
2019	0.000852	0.002348
2020	0.000852	0.002348

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 2018 (before adjustment for prior years' over/under estimates) is calculated by adding the USPCCs for Part A and Part B for 2018 and then dividing by the sum of the current estimates of the USPCCs for Part A and Part B for 2017.

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 IV. 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 2018

Comment: We received two comments thanking CMS for providing the early preview of growth rates. One commenter stated that this is helpful for bid planning purposes and encourages CMS to continue this process in future years. Another commenter encouraged CMS to continue providing more granular information regarding methodologies and analysis related to the development of the county benchmarks.

Response: We appreciate the support.

Comment: One commenter expressed concern about the inconsistency between the ESRD and non-ESRD growth rates. The commenter stated that over the years growth rates have continued to vary between ESRD and non-ESRD. In particular, the commenter stated that they did not understand how the ESRD growth rate presented in the 2017 Rate Announcement could show such a large adjustment and why this would be necessary. The commenter stated that it is not clear what this adjustment is measuring. In addition, the commenter also asked for clarification in regards to the negative differential between total ESRD and dialysis-only populations, stating that this seems incongruent with a growth rate that is based on dialysis spending and not on individuals who became eligible for Medicare due to ESRD but are not post-transplant.

Two commenters requested additional detail on how CMS calculates the ESRD growth rate, including data sources used, and encouraged CMS to publish the historical cost data, along with revisions.

Lastly, one commenter stated that they are concerned this negative growth rate, in combination with the higher normalization factor for the ESRD model, could have deleterious effects on beneficiaries enrolled in Medicare Advantage plans and the ability of these organizations to meet their complex needs.

Response: As stated in the 2017 Final Rate Announcement, the negative prior period adjustment for the 2017 ESRD growth rate was primarily due to lower experience for the dialysis population for calendar year 2014 combined with a negative differential in the growth rate in 2015 and 2016 between the total ESRD and dialysis-only populations. The prior period adjustment represented the effect of a restatement of prior estimates with more current experience. We have since learned that the 2013 and 2014 USPCC experience was not properly grossed up to eliminate the effects of sequestration. The current estimate for experience years 2013 – 2015 in the 2018 Rate Announcement does reflect the appropriate gross-up for sequestration.

Also, historical ESRD trends have been consistently lower for the dialysis-only ESRD population relative to the total ESRD population. Part of this differential is explained by higher

growth in the per-capita cost for kidney transplants, which are reflected in the total ESRD trend, but not the dialysis only trend.

Further, the Rate Announcement already includes historical per-capita ESRD cost data. Additionally, information on the methodology used to project Medicare fee-for-service enrollment and expenditures can be found in the Medicare Trustees' Report. Of particular interest are the Actuarial Methodology sections, which begins on page 115 of the 2016 report: https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/reportstrustfunds/downloads/tr2016.pdf.

Further, we agree that relatively low payment updates could have an adverse effect on MA enrollees through the imposition of higher plan premiums and/or lower supplemental benefits. We encourage plan sponsors to take into account beneficiary impacts in their design of 2018 MA and MA-PD plan benefits, consistent with CMS' policies.

Finally, please see the normalization section below for discussion of ESRD normalization factor.

Comment: One commenter stated that they believe the estimated national per capita MA growth percentage for CY 2018 is generally reasonable.

Response: We appreciate the support.

Comment: One commenter expressed concern that the current estimate of the 2018 FFS USPCC is lower than last year's estimate from the 2017 Rate Announcement released in April 2016. The commenter stated that, in comparison to last year's estimate, the current estimate reflects a drop in 2016 incurred Part A expenses, offset by an increase in 2016 Part B expenses. The commenter stated that these changes appear to be carried forward in the projection at different rates, with the result being a greater drop in the 2018 Part A USPCC than the corresponding increase in the 2018 Part B USPCC. The commenter requested that the Office of the Actuary provide additional detail on the drivers behind the changes in the 2016 USPCCs and the rationale for the difference in the projection slope between Part A and Part B. The commenter was also concerned about an observed larger than expected change in the current estimate of the 2011 FFS USPCC and requested an explanation of what factors are contributing to this change.

Response: The historical USPCCs for calendar years 2016 and earlier in the 2018 Rate Announcement reflect our latest tabulation of program experience. Further, the projection for 2017 and later years is based on this latest program experience and current projection factors, which have been revised relative to that reflected in the 2017 Rate Announcement. As can be expected, the projected USPCCs for the two Rate Announcements will differ due to factors such as historical trend, economic assumptions, regulations, and legislation. Generally, the update of these factors between two Rate Announcements will yield different impacts on Part A and Part B trends, as is the case this year.

Comment: One commenter asked for greater transparency in how CMS calculates the growth rate and the data used in these calculations.

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

Comment: One commenter urged CMS to exercise caution in making changes to the growth percentage, as plans will not have an opportunity to review any changes and provide comment. In addition, the commenter asked that CMS review all of its assumptions, including any changes in assumptions from prior years, to avoid unnecessary disruption to the program when setting the proposed growth rate and final growth rate.

Response: The growth percentages and total USPCC and FFS USPCCs reflected in Attachment III of this Rate Announcement are based on the Office of the Actuary's best estimate of historical program experience and projected trend. We continue to believe that the best practice is to base the growth rates on the most recent data and assumptions.

Comment: A few commenters expressed concern in regards to including beneficiaries enrolled in Part A only in the calculation of the USPCCs that determine the MA growth percentage and the FFS rates. Commenters recommended that CMS calculate FFS spending based on the combined Part A/B.

Response: We appreciate the feedback submitted by commenters regarding this issue. We will continue to review MedPAC's analysis and to conduct our own analysis and consider whether any adjustments to the methodology on this point may be warranted in future years.

Comment: One commenter encouraged CMS to note in the Advance Notice that the MA growth percentage is now used solely for the purposes of developing the benchmark cap. The commenter also stated that it would be helpful to indicate that MA and FFS growth rates should be very close to each other now that the county benchmarks are based solely on FFS costs.

Response: We agree that, on a current baseline, the expectation is for consistency in the Total USPCC and FFS USPCC growth rates. Differences may arise due to differences in demographic / risk profile and geographical mix between MA and FFS. In addition, there could be various payment issues that affect MA, but not FFS. Examples of MA-specific issues are those pertaining to bids, quality ratings, and risk scores.

Section B. MA Benchmark, Quality Bonus Payments and Rebate

Comment: A large number of commenters expressed concern that the pre-ACA rate cap diminishes incentives for high quality plans and plans that offer services in higher-cost areas. Commenters believe that the inclusion of the quality bonus in the benchmark cap calculation undermines the quality bonus program and unfairly penalizes plans that have invested in achieving higher star ratings for their beneficiaries. Commenters also believe that the cap methodology could reduce benefits to beneficiaries in high quality plans and could reduce plans' payments to physicians. Commenters expressed concern that the cap is inconsistent with the agency's longstanding goals of encouraging plans to continuously improve the quality of care provided to enrollees, and rewarding the delivery of high quality care. A few commenters believe that including the bonus in the cap calculation contradicts the intent of Congress to provide quality bonuses to high performing plans.

Commenters suggested that CMS review its options for exercising discretionary authority to eliminate the benchmark cap or to remove quality bonuses from the benchmark cap calculation. Commenters believe that the statute can be interpreted to allow the Secretary the discretion to exclude quality bonuses from the benchmark cap calculation. Commenters indicated that the language used in section 1853(n)(4) of the Act refers to "taking into account" the quality bonuses, suggesting that the Secretary could consider the quality bonus payments but then exercise discretion to omit them from the cap calculation. One commenter believes that a recent presidential executive order strengthens the discretionary authority to waive, or grant exemption from, the benchmark cap provision. Commenters encouraged CMS to work with Congress to explore options to address this issue. Two commenters recommended that CMS should exercise payment demonstration authority to eliminate the benchmark cap. One commenter suggested that the Applicable Amount was a cap on the blended benchmarks only during the Applicable Amount's phase-out period, and since the Applicable Amount is no longer included in the benchmark calculation, the statute does not require the cap to remain in place for 2017 and later years.

Response: As discussed in past Rate Announcements, 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 have not identified discretion under section 1853(n)(4) of the Act to eliminate application of the pre-ACA rate cap or exclude the bonus payment from the cap calculation.

Comment: Several commenters expressed concern regarding the change in the determination of qualifying counties, as it will result in fewer qualifying counties and could impact the benefits for the enrollees in affected counties.

While one commenter agreed with CMS' proposed approach to include GME costs in both the county and national costs, another commenter suggested that CMS should exclude (instead of

include) GME costs in both the county and national cost calculations. One commenter suggested that the national FFS cost should be the summation of county FFS costs, to ensure that the two are prepared on a consistent basis. Several commenters suggested that the change to the qualifying county methodology be phased in with a multi-year transition period to reduce payment volatility (such as, for an affected qualifying county, apply a 1.5x QBP percentage instead of a 2x QBP percentage, or apply a "hold harmless" provision for two years). One commenter requested the list of affected counties be published as soon as possible.

Response: We appreciate the concerns raised by the commenters. However, we believe the approach outlined in the Advance Notice will result in a consistent treatment of GME costs in both the county and national per capita cost calculations, and result in a more complete comparison of per capita spending between the county and national level. We do not believe that a phased-in approach suggested by these comments would be permissible under statute. In the 2018 county rate file, there are seven fewer qualifying counties resulting from this change in the determination of qualifying counties. The affected counties are: Wyandotte KS (17986), Campbell KY (18180), Lucas OH (36490), Montgomery OH (36580), Armstrong PA (39070), York PA (39800), and Kent RI (41010).

Comment: One commenter believes that revising the quality bonus rate structure would reduce payment volatility for plans and increase stability in benefit offerings. The commenter suggested that CMS should work with Congress to change the structure of the quality bonus percentages and the rebate percentages, to mitigate rate differences between 3.5 and 4.0 star plans, and rebate differences between 3.0 and 3.5 star plans. The commenter also suggested that CMS should exercise its payment demonstration authority to smooth out the bonus payment structure to recognize plan quality at additional levels. In addition, the commenter suggested that CMS should exercise its payment demonstration authority to increase the rebate percentage to 75% for all plans.

Response: We appreciate the feedback submitted by the commenter and will take these comments under advisement.

Comment: One commenter requested that, when an organization that has had a contract with CMS in the preceding three-year-period establishes a new contract, CMS should assign to the new contract a Star Rating that is based on the enrollment weighted average Star Rating of the parent organization's existing MA contracts and section 1876 Cost contracts.

Response: Star Ratings for plans that were converted from a Cost contract are based on section 1853(o)(4)(C) of the Act, which provides, in narrow circumstances, for using Star Rating data from cost plans for purposes of calculating the Star Rating of a converted MA plan. For other MA plans, section 1853(o)(4)(C) does not apply. As stated in the Advance Notice, for a parent organization that has had a contract with CMS in the preceding three-year-period, any new MA

contract under that parent organization will receive an enrollment-weighted average of the Star Ratings earned by the parent organization's existing MA contracts.

Comment: Two commenters provided detailed analysis and recommended that CMS reevaluate Puerto Rico's eligibility for the Qualifying County Bonus Payment. The commenters noted that all counties in Puerto Rico achieved two of the three conditions required to be considered a qualifying county. The one criterion that counties in Puerto Rico did not meet was that each county's 2004 MA capitation rate must have been based on the amount specified in section 1853(c)(1)(B) for a Metropolitan Statistical Area with a population of more than 250,000. Commenters pointed out that some counties in Puerto Rico were in Metropolitan Statistical Areas (MSAs) with populations of more than 250,000. Commenters also noted that, while counties in Puerto Rico were subject to a cap under § 1853(c)(1)(B)(iii)(II), the qualifying county bonus provision did not explicitly exclude counties with rates established under § 1853(c)(1)(B)(iii)(II).

Response: We appreciate these comments, and have reevaluated our interpretation of Section 1853(o)(3)(B) and §1853(c)(1)(B) of the Act as a result of the reasoning provided by commenters. This reinterpretation of the law will, for PY2018, identify those counties in Puerto Rico that would have had an urban floor county rate, but for the cap established under §1853(c)(1)(B)(iii)(II), to meet the criteria of having an MA capitation rate that, in 2004, was based on the amount specified in subsection (c)(1)(B) for a Metropolitan Statistical Area with a population of more than 250,000. In the ratebooks released concurrently herewith, CMS is publishing the list of qualifying counties that meet the three criteria required to be met to be a qualifying county: 2004 urban floors (Y/N) for each county, December 2009 Medicare Advantage penetration rate for each county, and average FFS county spending for 2018 that is less than the national average FFS spending for 2018.

Section C. Calculation of Fee for Service Cost

Comment: A large number of commenters requested that CMS calculate FFS spending based on beneficiaries enrolled in both Part A and Part B (rather than based on beneficiaries in either Part A or Part B). Commenters pointed out that in order to enroll in an MA plan, beneficiaries are required to be enrolled in both Part A and Part B. Commenters noted that beneficiaries enrolled in Part A-only had lower Part A spending than beneficiaries enrolled in both Part A and Part B. Commenters cited a recent MedPAC recommendation that benchmarks be calculated based on FFS data for beneficiaries with both Part A and Part B. Commenters requested that CMS apply a uniform approach in all counties to calculate benchmarks on beneficiaries with both Part A and Part B coverage, as is currently done in Puerto Rico. Commenters noted that other counties beyond Puerto Rico, such as in Hawaii, have high MA penetration rates and low FFS Part B enrollment. A few commenters also expressed support that the benchmarks in Puerto Rico be based on beneficiaries with both Part A and Part B coverage.

Response: We appreciate the feedback submitted by commenters regarding this issue. We will continue to analyze this issue and consider whether any adjustments to the methodology on this point may be warranted in future years. 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, we believe it is appropriate to adjust the FFS rate calculation in Puerto Rico used to determine MA rates so that it is based on beneficiaries who are enrolled in both Part A and Part B.

Comment: Several commenters expressed concern regarding rebasing and repricing adjustments resulting in rate unpredictability and fluctuation. One commenter requested that CMS provide more information about the decision to rebase and reprice the rates annually (including for 2018) and what the effects will be on the benchmarks overall, given that the agency is only required to rebase the rates once every three years. Another commenter proposed that CMS consider not updating the repricing adjustments every year. Two commenters suggested that CMS adopt a corridor to smooth the rebasing fluctuations whereby county benchmarks would be prevented from increasing or decreasing by more than a specified amount. One commenter proposed that CMS should not rebase every year, to promote stability of payments and benefits, and furthermore proposed that CMS then could use a 6-year rolling average (instead of 5-year) after the year in which CMS does not rebase. One commenter requested that any methodological changes to the AGA calculation should be scheduled on a regularly occurring basis (such as every three years), rather than annually.

Response: Given that MA county rates are based on FFS costs, we believe it is important to update the FFS rates using the most current FFS data available and apply repricing adjustments to reflect changes in FFS payment rules. We stated in previous Rate Announcements that we anticipate rebasing each year. We do not believe that "smoothing" the impacts of rebasing would be consistent with the statute's requirement of calculating the specified amount based on the estimated FFS rate for that county. We also note that our method for calculating the county level rates includes a five-year average that provides some measure of stability in the rates.

Comment: In the Advance Notice, CMS proposed to make adjustments to account for shared savings payments and losses under programs such as the Medicare Shared Savings Program (Shared Savings Program) and Pioneer Accountable Care Organizations (ACOs) Model. Two commenters noted that, as an increasing number of counties participate in such programs, these programs drive down the FFS cost in order to achieve savings, whereby the rates in those counties would decrease. One commenter requested that CMS account for all of the savings in the rates in order to truly reflect the cost of the FFS population. Another commenter expressed concern regarding being unable to assess the impact of such changes. One commenter expressed support for the inclusion of shared savings and losses incurred under the Shared Savings Program and Pioneer ACO Model and shared savings payments from the CPC Initiative.

Response: We believe that it is important to reflect in the historical FFS costs the shared savings payments and/or recoveries made associated with certain innovative payment models. We do not believe it is appropriate to adjust FFS experience beyond the shared savings or losses.

Comment: In the Advance Notice, CMS noted that historical FFS costs will not be adjusted to reflect Medicare spending on several innovation models funded under section 1115A of the Act, such as the Advance Payment ACO Model and the Federally Qualified Health Center Advanced Primary Care Practice Demonstration. One commenter expressed concern that not including payments made under these programs underestimates FFS spending. The commenter believes that these models are part of the FFS program and the funds appropriated under section 1115A were intended to be used in improving the FFS Medicare program. The commenter requested that CMS include funds appropriated under section 1115A in FFS spending totals when those funds are directed to services and benefits.

Response: As stated in the Advance Notice, funds appropriated and used under section 1115A are not from the Part A and Part B Trust Funds, from which Medicare claims are disbursed, so we do not consider those payments to be part of FFS costs. Accordingly, there will be not be any adjustment to historical FFS claims to account for payments made from the funds appropriated under section 1115A under the following innovation models during the 2011-2015 period: Advance Payment ACO Model, the Comprehensive Primary Care Initiative, and the Federally Qualified Health Center Advanced Primary Care Practice Demonstration.

Comment: One commenter requested that CMS continue to publish the Aged and Disabled FFS experience data separately, to maintain transparency of FFS expenditures.

Response: As discussed in the 2018 Advance Notice, separate aged and disabled fee-for-service (FFS) experience is not required to develop the Medicare Advantage ratebook. Therefore, publishing the aged and disabled experience provides no additional transparency into the ratemaking process. Therefore, we have proceeded with our proposal to combine the aged and disabled FFS historical experience.

Comment: Commenters requested more transparency on the calculation of the FFS rates, in order to provide comments on the proposed changes. Commenters requested that information related to rebasing be released with the Advance Notice. One commenter requested that CMS publish an initial estimate of the county rates, similar to the initial estimate of the growth percentages. Another commenter requested publication of estimated AGAs and other adjustment factors (such as GME, Veterans Affairs, etc.) with the Advance Notice. One commenter requested that CMS publish the forecasted impact of rebasing in the Advance Notice.

Response: We are publishing with the final Rate Announcement files that contain the wage indices in each claim year (i.e., 2011-2015), and the wage indices for 2017 by county. We annually publish, with the final Rate Announcement, files that contain the county-level adjustments that are applied to the FFS costs. We intend to publish the most recent year's FFS

cost data by county with the Advance Notice in future years to help stakeholders understand the potential impacts of proposed changes in the Advance Notice.

Comment: Two commenters support the approach that Medicare Advantage payment is based on FFS costs.

Response: We appreciate the support.

Comment: In the Advance Notice, CMS sought public comment on the possibility of adjusting FFS experience in Puerto Rico to reflect the propensity of zero dollar beneficiaries nationwide. Several commenters requested that CMS make an adjustment to the Puerto Rico MA rates to reflect the prevalence of zero dollar beneficiaries nationwide. Two commenters believe that PR beneficiaries in FFS are wealthier and healthier than MA enrollees, and therefore are more likely to report zero claims. Commenters expressed concern at the possibility that the adjustment would not be applied for 2018.

Response: The Secretary has directed the Office of the Actuary to adjust the fee-for-service experience for beneficiaries enrolled in Puerto Rico to reflect the propensity of zero dollar beneficiaries nationwide. For purposes of making this adjustment, consistent with the Secretary's instructions, the Office of the Actuary evaluated experience exclusively for beneficiaries that are enrolled in both Parts A and B and are not dually eligible for VA coverage.

The study analyzed experience for calendar years 2011 through 2015 and only considered FFS beneficiaries enrolled mid-year. On average, 14.4 percent of A&B Puerto Rico FFS beneficiaries were found to have no Medicare claim reimbursements per year. This compares to a nationwide, non-territory, proportion of 6.0 percent of FFS beneficiaries without Medicare spending. These results were applied to the Puerto Rico FFS experience by adjusting the weighting of the enrollment and risk scores for the zero-claim cohort to reflect the nationwide proportion of zero-claim beneficiaries. The resulting impact was an average increase in the standardized FFS costs in Puerto Rico of 4.4 percent for 2011 through 2015. Accordingly, a 4.4 percent adjustment was applied to the pre-standardized Puerto Rico FFS rates supporting the CY 2018 ratebook development.

Comment: A few commenters believe that FFS experience is not sufficient to establish accurate MA benchmarks in Puerto Rico, and expressed concern regarding payment disparity between Puerto Rico and the mainland. Commenters expressed concern that FFS data used by CMS to set the MA rates for Puerto Rico are not representative of the population to which rates are applied, citing the lower dual-eligible penetration in FFS than exists in MA. Commenters noted the low level of FFS enrollment in Puerto Rico, and noted that the FFS costs in Puerto Rico appear to have low levels of health care utilization. A few commenters suggested that CMS not permit reductions in rates in Puerto Rico that may result from rebasing. Two commenters requested that CMS use another jurisdiction as a proxy to set benchmarks in Puerto Rico.

Response: We appreciate the concerns commenters have raised regarding Puerto Rico. We believe that the FFS data in Puerto Rico is sufficient for establishing accurate MA benchmarks. We will continue to analyze these issues and consider whether any refinements to the methodology may be warranted in future years.

Comment: One commenter expressed support for repricing adjustments to FFS costs in the development of rates for Puerto Rico. Two commenters suggested that CMS include the changes in Part A Uncompensated Care. Several commenters suggested that the repricing include the full implementation of the new Part B Geographic Practice Cost Indices (GPCIs) applicable in 2018, as described in the 2017 Physician Fee Schedule Final Rule.

Response: Consistent with prior years, we have adjusted the historical ratebook FFS data to reflect payment parameters that are finalized at the time of the Rate Announcement. Accordingly, the CY 2018 ratebook repricing reflects the latest regulations for fiscal year 2017 (e.g., inpatient hospital, outpatient hospital, and skilled nursing facilities) and calendar year 2017 (e.g., geographic practice cost index and DMEPOS payment schedules). Further, the Secretary has directed the Office of the Actuary to adjust the fee-for-service experience for beneficiaries enrolled in Puerto Rico to reflect the 2018 GPCIs included in the 2017 Medicare Physician Fee Schedule Final Rule.

Section D. IME Phase Out

Comment: In the Advance Notice, CMS indicated that we will continue to phase out IME amounts from MA capitation rates. CMS will first calculate the 2018 FFS rates including the IME amount. This initial amount will serve as the basis for calculating the IME reduction that CMS will carve out of the 2018 rates. The maximum reduction for any specific county in 2018 is 5.4 percent of the FFS rate. One commenter requested that CMS release the data as soon as possible, and before the release of the final ratebook.

Response: As indicated in the Advance Notice, we publish the amount of IME for each county in the 2018 ratebook, and also publish the rates with and without the IME reduction with the Rate Announcement.

Section E. ESRD Rates

Comment: Two commenters noted that recent legislation will allow beneficiaries who have ESRD at the time of application to enroll in MA beginning in 2021. Commenters requested that CMS re-evaluate whether current ESRD rates are sufficient to cover the costs of these patients. Commenters recommended that, instead of state-based rates, ESRD rates should be developed based on costs incurred, based on FFS and other data.

Response: We appreciate the concerns commenters have raised. We will continue to analyze these issues and consider whether any refinements to the methodology may be warranted in future years.

Comment: One commenter recommended that organ acquisition costs be carved-out from the ESRD rates, as they believe that these costs are currently underfunded by the rates. The commenter suggested organ acquisition costs should be reimbursed at 100 percent of the FFS amount.

Response: Section 17006(b) of the 21st Century Cures Act (Pub. L. 114-255) amends sections 1853(k)(1) and 1853(n)(2)(E) of the Social Security Act to exclude the costs for kidney acquisitions from MA capitation rates and benchmarks beginning with 2021. Section 17006(c) amends sections 1852(a)(2)(i) and 1851(i) of the Act to provide that, starting in 2021, payment for MA enrollees' kidney acquisition costs will be made under Medicare FFS. For 2018, CMS will continue to include kidney acquisition costs in MA capitation rates and benchmarks.

Comment: Several commenters cited recent decreases in the ESRD rates in Puerto Rico and believe there are funding inadequacies for ESRD beneficiaries in Puerto Rico. One commenter stated that ESRD beneficiaries in Puerto Rico have a more complicated clinical profile than ESRD beneficiaries on the mainland, based on additional comorbidities. One commenter cited the low number of dialysis providers in Puerto Rico, which creates access issues, and the high incidence of diabetes among the population of Puerto Rico. Two commenters believe that the information used in developing the ESRD benchmark in Puerto Rico is missing data due to a different Medicaid coordination period. A few commenters suggested that CMS implement an alternative ESRD rate for Puerto Rico, such as by using the US Virgin Islands rate as a proxy.

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

Comment: One commenter expressed concern that the ESRD rates do not reflect repricing adjustments similar to those applied to Aged+Disabled county rates.

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.

Section F. Location of Network Areas for PFFS Plans in the Plan Year 2019

Comment: One commenter encouraged CMS to post the list of network areas as soon as possible so that Private FFS plans can continue their CY 2018 planning process.
Response: We will post the list of network areas on our website as soon as our assessment is complete. The list will be on the PFFS Plan Network Requirements webpage at: https://www.cms.gov/Medicare/Health-Plans/PrivateFeeforServicePlans/NetworkRequirements.html.

Section G. MA Employer Group Waiver Plans

As mentioned above, CMS will use the methodology and ratios that were applied in calculating the 2017 MA EGWP payment rates, described in the 2018 Advance Notice, to calculate the 2018 EGWP county payment rates.

Therefore, the bid-to-benchmark ratios applied in calculating 2018 MA EGWP Payment Rates will be:

Applicable Percentage	Bid to Benchmark Ratio
0.95	88.7%
1	92.2%
1.075	93.3%
1.15	93.6%

Comment: A significant number of commenters expressed support for CMS continuing to waive Part C bidding requirements for all organizations that offer Employer/Union Group Waiver Plans (EGWPs). These commenters agree that waiving the requirement to submit Part C bid pricing information allows plans to focus on offering high quality coverage by reducing the administrative burden.

Response: We appreciate the support.

Comment: A number of commenters recommended that CMS maintain the bid-to-benchmark ratios used in payment year 2017 that are weighted 50% MA EGWP bids from 2016 and 50% Individual market bids from 2016, and were opposed to CMS using only individual market plan bids from 2017 to calculate the bid-to-benchmark ratios in calculating the 2018 MA EGWP payment rates. Several commenters cited that maintaining the ratios used in payment year 2017 as calculated would create a greater level of stability and certainty for these plans, and reflects a more accurate relationship between the underlying costs of the two different markets, including a reflection of the differential in plan types that exists in the differing markets. Several commenters asserted that the 50/50 blend approach more accurately reflects the CMS share of costs to provide these benefits to eligible beneficiaries and does not pass these costs to the employer groups by means of higher premium or lesser benefits to the retirees. Many commenters asserted that using 100 percent of the individual bids in payment year 2018 represents an abrupt payment change for MA plans with large EGWP enrollment.

Response: We appreciate the support.

Comment: A significant number of commenters noted that EGWPs are predominately Preferred Provider Organization (PPOs), rather than Health Maintenance Organizations (HMOs), and argued that when comparing EGWPs and non-EGWPs by plan type, the disparity in the bid-to-

benchmark ratio shrinks significantly. Some of these commenters recommended that CMS maintain the bid-to-benchmark ratios used for payment year 2017, which are weighted 50% EGWP bids from 2016 and 50% individual market bids from 2016, but further recommended that the bid to benchmark calculations be modified to account for the different prevalence of plan type between the markets. Some commenters expressed understanding that EGWP bid data was not submitted for Plan Year 2017, to be used in developing the ratios for payment year 2018 and recommends that CMS utilize the latest EGWP bid data available by continuing to use 2016 bids in these calculations.

Some recommended that the ratio of HMO to PPO plans in EGWPs vs Non-EGWPs be taken into account, others recommended weighting the ratios by a blend of the HMO to PPO bids based on the proportion of those plan types in the EGWP market and those in the individual market, or to use exclusively PPO bids from individual plans in calculating the ratios, while some others recommended that the variation in plan type between the markets needs to be accounted for in the methodology. Some commenters also indicated that using a 50/50 blend based on product-specific bids will result in greater stability in funding and a more accurate reflection of the costs of the EGWP products as compared to the Individual market products, as the underlying cost structure are inherently different, and employers have specific reasons for preferring one product over another. Commenters suggested that incorporating these refinements to the payment methodology will prevent employers and unions from cutting benefits, terminating EGWPs and may even facilitate additional employers and unions to convert their existing coverage into an EGWP. A couple of commenters also cited MedPAC's statement from a December 13, 2013, public meeting in which they assert that MedPAC set forth "it would not be unreasonable" to account for the fact that EGWPs rely more heavily on PPOs than HMOs in calculating appropriate EGWP payments. A few additional commenters noted that their review of public data files suggests that the concerns CMS articulated regarding year-over-year instability in MA EGWP payment rates based on plan type weighting would appear to be unwarranted.

Response: CMS acknowledges that PPOs are more prevalent in the EGWP market than in the broader individual market, and CMS appreciates the detailed nature of the comments received on these issues. As noted above, for 2018, CMS is maintaining the methodology used to calculate the bid-to-benchmark ratios used in 2017 in response to the myriad of concerns raised by commenters about moving forward with full implementation of the policy to use only individual market plan bids from 2017 to calculate the bid-to-benchmark ratios for the 2018 MA EGWP payment rates. Prior to making a decision about an approach to either fully implement payments based on individual market plan bids, or whether and how a plan type adjustment should be incorporated into the payment methodology, CMS would like to develop a better understanding of the impact the new payment methodology is having on beneficiaries. This pause in transition will allow CMS to seek input and data from EGWP sponsors and other stakeholders on changes

in plan offerings in 2017 and 2018 and associated beneficiary impacts. We encourage stakeholders interested in this policy to respond to the RFI in Attachment I with their ideas.

Comment: A few commenters expressed support of the proposal to update the methodology to calculate the bid-to-benchmark ratios using only individual market plan bids from 2017 due to the government savings and greater payment equity between MA EGWP and MA non-EGWP plans and reiterated concerns about MedPAC's finding that MA payments to EGWPs were previously substantially higher than fee-for-service costs for comparable beneficiaries, despite the provisions that have better aligned overall Medicare Advantage payments with fee-for-service costs. A few also expressed concerns about CMS' bid analysis from recent years, where it was determined that the projected average risk scores for employer group members were lower than for individual market plan MA enrollees, while the average employer group bids were higher than those for individual market MA plans. One commenter indicated that enrollment figures suggest that MA EGWPs are still thriving under the new payment formula as enrollment in February 2017 (under the new payment methodology) grew 14 percent from December 2016 (under the prior payment methodology).

Response: We appreciate the support, but believe that it is appropriate to finalize the methodology for 2018 as described herein to increase stability in the payment rates for 2018, by continuing to waive or modify requirements that hinder the design of, the offering of, or the enrollment in employment-based Medicare plans offered by employers and unions to their members. CMS appreciates these comments and will continue to analyze data to refine the payment methodology for future years.

Comment: A few commenters asserted that the methodology used in payment year 2017 was complicated and requires further study before any changes are implemented in payment year 2018. Other commenters recommended that CMS analyze and study refinements to the methodology such as, reviewing the individual market bid-to-benchmark ratios by geographic area, e.g., Metropolitan Statistical Area, MA Region, county, using a different classification of counties, such as cohorts based on actual prior year (or prior years') enrollment for future implementation, suggesting there may be different market forces by geography that affect plans' bid-to-benchmark ratios that are not reflected by national averages contributing to the differences in cost. Several commenters also encouraged CMS to continue to investigate the underlying causes for the differences in payment rates between individual market and EGWP coverage. Another commenter also recommended further analysis by CMS of the actual cost and risk score differences between EGWP and Individual MA populations, using Worksheet 1 of historical plan bids to derive bid-to-benchmark ratios that would better align with EGWP costs. A few commenters also recommended that D-SNPs be excluded from the calculation of the bid-to-benchmark calculations, while another suggested that retrospective annual reporting by organizations of EGWP experience may be beneficial to future policy development.

Response: We appreciate these commenters' detailed suggestions. CMS is finalizing the methodology for 2018 as described herein to increase stability in the payment rates for EGWPs in 2018, but appreciates these comments and will continue to analyze data to refine the payment methodology for future years. As previously mentioned, we are interested in working with sponsors of EGWPs and other interested stakeholders to improve our understanding of the EGWP market and of the beneficiary impacts associated with payment changes for these plans. We encourage stakeholders interested in this policy to respond to the RFI in Attachment I with their ideas.

Comment: A few commenters expressed concern about the impact of the proposed payment changes on retiree benefits resulting from EGWPs no longer being able to pay the Part B premium on behalf of enrollees and urged the agency to explore options to allow EGWPs to provide this benefit, such as through a modification to the Plan Benefit Package submission or permitting employer plans to separately reimburse members for their Part B premiums.

Response: As stated last year, the Social Security Administration (SSA) must be able to accurately track beneficiary payments of the Part B premium. Under current payment rules, if an MAO chooses to buy down their beneficiaries' Part B premiums, a fixed, standard amount for each beneficiary in their plan is determined through the bid process. This standard amount is then deducted for each of their beneficiaries from the monthly plan payments made from CMS to the MAO, which is then transmitted from CMS to SSA on a beneficiary level. There is currently no mechanism to permit the administration or collection of information directly from MA EGWPs to SSA to capture a payment of the Part B premium for their beneficiaries. As a result, this is not currently a feasible solution. We continue to appreciate the concerns raised, and the creative solutions proposed, however, and will continue to explore these and other options for future implementation. It should be noted, however, that very few (approximately 2%) MA EGWPs used rebate dollars to buy down any portion of the Part B premium for their enrollees under the payment methodology in place prior to 2017, so this is still not expected to have a significant impact on beneficiaries enrolled in these plans. In addition, while an MAO may not buy down the Part B premium for MA EGWPs, MA EGWPs are not prohibited from offering other benefits or lower enrollee premiums in place of the Part B premium buy down, and CMS has waived the requirement for MA EGWPs to allocate rebate dollars to any specific purpose, which should provide increased flexibility in benefit offerings. The elimination of the option to buy down the Part B premium for MA EGWPs does not affect the MA payments made to the MAOs.

Comment: A few commenters expressed support for CMS' continuing to waive the requirement for EGWPs to allocate rebate dollars to any specific purpose for 2018.

Response: We appreciate the support.

Comment: A few commenters recommended that CMS publish the 100% individual market bid-to-benchmark ratios based on 2017 bids to increase transparency and to inform future opinions

on this issue for future years. Others asserted that it is difficult to fully assess how such a change may impact the rates and benefits to be offered in the employer group market without more data, and encouraged CMS to share more data with plans to allow the development of appropriate strategies that will minimize potential member disruption.

Response: CMS is committed to transparency. CMS does not require that sponsors of EGWPs provide information to CMS on how many employer group plans are offered under EGWP contracts, what specific benefits are provided in each of those employer group plans, or the associated underlying costs. As a result, CMS currently has limited information on the impact on beneficiaries of the payment changes implemented to date and what the impact of full implementation of payments based exclusively on individual plan bids might be. Notwithstanding the foregoing, MA EGWP enrollment grew significantly from 2016 to 2017, and we are interested in working with sponsors of EGWPs and other interested stakeholders to improve our understanding of the EGWP market and of the beneficiary impacts associated with payment changes for these plans. The bid to benchmark ratios that would have been applied in 2018 had CMS finalized a policy to calculate the bid to benchmark ratios using 100% individual market plan bids from 2017 would have been:

Applicable Percentage	Bid to Benchmark Ratio
0.95	82.1%
1	85.3%
1.075	87.4%
1.15	88.3%

Comment: One commenter indicated that retirees enrolled in EGWPs have a higher average age as compared to individual market MA plans. This age difference may be the result of a greater propensity for EGWP plan retirees to stay in their same EGWP plan until death, since group retiree health insurance is generally supported by employer/union contributions toward the premium, which provides an incentive for retirees to maintain continuous coverage under the group plan, and "end of life" medical expenses in EGWP plans are higher than in individual market plans. This commenter also asserted that while EGWP members may appear to have lower average risk scores, this is more an artifact of the widespread geographic coverage than actual member risk, also indicating that, in their plan covered population, EGWP members have higher risk scores on average than their non-EGWP enrollees when comparing only the demographic portions of their enrollee's risk scores, further evidencing the older population in EGWPs.

Response: We appreciate this commenter's concerns, however, the CMS-HCC risk adjustment model takes the age and health status of beneficiaries into account in an interactive fashion such that a comparison of solely the demographic portions of the risk score of any given population is insufficient to fully explain a population's differential risk. Moreover, while we understand that

there are variations within specific plans in the EGWP market, risk scores for MA EGWPs, on average, continue to be lower than those in the individual MA market. Notwithstanding the foregoing, CMS is interested in working with sponsors of EGWPs and other interested stakeholders to improve our understanding of the EGWP market and of the beneficiary impacts associated with payment changes for these plans. We appreciate these comments and will continue to analyze data to refine the payment methodology for future years. As previously mentioned, we also encourage stakeholders interested in this policy to respond to the RFI in Attachment I with their ideas.

Comment: A few commenters discussed several distinctions between MA EGWPs and MA non-EGWPs, such as better coordination of care programs, the ability to better coordinate between vendors providing more comprehensive case management for their beneficiaries, flexible pricing and plan design, consistency in coverage during the transition from employment coverage to retirement coverage and improved customer service. Other commenters indicated that MA EGWPs and MA non-EGWPs are distinct, as EGWPs serve a separate purpose such as providing comprehensive medical coverage by integrating Medicare benefits with employer or union-funded supplemental employee/retiree benefits. Unlike individual-market MA plans, employer-plan sponsors select a limited number of EGWP options from which retirees can choose to enroll. A few commenters stated that for MA EGWPs to attract employers, plans are frequently designed in ways that may lead to higher bids relative to the individual MA market. Both broad networks and a larger geographic distribution of beneficiaries can lead to higher costs in coverage. Moreover, these plans offer coverage to beneficiaries in areas that are underserved by individual market MA plans through extended service area options allowed under MA EGWP waivers currently in place. The service area waivers allow EGWPs to offer coverage in areas where a plan may not have a full network. However, they add to the cost of the product because enrollees in MA EGWPs utilize of out-of-network providers that have no contractual relationship with the plan in a significantly greater amount than in Individual market plans. This results in less opportunity to effectively engage in care coordination or to negotiate lower payment rates. A few other commenters asserted that the administrative costs for EGWP plans exceed those of individual market plans.

Response: We thank commenters for these observations regarding why there are differences between EGWP and non-EGWP plan offerings and designs. We look forward to working with EGWP sponsors and interested stakeholders to assess how these differences affect plan costs. By removing the bidding requirements, MAOs will need to compete for contracts with employers on access, quality, customer service, and wrap-around benefits.

Comment: Several commenters recommended that CMS investigate how the policy impacts employer-sponsored retiree coverage and the impact on health outcomes for retirees. Commenters expressed that federal policy should not increase costs for employers that are doing the right thing and contributing to their retirees' health care coverage. A few commenters stated their concern that the proposal will cause insurers to abandon the employer group MA market,

restrict provider networks, reduce coverage and/or increase premiums, which will lead to less choice for retirees and their former employers and discourage innovative plan design in these markets. Because this policy would disincent these plans, these commenters said, employers are likely to drop retiree coverage, and the burden shifts back to the government, with an increase of members in original Medicare. A few commenters also indicated that the 2017 policy has created significant premium increases, higher out of pocket costs, and the elimination of popular benefits such as dental, vision, hearing, fitness, prescription drug coverage, and has caused significant financial pressures for employer groups in certain markets. One commenter suggested that the MA funding cut was lessened somewhat by the moratorium of the health insurer tax in the 2017 plan year, but if the insurer fee is re-imposed in 2018 there will be significant changes. Other commenters stated that EGWP members have historically used benefits differently than individual market members and are accustomed to richer benefits. Commenters stated that a significant shift in cost to employer groups is likely to erode group coverage, since employer groups could look to balance increased costs with a significant reduction in benefits or simply choose not to offer these plans. A couple of commenters also suggested that some employer groups have moved beneficiaries to Medicare Supplemental coverage or dropped coverage altogether, thus disrupting benefits, interrupting care plans, interfering with patient-provider relationships, and potentially forcing beneficiaries into Medicare FFS with less care management and potentially higher long-term costs.

Response: We appreciate the commenters' concerns and are finalizing a policy for 2018 that provides payment stability in response to the myriad of concerns raised by commenters about moving forward with full implementation of the policy to use only individual market plan bids from 2017 to calculate the bid-to-benchmark ratios for the 2018 MA EGWP payment rates. As stated above, prior to making a decision about a payment approach for future years, CMS would like to develop a better understanding of the impact these changes are having on beneficiaries, and seek comment on how specific adjustments could be appropriately incorporated into the payment methodology. This pause in the transition will allow CMS to seek input and data from EGWP sponsors and other stakeholders on changes in plan offerings in 2017 and 2018 and associated beneficiary impacts. We encourage stakeholders interested in this policy to respond to the RFI in Attachment I with their ideas.

Comment: A few commenters asserted that it is important to understand that benefits offered under these plans have been carefully negotiated as an integral part of the accrued retirement package for labor union and other large group employer workers. In some cases, negotiated collective bargaining agreements require single employers to continue providing health care coverage to retirees. In addition, many are associated with Voluntary Employees' Beneficiary Associations (VEBAs) that provide health care benefits to retirees. In most cases, these VEBAs were established and are maintained in accordance with the terms of class action or bankruptcy settlement agreements that were approved by federal district and/or bankruptcy courts. Additionally, these products are often customized to finance the coverage offered to retirees,

and the full implementation of CMS' proposal may reduce benefits or lead to premium increases for enrollees.

Response: While we recognize that in certain circumstances the benefit package provided to retirees under an EGWP is the result of a collective bargaining or class action/bankruptcy agreement, the supplemental benefits provided under such an arrangement do not explain the higher bids that we have consistently observed from EGWPs. Buying down cost-sharing under Original Medicare is a supplemental benefit. Under the Medicare Advantage bidding process prior to 2017, all plans (both EGWPs and non EGWPs) submitted a bid for providing the benefits covered under original Medicare on an actuarially equivalent basis, with a separate bid amount for supplemental benefits that is not paid (except for the rebate) with federal dollars. Despite bidding on the same package of basic benefits, on average, EGWP bids for A/B benefits have consistently been significantly higher than those submitted by non-EGWPs. That notwithstanding, we appreciate the commenters' concern about the potential impact for beneficiaries of payment changes and look forward to working with sponsors of EGWPs and other interested stakeholders to improve our understanding of the EGWP market and of the beneficiary impacts associated with payment changes for these plans.

Comment: A few commenters suggested that CMS does not have the legal authority to implement this policy.

Response: CMS has statutory authority to waive the bid requirements and modify the payment methodology to facilitate the offering of MA plans by employers or under contracts between employers and MAOs. We refer readers to the discussion of the legal authority detailed in the 2017 Rate Announcement: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf

Comment: Several commenters opposed CMS continuing to waive Part C bidding requirements for sponsors of Part C EGWPs. They believe that CMS should reinstate the annual bidding process that existed prior to 2017. These commenters indicated that bids take into account claim experience, geographic location, and product coverage and, therefore, better reflect revenue requirements of EGWPs. A few commenters also suggested that while eliminating the burden of submitting bids does help to reduce the cost of administering EGWP plans, this cost reduction is marginal as these bids are submitted alongside the individual market bids with marginal additional efforts. A few commenters also recognized that CMS raised transparency concerns about returning to the bid requirements in place prior to 2017 that allowed organizations to submit composite bids and benefit packages, rather than unique bids and benefit information for each plan. These commenters suggested that CMS work with the industry to address the agency's concerns related to the administrative complexities inherent in an approach that would rely on the submission, review and approval of bids and benefit packages for each EGWP to return to a bid-based payment approach.

Response: While we understand the concerns raised, CMS continues to believe that the policy of allowing MAOs to submit composite bids and benefit packages is not an appropriate methodology for payment given the lack of competition and transparency associated with EGWP bids received prior to 2017. As noted last year, we considered whether to revert to the statutory and regulatory requirement of requiring EGWP sponsors to submit to CMS for review and approval benefit packages and bids for each of their employer plans. However, we concluded that the administrative burden for not just the government, but for MAOs and employers of such an approach would substantially hinder the offering of these plans as the MAO would have to commit to specific plan benefit packages at the time of the bid, the flexibility to modify benefits and customize plan offerings for employers would be significantly limited or eliminated entirely as compared to the flexibility provided under either the composite bid waiver or the current payment policy, and changes after bid submission or mid-year would be more difficult, or perhaps impermissible.

Section H. Medicare Advantage Coding Pattern Adjustment

Comment: The majority of commenters were pleased that CMS is not proposing an adjustment above the statutory minimum.

Response: CMS appreciates the support of the commenters.

Comment: Several commenters who support the statutory minimum indicated that the adjustment is nonetheless a significant reduction in payment and requested that the issue be revisited for future years. One commenter recommended that CMS use two years of diagnostic data to estimate the CMS-HCC model coefficients, which would improve the accuracy of chronic condition coding and also allow CMS to recalculate or reset the coding intensity adjustment should any coding differences remain. Some commenters suggested that CMS freeze the coding intensity adjustment, while a few other commenters recommended that CMS eliminate the adjuster. One commenter believed there should be no extension of the coding adjustment beyond the 2018 plan year.

A few commenters indicated that coding patterns in MA are heterogeneous and that applying an across the board adjustment is inequitable. One commenter suggested a tiered approach such that a low coding factor is applied to lower coding plans while a larger factor is applied to high coding plans. Another commenter suggested flexibility in moderating the impact of the coding intensity adjustment for specific plan types (e.g., Medicare-Medicaid Plans).

Response: CMS appreciates commenters' responses. CMS is required by law to adjust risk scores for differences in MA and FFS coding patterns until we implement "risk adjustment using Medicare Advantage diagnostic, cost, and use data." In other words, we must continue to apply the coding intensity adjuster until we recalibrate the risk adjustment model using MA encounter data.

Comment: A few commenters encouraged CMS to increase the coding adjustment in CMS' effort to achieve payment parity, both as a matter of equity between MA and traditional Medicare and as a means of appropriately safeguarding public funds.

Response: We thank commenters for their input.

Comment: One commenter urged CMS to reduce or eliminate the coding adjustment factor for C-SNPs to ensure accurate payment for specialized plans that truly serve the sickest beneficiaries. The commenter stated that it is impossible to compare C-SNP coding intensity to average FFS coding given the concentration of chronically ill beneficiaries in these plans and suggested that the level of the adjuster be based on a C-SNP's performance on SNP-specific Star measures. Another commenter requested flexibility to moderate the impact of the coding adjustment factor for Medicare-Medicaid-Plans (MMPs) to account for the anticipated enrollment volume of historically FFS enrolled individuals.

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

Comment: A few commenters believed that CMS incorrectly implied that any observed coding differentials between the FFS and MA populations are driven by inappropriate coding on the part of MA plans and urged CMS to recognize that higher coding does not necessarily equate to wrong coding. One commenter noted that the stringent auditing of coding practices administered through Risk Adjustment Data Validation (RADV) prevents widespread fraudulent coding practices and that the coding intensity adjustment factor has become artificially punitive and not reflective of current coding practices.

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

Comment: A few commenters recommended that the MA coding adjustment factor not be applied to the ED portion of the risk score.

Response: CMS is required by statute to apply the MA coding difference factor to risk scores as

long as we calibrate our CMS-HCC model solely on FFS data.

Section I. Normalization Factors

Comment: Many commenters questioned the accuracy of the historical Part C FFS risk score trend, particularly the 2016 data point. Commenters requested more information about how the underlying risk score data is calculated, why there is a significant increase in the average risk score in 2016, and whether or not that increase is expected to continue. Some commenters recommended that CMS exclude the 2016 data point from the normalization calculation.

Response: As discussed in the 2018 Advance Notice, CMS predicts the normalization factors from historical risk score data calculated with the risk adjustment model that will be used in the payment year. For each year in the FFS risk score trend, CMS selects all beneficiaries alive as of July 1st, entitled to Part A and enrolled in Part B, not designated as ESRD, or in hospice status. Beneficiary's diagnoses are selected from the FFS Standard Analytic File with 6 months run out for all years. CMS has found that a July cohort of beneficiaries is the best method to adjust for seasonality in risk score data and thus adequately represents the average risk score for a given payment year. Each year when calculating historical risk scores, we incorporate retroactive changes in enrollment, dates of death, and statuses such as ESRD and Medicaid, but we do not update the diagnosis code runout. This may result in slight changes to the average beneficiary risk score in some prior years. For Part C and ESRD, CMS uses risk scores calculated from the most recent years available for FFS beneficiaries. This allows for the best estimate of the payment year FFS risk score level from the historical risk score trend. For the Part D normalization factor, the historical risk score data is lagged an additional year because MA risk scores are included in the Part D risk score trend and, therefore, we need to wait until the risk adjustment deadline to calculate complete MA risk scores.

CMS has verified that the FFS risk scores were calculated correctly. We also note that several outside parties have also confirmed the increase in FFS risks score between 2015 and 2016. CMS research is showing that the increase in risk score between 2015 and 2016 is the result of changes in the composition of the FFS population (e.g., a smaller proportion of new enrollees in 2016 than in 2015, and a higher proportion of community beneficiaries), the mappings of some ICD-10 codes to HCCs, and changes in the reported health status of the FFS Medicare population. CMS believes that the increases in HCCs in 2016, especially to the extent that a portion of the increase is the result of changes in diagnostic coding patterns resulting from ICD-10 implementation and changing payment incentives in FFS Medicare, are not an aberration and that it would be inappropriate to disregard the 2016 experience. Despite this recent increase in risk scores, the Part C normalization factor for 2018 effectively assumes that risk scores will decline slightly from 2016 to 2018. If we were to adopt a Part C normalization factor lower than 1.017, it would require an assumption that risk scores will drop significantly between 2016 and 2018, which we believe is very unlikely given recent and historical patterns in FFS risk score changes.

Comment: Many commenters supported CMS' decision to switch from the quadratic to the linear methodology. While many commenters suggested that CMS not include the 2016 data point when calculating the normalization factor, several commenters supported CMS's proposal to calculate the normalization factor with the linear methodology and five years of data from 2012-2016. In addition, several commenters requested that CMS provide greater stability between updates in the Normalization factor.

Response: As discussed in the 2018 Advance Notice, the normalization factor is intended to maintain an average FFS risk score of 1.0 in each payment year, as well as provide payment stability between model calibrations. Given that CMS believes the 2016 data point is not an outlier, we will implement the normalization factor of 1.017 proposed in the 2018 Advance Notice. However, we do acknowledge the uncertainty caused by significant changes in the normalization factor. CMS will continue to explore options for providing greater stability between payment years.

Comment: Many commenters expressed concern about the larger than usual increase in the ESRD normalization factor from PY 2017 and wondered why the underlying data provided for the ESRD normalization factor were inconsistent with the proposed normalization factor of 1.08. In particular, several commenters questioned why the 2009 denominator year did not appear to be 1.0.

Response: CMS understands that the ESRD normalization factor proposed in the 2018 Advance Notice, 1.080, appears inconsistent with the historical trend data provided. While the risk score trend is correct, changing methodologies resulted in a larger change for the dialysis normalization factor. For 2018, we will apply the trend to the denominator year risk score that is part of the trend published in the Advance Notice. Using a denominator year risk score of 0.939 results in a normalization factor of 1.015 for PY 2018. The underlying trend, and the historical data used to calculate it, remain unchanged.

The formula for the 2018 ESRD dialysis normalization factor is listed below.

$$0.939 \times (1 + 0.0087)^9 = 1.015$$

Section J. Encounter Data as a Diagnosis Source for 2018

Comment: Many commenters stated their support of encounter data collection, but most commenters raised concerns over using encounter data for payment until operational issues have been resolved. A number of commenters suggested that if CMS were to use encounter data for payment, the risk score blend should be reduced to minimize the payment impact of operational issues. Various alternatives to the level of the risk score blend were proposed, including the blend of 90% of RAPS/FFS-based risk scores and 10% of encounter data/FFS-based risk scores that was used for PY 2016, and including encounter data as an additional source of data. A few plans suggested that CMS vary the blend based on submission rates. Many commenters stated

that an adjuster would be necessary if CMS maintained the proposed 75% of RAPS/FFS-based risk scores and 25% of encounter data/FFS-based risk scores.

Many commenters stated that, if CMS continued to use a blended risk score for payment, that we should apply an adjustment to encounter data based risk scores and, further, that the adjuster should fully account for any difference between RAPS-based risk scores and ED-based risk scores. Most commenters addressing this issue suggested the adjuster should be applied at the plan or contract level, while a few commenters suggested the adjuster be applied at the industry level. Additionally, some commenters suggested that the adjuster should not be applied to new enrollee risk scores, while others suggested that the adjuster should be applied to all beneficiaries. A few commenters objected to the use of an adjuster at all, asserting that it undermines the use of encounter data.

Response: CMS appreciates industry feedback related to the implementation of encounter data and is committed to working with stakeholders to resolve outstanding issues in a timely manner. We also believe that it is essential to paying Medicare Advantage plans accurately that CMS have adequate data to calibrate a risk adjustment model on MA data. CMS began collecting encounter data from MA organizations, with the goal of ultimately using these data in the development of the risk adjustment model, which would allow the program to minimize using Medicare FFS data as a basis for payment and improve the accuracy of risk adjusted payments for plans. In addition, by law, CMS will no longer be required to apply an MA coding adjustment to MA payments once the model is based on MA data.

To provide payment stability while also providing an incentive for plans to submit complete data, CMS will use a risk score blend that is the sum of 85% of the RAPS/FFS-based risk score and 15% of the encounter data/FFS-based risk score for PY2018. We will use this blend for Part C and ESRD risk scores.

In the Advance Notice, we solicited comment on whether to apply an additional payment adjustment along with the proposed 75%/25% blend. Given that we are finalizing the policy of using only 15% of the encounter data-based risk score in payment, we will not apply an adjustment to the encounter data-based risk scores.

While we are stepping back from the 75%/25% blend that we are using for PY 2017, we wanted to maintain an incentive for plans to submit complete data and demonstrate our intention to continue using encounter data to calculate payments; thus, we are not reverting to the blend we used for PY 2016.

Comment: Many commenters set forth detailed concerns about technical difficulties they identified as problematic for the calculation of risk scores using encounter data, including submission issues and the timing of reports they receive regarding their submissions. Many commenters referred to the GAO reports that provide recommendations to CMS about the steps that should be taken to improve encounter data before using it in payment. A few commenters

requested that CMS lay out a public and specific timeframe for correcting the encounter data risk score problems and using the data for payment over time.

Response: We appreciate commenters' concerns. CMS is committed to working collaboratively with the industry to increase transparency and minimize uncertainty from transitioning to encounter data as the source of data for payment. We will convey additional information on a transition plan in the near future.

Comment: A large number of providers associated with one MAO submitted comments expressing concern that CMS was moving too quickly to using encounter data, citing concerns that it may underestimate the health care needs of their patients and result in reduced payments and resources for them to deliver high quality care and services to their sickest patients.

Response: CMS appreciates the work of the provider community and the concerns raised. We will continue to work with interested stakeholders on technical and operational issues to improve the acceptance, completeness, and quality of encounter data.

Comment: One commenter expressed support for the continued methodology for PACE wherein encounter data is an additional source of data for the calculation of risk scores.

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

Comment: Several commenters requested that CMS make adjustments to payments in 2016 and 2017 based on CMS's acknowledgement that the ED portion of the risk score is lower than the RAPS risk score for a myriad of technical reasons.

Response: CMS is unable to make changes to payment methodologies for prior years.

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

Section A. Update of the RxHCC Model

Comment: One commenter expressed support for updating the model, but asked CMS to consider developing a hybrid prospective and concurrent risk adjustment model for the next recalibration to take into account new high cost curative or short term use drugs for which utilization and costs are likely to occur during the same year.

Response: CMS appreciates the support and the recommendation.

Comment: Two commenters suggested that CMS incorporate lower level chronic kidney disease into the model to drive performance improvement for earlier detection and account for the higher expenditures of this population.

Response: We appreciate the suggestion. Decisions on the inclusion or exclusion of specific diseases in the model are based on 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.

Section B. Encounter Data as a Diagnosis Source for 2018

Comment: Two commenters requested that any encounter data adjuster be applied to the Part D model as well, not just the Part C and ESRD as CMS proposed. One commenter requested that CMS analyze the data for Part D encounter based risk scores vs. those calculated using RAPS data and apply an adjuster if there is a differential.

Response: As with Part C, we are finalizing a PY2018 Part D risk score blend of 85% of the RAPS/FFS-based score and 15% of the encounter-data/FFS-based score and, therefore, will not apply any additional payment adjustment.

Section C. Part D Risk Sharing

Comment: Several commenters supported the decision not to change the Part D risk sharing parameters.

Response: CMS appreciates the support.

Section D. Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2018

Comment: Commenters were pleased that the adjustments to the Part D parameters are less significant in 2018 than they were in 2017. One commenter remains concerned, however, that, given drug cost trends, there likely will be large increases in beneficiary out-of-pocket liability

after 2019 due to the expiration of the statutory protections against large increases in the out-of-pocket threshold.

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

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

Comment: Two commenters expressed concern regarding the treatment of biosimilar products as "non-applicable drugs" under the Medicare coverage gap discount program, which they contend discourages the use of biosimilars in favor of the more expensive reference biologic products.

Response: While CMS appreciates the concerns of the commenters, section 1860D-14A of the Act explicitly excludes biosimilars from the definition of "applicable drugs."

Comment: One commenter requested clarification as to whether products approved under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) will remain "applicable drugs" for the purposes of the Medicare coverage gap discount program once the FDA implements the "Deemed to Be a License" provision of the Biologics Price Competition and Innovation (BPCI) Act of 2009.

Response: CMS appreciates the commenter's concerns and will address this issue in future guidance, as appropriate.

Section F. Part D Calendar Year Employer Group Waiver Plans

Comment: Commenters expressed support for the proposal to continue to pay Calendar Year Part D EGWPs prospective reinsurance in 2018, with one commenter asserting that this policy is in the interest of ensuring the stability of employer-sponsored retiree health drug coverage.

Response: We appreciate the support.

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

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

Annual Percentage Increases

	Annual percentage trend for 2017	Prior year revisions	Annual percentage increase for 2018
API: Applied to all parameters but (1) and (2)	3.94%	−2.62%	1.22%
July CPI (all items, U.S. city average): Applied to (1)	2.47%	−0.30%	2.17%
September CPI (all items, U.S. city average): Applied to (2)	2.41%	−0.20%	2.20%

Part D Benefit Parameters

	2017	2018
Standard Benefit		
Deductible	$400	$405
Initial Coverage Limit	$3,700	$3,750
Out-of-Pocket Threshold	$4,950	$5,000
Total Covered Part D Spending at Out-of-Pocket Threshold for Non-Applicable Beneficiaries (3)	$7,425.00	$7,508.75
Estimated Total Covered Part D Spending for Applicable Beneficiaries (4)	$8,071.16	$8,417.60
Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit		
Generic/Preferred Multi-Source Drug	$3.30	$3.35
Other	$8.25	$8.35
Full Subsidy-Full Benefit Dual Eligible (FBDE) Individuals (6)		
Deductible	$0.00	$0.00
Copayments for Institutionalized Beneficiaries (category code 3)	$0.00	$0.00
Copayments for Beneficiaries Receiving Home and Community-Based Services (5) (category code 3)	$0.00	$0.00
Maximum Copayments for Non-Institutionalized Beneficiaries		
Up to or at 100% FPL (category code 2)		
Up to Out-of-Pocket Threshold (1)		
Generic/Preferred Multi-Source Drug (6)	$1.20	$1.25
Other (6)	$3.70	$3.70
Above Out-of-Pocket Threshold	$0.00	$0.00
Over 100% FPL (category code 1)		
Up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$3.30	$3.35
Other	$8.25	$8.35
Above Out-of-Pocket Threshold	$0.00	$0.00

	2017	2018
Full Subsidy-Non-FBDE Individuals		
Applied or eligible for QMB/SLMB/QI or SSI and income at or below 135% FPL and resources ≤ $8,890 (individuals) or ≤ $14,090 (couples) (7) (category code 1)		
Deductible	$0.00	$0.00
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$3.30	$3.35
Other	$8.25	$8.35
Maximum Copayments above Out-of-Pocket Threshold	$0.00	$0.00
Partial Subsidy		
Applied and income below 150% FPL and resources below $13,820 (individual) or $27,600 (couples) (7) (category code 4)		
Deductible (6)	$82.00	$83.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$3.30	$3.35
Other	$8.25	$8.35
Retiree Drug Subsidy Amounts		
Cost Threshold	$400	$405
Cost Limit	$8,250	$8,350

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

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

(3) For a beneficiary who is not considered an "applicable beneficiary," as defined at section 1860D-14A(g)(1), and is not eligible for the Coverage Gap Discount Program, this is the amount of total drug spending required to reach the out-of-pocket threshold in the defined standard benefit.

(4) For a beneficiary who is considered an "applicable beneficiary," as defined at section 1860D-14A(g)(1), and is 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.

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

(6) The increases to the LIS deductible, generic/preferred multi-source drugs and other drugs copayments are applied to the unrounded 2017 values of $82.46, $1.22, and $3.65, respectively.

(7) These resource limit figures will be updated for contract year 2018.

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

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

Deductible: From $400 in 2017 and rounded to the nearest multiple of $5.

Initial Coverage Limit: From $3,700 in 2017 and rounded to the nearest multiple of $10.

Out-of-Pocket Threshold: From $4,950 in 2017 and rounded to the nearest multiple of $50.

Minimum Cost-Sharing in the Catastrophic Coverage Portion of the Benefit: From $3.30 per generic or preferred drug that is a multi-source drug and $8.25 for all other drugs in 2017, rounded to the nearest multiple of $0.05.

Maximum Copayments up to the Out-of-Pocket Threshold for Certain Low Income Full Subsidy Eligible Enrollees: From $3.30 per generic or preferred drug that is a multi-source drug and $8.25 for all other drugs in 2017, rounded to the nearest multiple of $0.05.

Deductible for Low Income (Partial) Subsidy Eligible Enrollees: From $82[1] in 2017 and rounded to the nearest $1.

Maximum Copayments above the Out-of-Pocket Threshold for Low Income (Partial) Subsidy Eligible Enrollees: From $3.30 per generic or preferred drug that is a multi-source drug and $8.25 for all other drugs in 2017, rounded to the nearest multiple of $0.05.

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

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

Section 1860D-14(a)(4) of the Act specifies that the annual percentage increase in the CPI, All Urban Consumers (all items, U.S. city average) as of September of the previous year is used to update the maximum copayments up to the out-of-pocket threshold for full benefit dual eligible enrollees with incomes not exceeding 100 percent of the Federal poverty line. These copayments are increased from $1.20 per generic or preferred drug that is a multi-source drug

[1] Consistent with the statutory requirements of section 1860D-14(a)(4)(B) of the Act, the update for the deductible for low income (partial) subsidy eligible enrollees is applied to the unrounded 2017 value of $82.46.

and $3.70 for all other drugs in 2017, rounded to the nearest multiple of $0.05 and $0.10, respectively.[2]

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

Additionally, section 1860D-2(b)(4) of the Act requires that the "annual percentage increase" applied to the out-of-pocket threshold in 2018 be the lesser of the API or CPI+2%. The change in CPI in this case is measured over the 12-month period ending in July of the previous year, as required by statute. The API over the 12-month period ending in July of 2017 is lower than the change in CPI during that period, and, therefore, the API will apply to the out-of-pocket threshold. The threshold is increased from $4,950 in 2017 and rounded to the nearest multiple of $50.

Section C. Calculation Methodology

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

For contract years 2007 and 2008, the APIs, as defined in section 1860D-2(b)(6) of the Act, were based on the National Health Expenditure (NHE) prescription drug per capita estimates because sufficient Part D program data was not available. Beginning with contract year 2009, the APIs are based on Part D program data. For the contract year 2018 benefit parameters, Part D program data is used to calculate the annual percentage trend as follows:

$$\frac{August\ 2016 – July\ 2017}{August\ 2015 – July\ 2016} = \frac{\$3{,}659.97}{\$3{,}521.22} = 1.0394$$

In the formula, the average per capita cost for August 2015 – July 2016 ($3,521.22) is calculated from actual Part D PDE data, and the average per capita cost for August 2016 – July 2017 ($3,659.97) is calculated based on actual Part D PDE data incurred from August 2016 – December 2016 and projected through July 2017.

The 2018 benefit parameters reflect the 2017 annual percentage trend as well as an update for revision to prior year estimates for API. Based on updated NHE prescription drug per capita costs and PDE data, the annual percentage increases are now estimated as summarized by Table VI-2.

[2] Consistent with the statutory requirements of section 1860D-14(a)(4)(A) of the Act, the copayments are increased from the unrounded 2017 values of $1.22 per generic or preferred drug that is a multi-source drug, and $3.65 for all other drugs.

Table VI-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	**4.69%**	**4.69%**
2010	**3.14%**	**3.14%**
2011	**2.36%**	**2.36%**
2012	**2.16%**	**2.16%**
2013	**2.53%**	**2.53%**
2014	**−3.13%**	**−3.14%**
2015	**10.03%**	**10.09%**
2016	**9.91%**	**9.90%**
2017	**6.99%**	**4.14%**

Accordingly, the 2018 benefit parameters reflect a multiplicative update of -2.62 percent for prior year revisions. In summary, the 2017 parameters outlined in Section A are updated by 1.22 percent for 2018, as summarized by Table VI-3.

Table VI-3. Revised Prior Years' Annual Percentage Increase

Annual percentage trend for July 2017	3.94%
Prior year revisions	−2.62%
Annual percentage increase for 2018	1.22%

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

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

To ensure that plan sponsors and CMS have sufficient time to incorporate the cost-sharing requirements into the development of the benefit, any marketing materials, and necessary systems, the methodology to calculate the annual percentage increase in the CPI for the 12 month period ending in September 2017 includes an estimate of the September 2017 CPI based on projections from the President's FY2018 Budget.

The September 2016 value is from the Bureau of Labor Statistics. The annual percentage trend in the September CPI for contract year 2018 is calculated as follows:

$$\frac{\text{Projected September 2017 CPI}}{\text{Actual September 2016 CPI}} \; or \; \frac{247.245}{241.428} = 1.0241$$

(Source: President's FY2018 Budget and Bureau of Labor Statistics, Department of Labor)

The 2018 benefit parameters reflect the 2017 annual percentage trend in the September CPI of 2.41 percent, as well as a revision to the prior estimate for the 2016 CPI increase over the 12 month period ending in September 2016. Based on the actual reported CPI for September 2016, the September 2016 CPI increase is now estimated to be 1.46 percent. Accordingly, the 2018 update reflects a -0.20 percent multiplicative correction for the revision to last year's estimate. In summary, the maximum copayments below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes not exceeding 100 percent of the Federal poverty line are updated by 2.20 percent for 2018, as summarized by Table VI-4.

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

Annual percentage trend for September 2017	2.41%
Prior year revisions	−0.20%
Annual percentage increase for 2018	2.20%

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

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

As is the case when calculating the annual CPI trend as of September 2017, the methodology to calculate the annual percentage increase in the CPI for the 12 month period ending in July 2017 includes an estimate of the July 2017 CPI based on projections from the President's FY2018 Budget.

The July 2016 value is from the Bureau of Labor Statistics. The annual percentage trend in CPI for contract year 2018 is calculated as follows:

$$\frac{\text{Projected July 2017 CPI}}{\text{Actual July 2016 CPI}} \; or \; \frac{246.580}{240.628} = 1.0247$$

(Source: President's FY2018 Budget and Bureau of Labor Statistics, Department of Labor)

The 2018 benefit parameters reflect the 2017 annual percentage trend in the July CPI of 2.47 percent as well as a revision to the prior estimate for the 2016 CPI increase. Based on the actual reported CPI for July 2016, the CPI increase over the 12 month period ending in July 2016 is estimated to be 0.83 percent. The prior year revision here reflects the difference between this actual 0.83 percent increase in CPI observed in July 2016 and the 2016 CPI increase estimate from the CY 2017 Rate Announcement.

In summary, the cumulative annual percentage increase in July CPI for 2018 is 2.17 percent, as summarized by Table VI-5. This value plus two percentage points is greater than the 1.22 percent cumulative API for 2018 described above. Thus, the out-of-pocket threshold will be increased by 1.22 percent for 2018.

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

Annual percentage trend for July 2017	2.47%
Prior year revisions	−0.30%
Annual percentage increase for 2018	2.17%

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

Section D. Retiree Drug Subsidy Amounts

Per § 42 CFR 423.886(b)(3) of our regulations, the cost threshold and cost limit for qualified retiree prescription drug plans are also updated using the API, as defined previously in this document. The updated cost threshold is rounded the nearest multiple of $5 and the updated cost limit is rounded to the nearest multiple of $50. The cost threshold and cost limit are defined as $360 and $7,400, respectively, for plans that end in 2016, and, as $400 and $8,250, respectively, for plans that end in 2017. For 2018, the cost threshold is $405 and the cost limit is $8,350.

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

For 2018, the total covered Part D spending at out-of-pocket threshold for applicable beneficiaries is $8,417.60. The figure is calculated given the following basic assumptions:

- 100 percent beneficiary cost sharing in the deductible phase.
- 25 percent beneficiary cost sharing in the initial coverage phase
- 44 percent beneficiary cost sharing for non-applicable (generic) drugs purchased in the coverage gap phase of the benefit.
- 85 percent cost sharing for the ingredient cost and sales tax for applicable (brand) drugs purchased in the coverage gap phase of the benefit—comprised of 35 percent beneficiary coinsurance and 50 percent Coverage Gap Discount Program discount.
- 35 percent cost sharing for the dispensing and vaccine administration fees for applicable (brand) drugs purchased in the coverage gap phase of the benefit.

In this estimate, it is also assumed that the dispensing and vaccine administration fees account for 0.08 percent of the gross covered brand drug costs used by non-LIS beneficiaries in the coverage gap. Therefore, a 65 percent reduction in cost sharing for dispensing and vaccine administration fees results in an overall reduction of 0.04 percent to 84.96 percent in cost sharing for applicable (brand) drugs in the coverage gap.

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

$$\text{ICL} + \frac{\text{100\% beneficiary cost sharing in the gap}}{\text{weighted gap coinsurance factor}} \quad or \quad \$3{,}750 + \frac{\$3{,}758.75}{80.5286\%} = \$8{,}471.60$$

- *ICL* is the Initial Coverage Limit equal to $3,750
- *100 percent beneficiary cost sharing in the gap* is the estimated total drug spending in the gap assuming 100 percent coinsurance and is equivalent to:

  *(*OOP threshold) – (OOP costs up to the ICL) *or* $5,000 − $1,241.25 = $3,758.75

- *Weighted gap coinsurance factor* is calculated as follows:

  (Brand GDCB % for non-LIS × 84.96% gap cost sharing for applicable drugs) + (Generic GDCB % for non-LIS × 44% gap cost sharing for non-applicable drugs)

  or

  (89.18% × 84.96%) + (10.82% × 44%) = 80.528%

  - *Brand GDCB % for non-LIS* is the percentage of gross covered drug costs below the OOP threshold for applicable beneficiaries (i.e., non-LIS) attributable to applicable (brand) drugs, as reported on the 2016 PDEs.
  - *Gap cost sharing for applicable drugs* is the coinsurance incurred by applicable beneficiaries (i.e., non-LIS) for applicable (brand) drugs in the coverage gap, where:
    - *Coinsurance for applicable drugs* = is calculated as follows:

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

      or

      84.96% = [(99.92% × 85%) + (0.08% × 35%)]

  - *Generic GDCB % for non-LIS* is the percentage of gross covered drug costs below the OOP threshold for applicable beneficiaries (i.e., non-LIS) attributable to non-applicable (generic) drugs as reported on the 2016 PDEs.
  - *Gap cost sharing for non-applicable drugs* is the coinsurance incurred by applicable beneficiaries (i.e., non-LIS) for non-applicable (generic) drugs in the coverage gap.

Attachment VII. RxHCC Risk Adjustment Factors

Table VII-1. RxHCC Model Relative Factors for Continuing Enrollees

Continuing Enrollees (CE) RxHCC Model Segments

Variable	Disease Group	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
Female						
0-34 Years		-	0.306	-	0.435	1.791
35-44 Years		-	0.450	-	0.625	2.035
45-54 Years		-	0.553	-	0.725	1.716
55-59 Years		-	0.524	-	0.704	1.565
60-64 Years		-	0.485	-	0.638	1.424
65-69 Years		0.239	-	0.389	-	1.488
70-74 Years		0.239	-	0.365	-	1.362
75-79 Years		0.225	-	0.355	-	1.254
80-84 Years		0.205	-	0.316	-	1.159
85-89 Years		0.182	-	0.282	-	1.068
90-94 Years		0.135	-	0.228	-	0.950
95 Years or Over		0.072	-	0.141	-	0.759
Male						
0-34 Years		-	0.271	-	0.474	1.827
35-44 Years		-	0.389	-	0.600	1.818
45-54 Years		-	0.489	-	0.667	1.679
55-59 Years		-	0.524	-	0.674	1.493
60-64 Years		-	0.502	-	0.621	1.366
65-69 Years		0.263	-	0.367	-	1.319
70-74 Years		0.270	-	0.342	-	1.271
75-79 Years		0.245	-	0.342	-	1.199
80-84 Years		0.185	-	0.304	-	1.148
85-89 Years		0.140	-	0.287	-	1.077
90-94 Years		0.083	-	0.240	-	0.986
95 Years or Over		0.047	-	0.224	-	0.867
Originally Disabled Interactions with Sex						
Originally Disabled_Female		0.102	-	0.198	-	0.072
Originally Disabled_Male		-	-	0.135	-	0.072
Disease Coefficients	**Description Label**					
RXHCC1	HIV/AIDS	3.192	3.871	3.783	4.127	2.577
RXHCC5	Opportunistic Infections	0.261	0.097	0.175	0.162	0.177
RXHCC15	Chronic Myeloid Leukemia	7.383	7.519	8.142	9.906	4.907
RXHCC16	Multiple Myeloma and Other Neoplastic Disorders	3.946	4.179	3.227	3.663	1.094
RXHCC17	Secondary Cancers of Bone, Lung, Brain, and Other Specified Sites; Liver Cancer	1.771	1.708	1.601	1.588	0.579
RXHCC18	Lung, Kidney, and Other Cancers	0.294	0.260	0.324	0.316	0.069

Continuing Enrollees (CE) RxHCC Model Segments

Variable	Disease Group	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
RXHCC19	Breast and Other Cancers and Tumors	0.096	0.085	0.079	0.115	0.069
RXHCC30	Diabetes with Complications	0.425	0.461	0.501	0.695	0.475
RXHCC31	Diabetes without Complication	0.280	0.262	0.316	0.389	0.321
RXHCC40	Specified Hereditary Metabolic/Immune Disorders	2.990	10.494	3.113	10.451	0.468
RXHCC41	Pituitary, Adrenal Gland, and Other Endocrine and Metabolic Disorders	0.100	0.201	0.060	0.228	0.087
RXHCC42	Thyroid Disorders	0.101	0.178	0.099	0.166	0.076
RXHCC43	Morbid Obesity	0.056	-	0.074	0.068	0.171
RXHCC45	Disorders of Lipoid Metabolism	0.038	-	0.068	0.088	0.052
RXHCC54	Chronic Viral Hepatitis C	3.202	3.685	2.922	2.947	0.945
RXHCC55	Chronic Viral Hepatitis, Except Hepatitis C	0.521	0.335	0.859	0.533	0.371
RXHCC65	Chronic Pancreatitis	0.265	0.188	0.159	0.203	0.173
RXHCC66	Pancreatic Disorders and Intestinal Malabsorption, Except Pancreatitis	0.105	0.188	0.116	0.203	0.117
RXHCC67	Inflammatory Bowel Disease	0.527	0.461	0.458	0.830	0.211
RXHCC68	Esophageal Reflux and Other Disorders of Esophagus	0.076	0.061	0.142	0.169	0.077
RXHCC80	Aseptic Necrosis of Bone	0.177	0.248	0.109	0.144	0.112
RXHCC82	Psoriatic Arthropathy and Systemic Sclerosis	0.769	0.738	1.295	2.065	0.655
RXHCC83	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	0.377	0.409	0.483	0.805	0.185
RXHCC84	Systemic Lupus Erythematosus, Other Connective Tissue Disorders, and Inflammatory Spondylopathies	0.212	0.333	0.239	0.354	0.168
RXHCC87	Osteoporosis, Vertebral and Pathological Fractures	0.052	0.153	0.121	0.204	-
RXHCC95	Sickle Cell Anemia	0.086	0.288	0.048	0.789	0.343
RXHCC96	Myelodysplastic Syndromes and Myelofibrosis	0.959	1.135	0.772	0.710	0.546
RXHCC97	Immune Disorders	0.553	0.509	0.488	0.454	0.342
RXHCC98	Aplastic Anemia and Other Significant Blood Disorders	0.086	0.155	0.048	0.220	0.044
RXHCC111	Alzheimer`s Disease	0.476	0.243	0.177	0.034	-
RXHCC112	Dementia, Except Alzheimer`s Disease	0.196	0.104	0.041	-	-
RXHCC130	Schizophrenia	0.261	0.291	0.404	0.700	0.199
RXHCC131	Bipolar Disorders	0.255	0.278	0.284	0.444	0.199
RXHCC132	Major Depression	0.127	0.207	0.143	0.311	0.166

Continuing Enrollees (CE) RxHCC Model Segments

Variable	Disease Group	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
RXHCC133	Specified Anxiety, Personality, and Behavior Disorders	0.127	0.172	0.143	0.311	0.108
RXHCC134	Depression	0.127	0.172	0.137	0.206	0.108
RXHCC135	Anxiety Disorders	0.051	0.113	0.085	0.171	0.108
RXHCC145	Autism	0.127	0.172	0.368	0.374	0.108
RXHCC146	Profound or Severe Intellectual Disability/Developmental Disorder	-	0.172	0.368	0.334	-
RXHCC147	Moderate Intellectual Disability/Developmental Disorder	-	-	0.240	0.158	-
RXHCC148	Mild or Unspecified Intellectual Disability/Developmental Disorder	-	-	0.096	0.033	-
RXHCC156	Myasthenia Gravis, Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.361	0.565	0.388	0.574	0.179
RXHCC157	Spinal Cord Disorders	0.114	0.088	0.094	0.057	0.054
RXHCC159	Inflammatory and Toxic Neuropathy	0.171	0.385	0.169	0.331	0.079
RXHCC160	Multiple Sclerosis	2.350	3.951	2.012	4.067	0.970
RXHCC161	Parkinson`s and Huntington`s Diseases	0.505	0.699	0.316	0.436	0.224
RXHCC163	Intractable Epilepsy	0.298	0.550	0.311	1.031	0.093
RXHCC164	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	0.121	0.075	0.048	0.148	-
RXHCC165	Convulsions	0.053	0.024	0.029	0.068	-
RXHCC166	Migraine Headaches	0.138	0.207	0.127	0.141	0.110
RXHCC168	Trigeminal and Postherpetic Neuralgia	0.134	0.294	0.157	0.212	0.193
RXHCC185	Primary Pulmonary Hypertension	0.740	2.201	0.633	1.800	0.255
RXHCC186	Congestive Heart Failure	0.166	0.146	0.225	0.143	0.138
RXHCC187	Hypertension	0.123	0.072	0.189	0.108	0.059
RXHCC188	Coronary Artery Disease	0.125	0.012	0.141	-	0.011
RXHCC193	Atrial Arrhythmias	0.288	0.100	0.140	0.010	0.087
RXHCC206	Cerebrovascular Disease, Except Hemorrhage or Aneurysm	0.044	-	0.040	-	-
RXHCC207	Spastic Hemiplegia	0.191	0.148	0.032	0.160	-
RXHCC215	Venous Thromboembolism	0.145	0.189	0.094	0.107	0.049
RXHCC216	Peripheral Vascular Disease	-	-	0.021	-	-
RXHCC225	Cystic Fibrosis	0.745	5.449	0.364	5.262	1.159
RXHCC226	Chronic Obstructive Pulmonary Disease and Asthma	0.334	0.139	0.364	0.257	0.201
RXHCC227	Pulmonary Fibrosis and Other Chronic Lung Disorders	0.334	0.139	0.174	0.257	0.039

Continuing Enrollees (CE) RxHCC Model Segments

Variable	Disease Group	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
RXHCC241	Diabetic Retinopathy	0.307	0.231	0.226	0.150	0.160
RXHCC243	Open-Angle Glaucoma	0.280	0.235	0.335	0.271	0.228
RXHCC260	Kidney Transplant Status	0.330	0.163	0.380	0.419	0.187
RXHCC261	Dialysis Status	0.246	0.508	0.484	0.928	0.409
RXHCC262	Chronic Kidney Disease Stage 5	0.093	0.119	0.084	0.043	0.057
RXHCC263	Chronic Kidney Disease Stage 4	0.093	0.119	0.084	0.043	0.057
RXHCC311	Chronic Ulcer of Skin, Except Pressure	0.162	0.166	0.102	0.099	0.055
RXHCC314	Pemphigus	0.356	0.650	0.195	0.123	0.041
RXHCC316	Psoriasis, Except with Arthropathy	0.205	0.249	0.408	0.720	0.277
RXHCC355	Narcolepsy and Cataplexy	0.806	1.332	0.649	1.351	0.251
RXHCC395	Lung Transplant Status	1.201	0.781	0.985	0.861	0.871
RXHCC396	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	1.039	0.781	0.985	0.861	0.187
RXHCC397	Pancreas Transplant Status	0.330	0.163	0.380	0.233	0.187
Non-Aged Disease Interactions						
NonAged_RXHCC1	NonAged * HIV/AIDS	-	-	-	-	0.907
NonAged_RXHCC130	NonAged * Schizophrenia	-	-	-	-	0.276
NonAged_RXHCC131	NonAged * Bipolar Disorders	-	-	-	-	0.275
NonAged_RXHCC132	NonAged * Major Depression	-	-	-	-	0.184
NonAged_RXHCC133	NonAged * Specified Anxiety, Personality, and Behavior Disorders	-	-	-	-	0.224
NonAged_RXHCC134	NonAged * Depression	-	-	-	-	0.113
NonAged_RXHCC135	NonAged * Anxiety Disorders	-	-	-	-	0.189
NonAged_RXHCC160	NonAged * Multiple Sclerosis	-	-	-	-	1.327
NonAged_RXHCC163	NonAged * Intractable Epilepsy	-	-	-	-	0.246

Note: The Part D Denominator used to calculate relative factors is $1,047.96. This Part D Denominator is based on the combined PDP and MA-PD populations.

Source: RTI Analysis of 100% 2015 PDE, 2014 Carrier NCH, 2014 Inpatient SAF, 2014 Outpatient SAF, 2015 HPMS, 2015 CME, 2014-2015 Denominator, Part D Intermediate File, and 2014 Medicare Advantage Diagnoses File.

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

Variable	Not Concurrently ESRD, Not Originally Disabled	Concurrently ESRD, Not Originally Disabled	Originally Disabled, Not Concurrently ESRD	Originally Disabled, Concurrently ESRD
Female				
0-34 Years	0.697	0.946	-	-
35-44 Years	1.208	1.208	-	-
45-54 Years	1.312	1.583	-	-
55-59 Years	1.255	1.744	-	-
60-64 Years	1.245	1.930	-	-
65 Years	0.531	1.930	1.142	1.930
66 Years	0.581	1.930	1.168	1.930
67 Years	0.595	1.930	1.168	1.930
68 Years	0.612	1.930	1.168	1.930
69 Years	0.637	1.930	1.168	1.930
70-74 Years	0.666	1.930	1.057	1.930
75-79 Years	0.685	1.930	0.803	1.930
80-84 Years	0.620	1.930	0.620	1.930
85-89 Years	0.614	1.930	0.614	1.930
90-94 Years	0.351	1.930	0.351	1.930
95 Years or Over	0.351	1.930	0.351	1.930
Male				
0-34 Years	0.462	0.840	-	-
35-44 Years	0.853	1.251	-	-
45-54 Years	1.149	1.584	-	-
55-59 Years	1.223	1.793	-	-
60-64 Years	1.194	2.101	-	-
65 Years	0.594	1.948	1.029	1.948
66 Years	0.639	1.948	1.024	1.948
67 Years	0.656	1.948	1.024	1.948
68 Years	0.686	1.948	1.024	1.948
69 Years	0.706	1.948	1.024	1.948
70-74 Years	0.751	1.948	0.951	1.948
75-79 Years	0.778	1.948	0.778	1.948
80-84 Years	0.705	1.948	0.705	1.948
85-89 Years	0.659	1.948	0.659	1.948
90-94 Years	0.314	1.948	0.314	1.948
95 Years or Over	0.314	1.948	0.314	1.948

Notes:

1. The Part D Denominator used to calculate relative factors is $1,047.96. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. Originally Disabled is defined as originally entitled to Medicare by disability only (OREC = 1).
3. For new enrollees, the concurrent ESRD marker is defined as at least one month in the payment year of ESRD status—dialysis, transplant, or post-graft.

Source: RTI Analysis of 100% 2015 PDE, 2014 Carrier NCH, 2014 Inpatient SAF, 2014 Outpatient SAF, 2015 HPMS, 2015 CME, 2014-2015 Denominator, Part D Intermediate File, and 2014 Medicare Advantage Diagnoses File.

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

Variable	Not Concurrently ESRD, Not Originally Disabled	Concurrently ESRD, Not Originally Disabled	Originally Disabled, Not Concurrently ESRD	Originally Disabled, Concurrently ESRD
Female				
0-34 Years	1.024	2.151	-	-
35-44 Years	1.531	2.198	-	-
45-54 Years	1.583	2.285	-	-
55-59 Years	1.466	2.401	-	-
60-64 Years	1.376	2.234	-	-
65 Years	0.901	2.185	1.249	2.185
66 Years	0.601	2.185	0.836	2.185
67 Years	0.601	2.185	0.836	2.185
68 Years	0.601	2.185	0.836	2.185
69 Years	0.601	2.185	0.836	2.185
70-74 Years	0.606	2.185	0.787	2.185
75-79 Years	0.664	2.185	0.664	2.185
80-84 Years	0.664	2.185	0.664	2.185
85-89 Years	0.664	2.185	0.664	2.185
90-94 Years	0.564	2.185	0.564	2.185
95 Years or Over	0.564	2.185	0.564	2.185
Male				
0-34 Years	0.883	2.248	-	-
35-44 Years	1.264	2.252	-	-
45-54 Years	1.462	2.331	-	-
55-59 Years	1.376	2.189	-	-
60-64 Years	1.289	2.141	-	-
65 Years	0.896	2.033	1.145	2.033
66 Years	0.579	2.033	0.742	2.033
67 Years	0.554	2.033	0.742	2.033
68 Years	0.509	2.033	0.742	2.033
69 Years	0.509	2.033	0.742	2.033
70-74 Years	0.527	2.033	0.591	2.033
75-79 Years	0.545	2.033	0.545	2.033
80-84 Years	0.555	2.033	0.555	2.033
85-89 Years	0.528	2.033	0.528	2.033
90-94 Years	0.412	2.033	0.412	2.033
95 Years or Over	0.412	2.033	0.412	2.033

Notes:

1. The Part D Denominator used to calculate relative factors is $1,047.96. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. Originally Disabled is defined as originally entitled to Medicare by disability only (OREC = 1).
3. For new enrollees, the concurrent ESRD marker is defined as at least one month in the payment year of ESRD status—dialysis, transplant, or post-graft.

Source: RTI Analysis of 100% 2015 PDE, 2014 Carrier NCH, 2014 Inpatient SAF, 2014 Outpatient SAF, 2015 HPMS, 2015 CME, 2014-2015 Denominator, Part D Intermediate File, and 2014 Medicare Advantage Diagnoses File.

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

Variable	Not Concurrently ESRD	Concurrently ESRD
Female		
0-34 Years	2.783	2.796
35-44 Years	2.783	2.796
45-54 Years	2.431	2.796
55-59 Years	2.512	2.796
60-64 Years	2.116	2.796
65 Years	2.204	2.796
66 Years	1.929	2.796
67 Years	1.929	2.796
68 Years	1.929	2.796
69 Years	1.929	2.796
70-74 Years	1.802	2.796
75-79 Years	1.570	2.796
80-84 Years	1.430	2.796
85-89 Years	1.367	2.796
90-94 Years	1.090	2.796
95 Years or Over	1.090	2.796
Male		
0-34 Years	2.419	2.812
35-44 Years	2.603	2.812
45-54 Years	2.374	2.812
55-59 Years	2.166	2.812
60-64 Years	2.109	2.812
65 Years	2.063	2.812
66 Years	1.794	2.812
67 Years	1.794	2.812
68 Years	1.794	2.812
69 Years	1.794	2.812
70-74 Years	1.699	2.812
75-79 Years	1.699	2.812
80-84 Years	1.508	2.812
85-89 Years	1.343	2.812
90-94 Years	1.343	2.812
95 Years or Over	1.343	2.812

Notes:

1. The Part D Denominator used to calculate relative factors is $1,047.96. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. For new enrollees, the concurrent ESRD marker is defined as at least one month in the payment year of ESRD status—dialysis, transplant, or post-graft.

Source: RTI Analysis of 100% 2015 PDE, 2014 Carrier NCH, 2014 Inpatient SAF, 2014 Outpatient SAF, 2015 HPMS, 2015 CME, 2014-2015 Denominator, Part D Intermediate File, and 2014 Medicare Advantage Diagnoses File.

Table VII-5. List of Disease Hierarchies for RxHCC Model

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

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

Source: RTI International.

Attachment VIII. 2018 Call Letter

CY 2018 Call Letter
Table of Contents

How to Use This Call Letter

The 2018 Call Letter contains information on the Part C and Part D programs that Medicare Advantage Organizations (MAOs), Part D sponsors, and Medicare-Medicaid Plans (MMPs) need to take into consideration in preparing their 2018 bids.

If you have questions concerning this Call Letter, please contact: Jelani Murrain at Jelani.Murrain@cms.hhs.gov (Part C issues), Lucia Patrone at Lucia.Patrone@cms.hhs.gov (Part D issues) and mmcocapsmodel@cms.hhs.gov (MMP issues).

Section I – Parts C and D

Annual Calendar

Below is a combined calendar listing of 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, including the date when bids are due to CMS, the date that organizations must inform CMS of their contract non-renewal, and dates for beneficiary mailings.

2018*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
January 10, 2017	Release of Contract Year CY 2018 Initial and Service Area Applications for MA/MA-PD/PDP, MMP, SNP, EGWP, and 1876 Cost Plan Expansions.	✓	✓	✓	✓
January 10, 2017	MOC Renewal Submission period begins for SNP and MMP MOCs with approvals ending 12/31/2017.	✓			✓
January 2017	Industry Training and Technical Assistance for CY 2018 Model of Care (MOC) Submissions.	✓			✓
January 11 & 18, 2017	Industry training on 2018 Applications.	✓	✓	✓	✓
February 15, 2017	CY 2018 Initial and Service Area Expansion Application for MA/MA-PD/PDP, MMP, SNP, EGWP, and 1876 Cost Plan Expansion are due in the Health Plan Management System (HPMS) by 8pm EST.	✓	✓	✓	✓
February 15, 2017	MOC Renewals Submissions for SNP and MMP MOCs with approvals ending as of 12/31/2017 are due in HPMS by 8pm EST.	✓			✓
Late February, 2017	Submission of meaningful use HITECH attestation for qualifying MA Employer Plans and MA-affiliated hospitals.	✓			
February, 2017	CMS releases instructional memo concerning updates to Parent Organization designations in HPMS.	✓	✓	✓	✓
March 17, 2017	Parent Organization Update requests from MAOs and sponsors due to CMS (instructional memo released in February 2017).	✓	✓	✓	✓
Mid-Late March, 2017	Release of CY 2018 Formulary Reference File (FRF).	✓	✓	✓	✓
March 24, 2017	Release of the Fiscal Soundness Module in HPMS.	✓	✓	✓	✓
March/April, 2017	CMS coordinates with MAOs and PDP Sponsors to resolve low enrollment issues for CY 2018.	✓	✓	✓	

2018*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
Early April, 2017	CY 2018 Out Of Pocket Cost (OOPC) model and OOPC estimates for each plan made available to MAOs, 1876 cost plans submitting MA conversion bids, and Part D sponsors for download from the CMS website. Information will assist plans in meeting meaningful difference and Total Beneficiary Cost (TBC) requirements prior to bid submission.	✓	✓	✓	
Early April, 2017	Information about renewal options for CY 2018 (including HPMS crosswalk charts) provided to plans.	✓	✓		
April 3, 2017	Release of the 2018 Final Announcement of Medicare Advantage Capitation Rates and MA and Part D Payment Policies released, including the CY 2018 Call Letter.	✓	✓	✓	✓
April 5, 2017	Conference call with industry to discuss the Rate Announcement and CY 2018 Call Letter.	✓	✓	✓	✓
April 5, 2017	Industry training on CY 2018 Part D Formulary and Benefit Submission/Compliance Training.	✓	✓	✓	✓
April 7, 2017	Release of the CY 2018 Plan Benefit Package (PBP) online training module.	✓	✓	✓	✓
April 7, 2017	Release of the CY 2018 Plan Creation Module, PBP, and Bid Pricing Tool (BPT) software in HPMS.	✓	✓	✓	✓
April 11, 2017	Deadline for MAOs and cost plans to submit requests for full contract consolidations for CY 2018.	✓		✓	
Mid-April, 2017	Release of HPMS Memo: Contract Year 2018 Medicare Advantage Bid Review and Operations Guidance.	✓			
April 17, 2017	Release of the CY 2018 Medication Therapy Management (MTM) Program Submission in HPMS (11:59 p.m. PDT).		✓		✓
Mid-Late April, 2017	MAOs submit plan requests for tiering of medical benefits and justifications to CMS for review and consideration.	✓			
Late April, 2017	Total Beneficiary Cost data for CY 2018 Bid Preparation Release.	✓			
May, 2017	Final ANOC/EOC, LIS rider, Part D EOB, formularies, transition notice, provider directory, pharmacy directory, and MMP models for CY 2018 available for all organizations.	✓	✓	✓	✓
May 1, 2017	MA, MA-PD and PDP plans to notify CMS of intention to non-renew, as applicable, a county (ies) or region(s) for individuals, but continue the county (ies) or region(s) 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.	✓	✓	✓	

2018*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
May 1, 2017	Deadline for submission of CY 2018 MTM Programs from all sponsors offering Part D including Medicare-Medicaid Plans (except those participating in the Enhanced MTM Model test) (11:59 p.m. PDT).		✓		✓
May, 2017	2017 Medicare Advantage & Prescription Drug Plan Spring Conference & Webcast.	✓	✓	✓	✓
May 5, 2017	Release of the CY 2018 Bid Upload Functionality in HPMS.	✓	✓	✓	✓
May 15, 2017	Deadline for submission of CY 2018 MTM Program attestations in HPMS (11:59pm PDT).		✓		✓
May 15, 2017	Release of CY 2018 Formulary Submission Module in HPMS.	✓	✓	✓	✓
May 19, 2017	Release of CY 2018 Actuarial Certification Module in HPMS.	✓	✓	✓	
Mid-Late May, 2017	Release of CY 2018 Formulary Reference File Update.	✓	✓	✓	✓
May 26, 2017	Plans/Part D sponsors begin to upload agent/broker compensation information in HPMS.	✓	✓	✓	✓
May 26, 2017	Release of the CY 2018 Marketing Module in HPMS. Plans/Part D sponsors begin to submit 2018 marketing materials.	✓	✓	✓	✓
Late May/Early June, 2017	Release of the CY 2018 Medicare Marketing Guidelines in HPMS.	✓	✓	✓	✓
Late May, 2017	CMS sends qualification determinations to applicants based on review of the CY 2018 applications for new contracts or service area expansions.	✓	✓	✓	✓
June 2017	Release of state-specific marketing guidance for MMPs.				✓
June 1, 2017	Release of the 2016 DIR Submission Module in HPMS.	✓	✓	✓	✓

2018*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
June 5, 2017	Deadline for submission of CY 2018 bids (including Service Area Verification) for all MA plans, MA-PD plans, PDP, cost-based plans offering a Part D benefit, Medicare-Medicaid Plans (MMPs), "800 series" EGWP and direct contract EGWP applicants and renewing organizations; deadline for cost-based plans wishing to appear in the 2018 Medicare Plan Finder to submit PBPs (11:59 p.m. PDT). Deadline for submission of CY 2018 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 2018 contract non-renewal, service area reduction notice to CMS from MA plans, MA-PD plans, MMPs, 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 2018.	✓	✓	✓	✓ *Non-bid related items only*
Early June to Early September, 2017	CMS completes review and approval of CY 2018 bid data, to include pricing, plan benefit packages, and formularies. Plans/Part D sponsors submit attestations, contracts, initial actuarial certifications, and final actuarial certifications.	✓	✓	✓	✓
June 6-9, 2017	Window for submitting first round of crosswalk exception requests through HPMS.	✓	✓	✓	
June 9, 2017	Deadline for submission of CY 2018 Supplemental Formulary files, Free First Fill file, Partial Gap file, Excluded Drug file, Over the Counter (OTC) drug file, Home Infusion file, and Non-Extended Day Supply file through HPMS (11:59 a.m. EDT).		✓		✓
June 9, 2017	Deadline for submission of Medicare Advantage Value Based Insurance Design (VBID) file *(Only applicable to Medicare Advantage Plans that have been preapproved for Part D VBID benefits)* (11:59 a.m. EDT).	✓			
June 9, 2017	Deadline for submission of Additional Demonstration Drug (ADD) file *(Medicare-Medicaid Plans Only)* (11:59 a.m. EDT).				✓
June, 2017	2017 MA and PDP Audit and Enforcement Conference and Webcast.	✓	✓	✓	✓
Late June, 2017	CMS sends an acknowledgement letter to all MA, MA-PD, MMP, PDP and Medicare cost-based plans that are non-renewing or reducing their service area.	✓	✓	✓	✓

2018*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
Early July, 2017	2018 Plan Finder pricing test submissions begin.	✓	✓	✓	✓
July 1, 2017	Deadline for D-SNPs to upload required State Medicaid Agency Contract and Contract Matrix to HPMS.	✓			
July 1, 2017	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, 2017	Plans' deadline to submit non-model Low Income Subsidy (LIS) riders to the appropriate Regional Office for review.	✓			
Mid July, 2017	Release of CY 2018 FRF Update in advance of the Limited Formulary Update Window.	✓	✓	✓	✓
Mid-Late July, 2017	CY 2018 Limited Formulary Update Window.	✓	✓	✓	✓
Late July, 2017	Submission deadline for agent/broker compensation information via HPMS.	✓	✓	✓	✓
Mid-Late July, 2017	Second window for submitting HPMS crosswalk exceptions.	✓	✓	✓	
Late July / Early August, 2017	CMS releases the 2018 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, 2017	Rebate reallocation period begins after release of the above bid amounts.	✓	✓	✓	
No Later Than July 29, 2017	CMS informs currently contracted organizations of its decision to not renew a contract for 2018.	✓	✓	✓	
August 1, 2017	Plans expected to submit model Low Income Subsidy (LIS) riders in HPMS.	✓	✓	✓	
August 18, 2017	Deadline for organizations to complete the plan connectivity data in HPMS to ensure timely approval of contracts.	✓	✓	✓	✓
August 17-21, 2017	CY 2018 preview of the 2018 *Medicare & You* plan data in HPMS prior to printing of the CMS publication (not applicable to EGWPs).	✓	✓	✓	✓
August 23-25, 2017	First CY 2018 Medicare Plan Finder (MPF) Preview and Out- of-Pocket Cost (OOPC) Preview in HPMS.	✓	✓	✓	✓ *MPF only*
August 31, 2017	CY 2018 MTM Program Annual Review completed.		✓		✓
Late August, 2017	Contracting Materials submitted to CMS.	✓	✓	✓	
End of August/Early September, 2017	Plan preview periods of Part C & D Star Ratings in HPMS.	✓	✓	✓	
Early September, 2017	CMS begins accepting plan correction requests upon contract approval.	✓	✓	✓	

2018*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
Mid- September, 2017	All 2018 contracts fully executed (signed by both parties: Part C/Part D Sponsor and CMS).	✓	✓	✓	
September 5-8, 2017	Second CY 2018 Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HPMS.	✓	✓	✓	✓ *MPF only*
September 16 -30, 2017	CMS mails the 2018 *Medicare & You* handbook to Medicare beneficiaries.	✓	✓	✓	✓
Late September, 2017	D-SNPs that requested review for FIDE SNP determination notified as to whether they meet required qualifications.	✓			
Late September , 2017	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.	✓	✓	✓	
September 30, 2017	Deadline for plans to provide the following documents to current enrollees: • Standardized Annual Notice of Change/Evidence of Coverage (ANOC/EOC) for all MA, MA-PD, PDP, and cost-based plans (including those not offering Part D and those that do offer Part D). • Standardized ANOC with the Summary of Benefits for D-SNPs and MMPs that choose to separate the ANOC from the EOC. • Abridged or comprehensive formularies • LIS rider • Pharmacy/Provider directories The documents identified above are the only CY 2018 documents permitted to be sent prior to October 1, 2017.	✓	✓	✓	✓
October 1, 2017	Organizations may begin marketing their CY 2018 plan benefits. Note: Once an organization begins marketing CY 2018 plans, the organization must cease marketing CY 2017 plans to anyone other than beneficiaries who are eligible for valid enrollment (e.g. age-ins and special enrollment periods (SEP)). Organizations may still provide CY 2017 materials upon request, conduct one-on-one sales appointments, and process enrollment applications.	✓	✓	✓	✓
October 1, 2017	Tentative date for CY 2018 plan and drug benefit data to be displayed on Medicare Plan Finder on Medicare.gov (not applicable to EGWPs).	✓	✓	✓	✓
October 2, 2017	The final personalized beneficiary non-renewal notification letter must be received by PDP, MA plan, MA-PD plan, MMP and cost-based plan enrollees. PDPs, MA plans, MA-PD plans, MMPs and cost-based organizations may not market to beneficiaries of non-renewing plans until after October 2, 2017.	✓	✓	✓	✓

2018*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
October 11, 2017	Part C & D Star Ratings go live on medicare.gov on or around October 11, 2017.	✓	✓	✓	
October 15, 2017	Part D sponsors must post prior authorization and step therapy criteria on their websites for CY 2018.		✓		✓
October 15, 2017	2018 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).	✓	✓		✓
Mid October, 2017	Release of the online CY 2019 Notice of Intent to Apply for a New Contract or a Contract Expansion (MA, MA-PD, MMP, PDPs, and "800 series" EGWPs and Direct Contract EGWPs).	✓	✓	✓	✓
November 13, 2017	Notices of Intent to Apply (NOIA) for CY 2019 due for MA and MA-PD plans, MMP, PDPs, and "800 series" EGWPs and Direct Contract EGWPs.	✓	✓		✓
Early November, 2017	First display of Plan Finder data for sponsors/MA organizations that submitted a plan correction request after bid approval.	✓	✓	✓	✓
Late November, 2017	Part C & D display measures data are posted in HPMS for plan preview.	✓	✓	✓	
November – December, 2017	CMS issues "close out" information and instructions to MA plans, MA-PD plans, MMPs, PDPs, and cost-based plans that are non- renewing or reducing service areas.	✓	✓		✓
December 1, 2017	Enrollees in Medicare cost-based plans not offering Part D must receive the combined ANOC/EOC.			✓	
December 1, 2017	Cost-based plans must publish notice of non-renewal, as per §417.494 of Title 42 of the CFR.			✓	
December 7, 2017	End of the Annual Election Period.	✓	✓		✓
Mid December, 2017	Part C & D display measures data on cms.gov updated.	✓	✓	✓	
December 31, 2017	Deadline for MMPs that separated the ANOC from the EOC to provide the EOC to enrollees.				✓
2018					
January 1, 2018	Plan Benefit Period Begins.	✓	✓	✓	✓
January 1 – February 14, 2018	Annual 45-Day Medicare Advantage Disenrollment Period (MADP).	✓			
Early January 2018	Release of CY 2019 MAO/MA-PD/MMP/PDP/SAE/EGWP applications.	✓	✓		✓
Mid-January, 2018	Industry training on CY 2019 applications.	✓	✓	✓	✓
Mid-February 2018	Applications due for CY 2019.	✓	✓	✓	✓

2018*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		*Part C	*Part D	Cost	MMP
June 4, 2018	CY 2019 Deadline for bid and formulary submission.	✓	✓	✓	✓ *Non-bid related items only*

Social Security Number Removal Initiative (SSNRI)

The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (PL 114-10 §501) included a mandate to remove the current Health Insurance Claim Number (HICN) from Medicare cards. This is a reminder that beginning in 2018 the current Social Security based HICN will be replaced with a Medicare Beneficiary Identification number (MBI). MBIs will be assigned to all Medicare recipients, and cards will be mailed to beneficiaries beginning April 2018.

CMS is aware that plans are preparing to modify applicable systems, processes, and relevant forms to account for use of either a HICN or MBI. This includes being able to accept and process enrollment requests which include either the HICN or the MBI via all CMS-approved enrollment mechanisms, as well as planning for potential impacts on appeals-related and Part D Coordination of Benefits-related functions. Additional policy and operational information for these business processes as well as for other business processes and systems will be issued in the future to assist plans with making these changes.

SSNRI-related information for Medicare health and drug plans will be disseminated in the same manner that all other policy and system updates are distributed. The information will also be posted to a Social Security Number Removal Initiative (SSNRI) webpage, https://www.cms.gov/Medicare/SSNRI/Index.html. CMS posts updates as they become available, and plans can use that site as an additional resource. For questions about how SSNRI will impact various systems, please refer to the contact list provided in the HPMS memorandum released on November 18, 2016, titled "Social Security Number Removal Initiative (SSNRI) Selected Updates for Medicare Advantage and Part D Plans."

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 2018, the bid submission deadline is June 5, 2017 at 11:59 PM Pacific Daylight Time.

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

- Plan Benefit Package (PBP),
- Bid Pricing Tool (BPT) (if applicable),
- Service Area Verification (SAV),
- Plan Crosswalk (if applicable),
- Cost Sharing Justification (if applicable, as described in the "Part C Cost Sharing Standards" section of this Call Letter),
- Formulary Submission (if offering a Part D plan with a formulary),
- Formulary Crosswalk (if offering a Part D plan with a formulary); and
- Substantiation (supporting documentation for bid pricing).

MA, MA-PD, PDP, and cost-based plans are responsible for confirming that complete and accurate bids are submitted by the June deadline. Consistent with past years, CMS reminds organizations that all required components of an organization's bid must be submitted by the deadline in order for the bid to be considered complete. If any of the required components are not successfully 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) 2017 Bid Upload Functionality in HPMS," dated May 6, 2016).

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. Organizations should 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 the HPMS Help Desk at hpms@cms.hhs.gov about any technical upload or validation errors well in advance of the bid submission deadline. All organizations should make sure that appropriate personnel are available both before and after the bid submission deadline to address any ongoing bid upload and/or validation issues that might prevent the bid from proceeding to desk review.

Inaccurate Submissions

CMS reminds organizations that it will only approve a Part D bid under 42 C.F.R. §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' and sponsors' time and call into question an organization's or a sponsor'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 the CY 2018 Call Letter, or
- A Part D bid that includes an incorrect PBP-to-formulary crosswalk.

CMS will issue a compliance notice or request for a corrective action plan to organizations and sponsors that submit clearly inaccurate bids on June 5, 2017 or otherwise violate bidding procedures. Actions triggering such compliance action could include, but are not limited to, the resubmission of bids prior to CMS authorization for bid modification, failure to meet Part C and D requirements, or failure to meet established thresholds. In addition, organizations and sponsors that submit inaccurate bids may not be allowed to revise their bids to correct inaccuracies, and the bids may be denied. Organizations and sponsors should engage in sufficient due diligence to make certain their bids are accurate before submission.

Plan Corrections

As required by 42 C.F.R. §§422.254, 423.265(c)(3) and 423.505(k)(4), completion of the final actuarial certification serves as documentation that the final bid, as uploaded, has been verified and is complete and accurate at the time of submission. A request by an organization or sponsor for a plan correction indicates the presence of inaccuracies and/or the incompleteness of a bid and calls into question an organization's or sponsor's ability to submit correct bids and the validity of the final actuarial certification and bid attestation.

After bids are approved, CMS will not reopen the submission gates to correct errors identified by the organization or sponsor until the plan correction window in September. The plan correction window will be open from early September to late September 2017 and the specific dates will be announced in future guidance. The only changes to the PBP that are 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 and can use the HPMS bid reports to verify the accuracy of the submitted bids. 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 requests for corrective action plans to organizations and sponsors that have demonstrated a consistent pattern of bid submission errors over multiple contract years and/or previously received a compliance notice relating to a plan correction for CY 2017.

We received a few comments expressing concerns about CMS issuing compliance actions for minor data input errors. The organizations asked CMS to define what types of errors need to be submitted as a plan correction. A plan correction provides plans with the opportunity to change information in the PBP and must be supported by the BPT. Typos or minor data input errors that do not affect benefits do not need to be submitted as a plan correction. MA organizations are encouraged to conduct a quality review prior to bid submission, and are permitted to make necessary changes during the bid review process to align information in the PBP with the submitted BPT.

Enhancements to the 2018 Star Ratings and Beyond

One of CMS' most important strategic goals is to improve the quality of care and general health status for Medicare beneficiaries. For the 2018 Star Ratings, CMS continues to enhance the Star Ratings methodology to align with our policy goals. In this document, we describe enhancements for the 2018 Star Ratings and beyond. Except as noted below, the methodology to calculate the ratings will remain the same as the 2017 Star Ratings. In the coming year CMS will continue to include stakeholders in discussions about how the Star Ratings program, including our data integrity review process, should continue to evolve. We will continue to engage with stakeholders about these efforts and to explore the potential overlap of various CMS measurements, such as Star Ratings, past performance criteria, audits, and enforcement actions, so as to discern the way each of these should relate to the others and best accomplish their particular purpose. As part of the process discussed in Attachment I, CMS welcomes ideas from advocates and health and drug plans about improving the rigor and validity of the Star Ratings to reflect the quality of care provided.

CMS publishes the Part C and D Star Ratings each year to measure both the quality of and reflect the experiences of beneficiaries in Medicare Advantage (MA) and Prescription Drug Plans (PDPs or Part D plans), assist beneficiaries in finding the best plan, and determine MA Quality

Bonus Payments. Further, the Star Ratings support the efforts of CMS to improve the level of accountability for the care provided by physicians, hospitals, and other providers.

Given the pivotal role of the Star Ratings in achieving our goals, CMS continually reviews the measures and the methodology (used to generate the ratings) to incentivize plans, and provide information that is a true reflection of plan performance and enrollee experience. We remain cognizant of the unique challenges of serving traditionally underserved subsets of the population. In addition to conducting our own research, CMS stays abreast of the related research and listens carefully to any concerns about the Star Ratings. CMS works in collaboration with beneficiaries, stakeholders, measure developers, researchers, and other HHS collaborators to improve the Star Ratings.

For reference, the list of measures and a description of the methodology for the 2017 Star Ratings are included in the Technical Notes available on the CMS webpage: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html.

CMS assigns stars for each numeric measure score by applying one of three methods: clustering, relative distribution and significance testing, or fixed cut points. Each method is described in detail in the Technical Notes. Relative distribution and significance testing are applied to determine valid star cut points for CAHPS measures. The Beneficiary Access and Performance Problems measure uses fixed cut points. Clustering is applied to other Star Ratings measures. The cut points to determine star assignments for all measures and case-mix coefficients for the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey and Health Outcomes Survey (HOS) will be updated for 2018 using the most current data available.

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

Part C and D sponsors should regularly review their underlying measure data that are the basis for the Part C and D Star Ratings. CMS expects sponsors to routinely monitor these data and immediately alert CMS if errors or anomalies are identified so any issues can be resolved prior to the first plan preview period. For example, any necessary changes to the Independent Review Entity (IRE) data must be made by June 30 of the following year in order for the changes to be reflected in a contract's Star Ratings data (e.g., changes to 2016 IRE data must be made by June 30, 2017 for the 2018 Star Ratings).

We appreciate the feedback we received on the draft CY 2018 Call Letter. A summary of comments is available in Appendix 2.

New and Returning Measures for 2018

- **Medication Reconciliation Post Discharge (Part C)**. The Medication Reconciliation Post-Discharge (MRP) measure assesses the percentage of discharges from acute or non-acute inpatient facilities for members 66 years of age and older for whom medications were reconciled within 30 days of discharge. This measure has been collected in SNP HEDIS since 2008 but was expanded for the 2015 performance year to all MA plans, rather than only Medicare SNPs, and was expanded to cover all members age 18 years and older. Both of these changes are important steps to measure the quality of care coordination post-discharge for MA beneficiaries as well as ensuring patient safety. CMS included this measure on the 2017 display page. Going forward and depending on the performance of the wider range of plans, CMS is considering combining this indicator with other measures into a more comprehensive measure of care transitions. A more comprehensive measure might be more time sensitive to deficits in quality than a measure that is more focused on individual measures. Please refer to the NCQA HEDIS 2017 Technical Specifications for Health Plans Volume 2 for measure construction and technical specifications. CMS shared all comments received on this measure with NCQA. This measure will be classified as a process measure with a weight of 1 for the 2018 Star Ratings.

- **Improving Bladder Control (Part C).** This measure, collected through the Health Outcomes Survey (HOS), assesses the percentage of beneficiaries with urine leakage who discussed their problem with their provider and received treatment for the issue. NCQA made three changes to this measure. First, NCQA changed the denominator of both indicators to include all adults with urinary incontinence, as opposed to limiting the denominator to those who consider urinary incontinence to be a problem. This action removed 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 modification changed the measure focus from "receiving potentially inappropriate treatments", which often have adverse side effects, to "shared decision making" between the patient and provider about the appropriateness of treatment. Third, NCQA added an outcome indicator to assess the degree to which urinary incontinence impacts beneficiaries' quality of life.

  The revised questions were first used in the survey administered in 2015. As a result of these changes, and consistent with past policy regarding measures that have a specification change, this measure was temporarily moved to the display page in the 2016 and 2017 Star Ratings. CMS will move this measure from the display page and return it to the Star Ratings beginning in 2018. For the 2018 Star Ratings, this process measure will revert to the original weight of 1.

Changes to Measures for 2018

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

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

Other modifications for the 2018 Star Ratings include:

- **Improvement measures (Part C & D).** Refer to Appendix 1, Improvement Measures (Part C & D), for updates to the measures to be used to calculate the 2018 improvement measures.

  As announced in the CY 2017 Call Letter, CMS implemented updates to the MA & PDP CAHPS surveys to reflect the CAHPS 5.0 Health Plan Survey starting in 2017. The 5.0 update applies recent improvements in survey design that resulted from development and testing of the Clinician & Group Surveys. The 5.0 version of the CAHPS Health Plan Survey incorporates some minor changes into the wording of core items, and a change in the placement of one core item that also resulted in the deletion of a screener item. Consistent with past practice, we will use the following standard for deciding whether the change is significant enough to exclude the measure from the improvement measure calculation: (1) at least one item within the measure changed in wording, had a wording change in its screener, or had a wording change in the immediately preceding item, and (2) the measure score in version 5.0 was significantly different from the measure score in version 4.0, using data from the 5.0 experiment we conducted in 2015 to understand if/how performance on CAHPS measures differs between versions 4.0 and 5.0. Three MA measures meet this standard: Getting Care Quickly, Customer Service, and Care Coordination. Thus, these three measures will be excluded from the Part C improvement measure for the 2018 Star Ratings.

- **Members Choosing to Leave the Plan (Part C & D).** CMS will modify the list of exclusions in the Technical Notes in this measure by removing the exclusions for

"Members who moved out of the service area" and "SNPs disproportionate share members who do not meet the SNP criteria." CMS enrollment/disenrollment systems identify and exclude these members earlier in the process of data transmission. Therefore, no active reference to exclusion of these data from the numerator is needed in the specification. This change does not affect the data or methodology of how this measure is calculated; it only changes the description of the measure in the Technical Notes.

- **SNP Care Management (Part C) and Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) Measure (Part D).** We will change the display of these measures beginning with the 2018 Star Ratings from a percentage with one decimal point to an integer. The measure values will be rounded to an integer using standard rounding rules prior to applying the clustering methodology to calculate star assignments. This is consistent with CMS' rounding of other measures' data prior to star assignments. CMS tested these data in simulations and found that contracts' Star Ratings either remained the same or increased when these rates were changed from a percentage with one decimal point to an integer. No others changes are being made to the specifications for these measures.

- **Call Center – Foreign Language Interpreter and TTY Availability (Part C & D).** As discussed in the CY 2017 Call Letter, when testing interpreter availability, CMS will allow the interpreter an extra 60 seconds to answer an introductory question. Interpreters will be permitted up to eight minutes to answer the introductory question and up to seven minutes to answer each of the three accuracy questions that follow.

- **MPF Price Accuracy (Part D).** As discussed in the CY 2016 and CY 2017 Call Letters, CMS will enhance this measure for the 2018 Star Ratings, using 2016 Medicare Plan Finder (MPF) pricing and PDE claims. Details about the methodology changes can be found in the CY 2016 Call Letter. These changes 1) modify the PDEs included in this measure, and 2) account for the frequency and magnitude of difference between PDE and MPF prices when a contract's PDE prices are higher than the MPF prices. These changes are intended to better depict the accuracy of a contract's MPF posted prices. Simulations of these changes show generally little impact to contracts' performances, relative to others. Similar to other measures, this measure's cutpoints are generated based on current data. CMS is aware that while the MPF display is updated every two weeks, real time pricing at the point of sale can change as often as every day. Some sponsors have expressed concern that in order to perform well in this measure, they cannot offer lower prices at point of sale in real time than the prices that are displayed on MPF. We note that PDEs priced lower than MPF displayed pricing do not lower a contract's score in this

measure. For consistency, these changes will also be made to the 2018 display measure, Plan Submitted Higher Prices for Display on MPF.

- **Complaints about the Health Plan (Part C) and Complaints about the Drug Plan (Part D).** In the December 16, 2016 HPMS memo, Upcoming Complaints Tracking Module (CTM) Redesign, CMS announced that a redesigned CTM will be launched on March 18, 2017. On February 24, 2017, CMS released an HPMS memo on the Updated Complaints Tracking Module (CTM) Standard Operating Procedures (SOP). The SOP included revisions to the complaint categories and subcategories, including labels to indicate that they are excluded from the Star Ratings complaints measures. For the 2019 Star Ratings, we plan to apply the updated exclusions per the SOP to complaint data for January 1 – December 31, 2017. The updated exclusions were included as part of the CTM redesign implemented in March 2017.

Removal of Measures from Star Ratings

- **High Risk Medication (Part D).** The Pharmacy Quality Alliance (PQA) High Risk Medication (HRM) measure calculates the percentage of Medicare Part D beneficiaries 65 years 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. Based on feedback to the draft CY 2017 Call Letter, the HRM measure remained in the Star Ratings for 2017 (based on 2015 data). As indicated in the final CY 2017 Call Letter, we will move this measure to the display page for 2018 (based on 2016 data) and will continue to provide HRM measure reports to Part D sponsors through the Patient Safety Analysis website and to identify outliers.

Adjusting Star Ratings for Audits and Enforcement Actions

In an HPMS memo released on March 8, 2016, CMS suspended the reduction in the overall and summary Star Ratings of contracts that are under sanction while CMS re-evaluates the impact of sanctions, audits, and civil money penalties (CMPs) on the Star Ratings.

In the process of our review, CMS received input from many stakeholders including MA organizations, PDP sponsors, beneficiary advocates, and providers in response to the draft CY 2017 Call Letter, the MA & PDP Fall Conference and Webcast on September 8, 2016[3], and the Request for Comments (RFC), released on November 10, 2016[4]. CMS appreciates the careful consideration by commenters of the use of audit findings and enforcement actions in the Star Ratings Program. The valuable feedback helped guide the framework of the policy proposed in

[3] https://www.cms.gov/outreach-and-education/training/cteo/event_archives.html

[4] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Request-for-Comments-2018-Stars.pdf

the draft CY 2018 Call Letter that focused on revisions to the Beneficiary Access and Performance Problems (BAPP) measure.

The current BAPP measure is based on CMS' sanctions, CMPs related to beneficiary access, and Compliance Activity Module (CAM) data and has been in use for Star Ratings since 2010. (The detailed BAPP measure specification can be found in the 2017 Star Ratings Technical Notes[5] on pages 50 and 51.) Currently, the BAPP measure receives a weight of 1.5 and is classified as an access measure. The data timeframe for the measure spans from January 1st to December 31st of the measurement period for the Star Ratings year. (For example, for the 2017 Star Ratings, the timeframe used for the BAPP measure was January 1, 2015 through December 31, 2015.) Every contract begins with a BAPP measure score of 100. A contract's score is then reduced contingent on its sanction status, CAM score, and each CMP related to beneficiary access. Contracts under sanction have their score reduced to zero and receive one star for this measure. The CAM portion of the BAPP score combines information on the notices of non-compliance, warning letters (with or without business plan), and ad-hoc CAPs and their severity. The CAM score per contract is calculated and then converted to deductions ranging from 0 to 80 in increments of 20 (see the Technical Notes for details). The CMP portion of the BAPP measure currently carries a 40-point deduction per CMP.

The majority of the comments received in response to the draft CY 2018 Call Letter echoed those received for the November 2016 RFC. Many MAOs and sponsors preferred the decoupling of audits and enforcement actions from Star Ratings, and cited reasons including: the differences in methodologies and goals, the subjective nature of audits, and the absence of audit information for each plan each year. Advocates, however, expressed concern about the increasing disconnect between the audit process and the Star Ratings Program and pushed CMS to reconsider the sanction reduction policy suspended in March 2016. Several commenters suggested an increase in the weight of the BAPP measure to accurately reflect the seriousness of the audit and enforcement actions. If CMS were to move forward with a revised BAPP measure, many commenters preferred CMS maintain the current BAPP measure in the 2018 Star Ratings and introduce the revised BAPP measure in the 2019 Star Ratings, in order to be consistent with the long-standing CMS policy of transparency and prior notice when implementing new or revised measures. Some commenters expressed concern about the proposed data timeframe because it crosses contract years, but others supported the use of more recent data. There was widespread support for the proposed CMP deduction cap of 40 points, the revised CMP deduction methodology, and the revision of the BAPP cut points.

[5] The 2017 Technical Notes can be accessed using the following link: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/ PerformanceData.html.

After consideration of all of the feedback, CMS will retain the current BAPP measure in the 2018 Star Ratings. CMS is not reinstating the reduction in the overall and summary Star Ratings of contracts that are under sanction for the 2018 Star Ratings.

For 2019, CMS intends to remove all enforcement actions and the reduction for plans under sanction due to audit from this measure. As a result of this change, CMS would retire the current BAPP measure for the 2019 Star Ratings. CMS expects to introduce a revised BAPP measure on the 2019 display page. We are considering whether it is feasible to revise the measure to no longer include enforcement actions such as CMPs and sanctions, and instead base it only on CAM data and still have an accurate and valid measure of beneficiary access. We will continue our dialogue with stakeholders and examine the interplay between audits, compliance/enforcement actions, and the Star Ratings, as well as further specification changes to the BAPP measure and the role it should play in Star Ratings. The fall Request for Comments will seek additional input on this issue.

Data Integrity

Data used for the Part C and D Star Ratings must be accurate and reliable. CMS' longstanding policy has been to reduce a contract's measure rating to 1 star if we determine that a contract's measure data are incomplete, biased or erroneous. As discussed in previous Call Letters, these reductions may result if CMS identifies mishandling of data, inappropriate processing, or implementation of incorrect practices impacted specific measure(s). 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' modifications to measure-specific ratings due to data integrity issues are separate from any CMS compliance or enforcement actions related to a sponsor's deficiencies. This policy is necessary to avoid assigning falsely high stars, especially when deficiencies have been identified that show CMS cannot objectively evaluate a sponsor's performance in an area.

Sponsors should refer to specific guidance and technical instructions related to requirements in each of these areas. For example, information about HEDIS measures and technical specifications are posted on: http://www.ncqa.org/HEDISQualityMeasurement/HEDISMeasures.aspx. Information about Data Validation of Reporting Requirements data is posted on https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html.

Given the financial and marketing incentives associated with higher performance in Star Ratings, safeguards are needed to protect the Star Ratings from attempts to inflate performance or mask

deficiencies. CMS has taken several steps in the past years to protect the integrity of the data we use to calculate Star Ratings; however, we continue to identify new vulnerabilities where inaccurate or biased data could result from sponsors' practices. Therefore, CMS will continue to expand reviews to identify incomplete or biased Star Ratings measure data.

CMS piloted a new program audit protocol in 2016 evaluating Part D sponsors' MTM programs. Findings identified during pilots of the new MTM audit protocols are not currently applied to Star Ratings. After the pilot phase, we will review and apply any relevant MTM program audit findings for data integrity reviews for the MTM Comprehensive Medication Review (CMR) Completion Rate measure that could demonstrate systemic failures by sponsors that resulted in biased MTM data.

All four Star Rating appeals measures use data reported by sponsors to the IRE, currently Maximus Federal Services, in compliance with statutory and regulatory requirements. Information collected about a sponsor's processing of Medicare Parts C and D organization/coverage determinations and appeals for an audit may be one source of evaluating the integrity or completeness of sponsors' IRE data. Additionally, targeted review of outlier sponsors' IRE cases is another source of evidence that the sponsors' reporting to the IRE were incomplete or inaccurate.

Even though it is not the only source, sponsors have raised concerns about CMS' use of information provided for an audit to determine if processing errors by the plan have affected the completeness of the IRE data used for Star Ratings, since audits are conducted on a subset of sponsors each year. In addressing this issue, CMS has implemented a monitoring project to assess the completeness of IRE data across all contracts. This project was discussed in the November 28, 2016 HPMS memo, "Industry-wide Appeals Timeliness Monitoring." CMS began the monitoring project in 2017 (using 2016 data on Part C organization determinations and reconsiderations and Part D coverage determinations and redeterminations). CMS will review the findings, and if they are found valid and accurate, incorporate them as part of the data integrity reviews for the four appeals measures beginning with the 2018 Star Ratings. More information will be available after the data are collected from plans in the spring. This approach ensures a level playing field for all sponsors in evaluating their IRE data.

As the draft Call Letter did not propose any change, there is no proposal to finalize regarding this topic. In past Call Letters, when CMS had solicited feedback about making reductions reflect the proportionality of errors, some sponsors were opposed, as they felt this would be subjective. We will examine the appeals timeliness monitoring results with the aim of finding a method for scaled reductions instead of the standard reduction to 1 star. We also welcome additional input about other sources or bases on how to implement such scaled reductions. Conducting comprehensive studies to examine sponsors' IRE data is critical to having accurate measures of health and drug plan performance in the Star Ratings program. We will continue to engage with stakeholders about these efforts.

2018 Star Ratings Program and the Categorical Adjustment Index

In the draft and final CY 2017 Call Letters, CMS described extensive research that was conducted to develop an interim analytical adjustment for the average within-contract disparity in performance associated with a contract's percentages of beneficiaries with low income subsidy and/or dual eligible (LIS/DE) and disability status. CMS' interim response to address the LIS/DE and disability effect revealed in our comprehensive research culminated in the creation of the Categorical Adjustment Index (CAI). The details of the methodology and the 2017 CAI values were released in the final CY 2017 Call Letter and detailed in the 2017 Medicare Part C & D Star Rating Technical Notes available on the CMS webpage at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html.

For the 2018 Star Ratings Program, CMS will continue to use the interim analytical adjustment, the CAI.

As stated in the CY 2017 Call Letter (CY 2017 Rate Announcement, Attachment VII, pages 131-133), the CAI values are updated annually and published in the final Call Letter. The CAI values are determined using the previous rating year's measurement period, which allows the release of the CAI values in advance of the first Star Ratings preview period. Thus, the 2018 CAI values were determined using data from the 2017 Star Ratings, which employ performance data from measurement year 2015.

LIS/DE status for the 2018 Star Ratings is based on the Medicare enrollment data from CY 2016. The disability status of an enrollee is determined using information from the Social Security Administration (SSA) and Railroad Retirement Board (RRB) record systems for CY 2016. Disability status is based on the original reason for entitlement code (OREC).

For the 2018 Star Ratings Program, the analysis and criteria used to select measures for adjustment were the same as those used for the 2017 Star Ratings program. CMS updated its analyses of the measures using the 2015 measurement period data and evaluated the variability of within-contract differences in performance for a similar subset of Star Ratings measures[6] examined last year. A summary of the updated analysis conducted to select the measures including the minimum, median, and maximum values for the within-contract variation for the LIS/DE differences is posted at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/

[6] The 16 clinical quality measures that comprised the subset of the Star Ratings measures examined for the 2017 CAI included: adult BMI assessment, rheumatoid arthritis management, breast cancer screening, controlling blood pressure, diabetes care – blood sugar controlled, diabetes care – eye exam, diabetes care – kidney disease monitoring, colorectal cancer screening, osteoporosis management in women who had a fracture, plan all-cause readmissions, annual flu vaccine, monitoring physical activity, reducing the risk of falling, medication adherence for diabetes medications, medication adherence for hypertension, and medication adherence for cholesterol. For the 2018 CAI analysis, reducing the risk of falling was removed for possible adjustment because it will not be included in the 2018 Star Ratings Program due to a specification change. In addition, plan all-cause readmissions was removed because revisions are under consideration. One new measure was added to the analysis for the 2018 Star Ratings, Medication Therapy Management (MTM) Program Completion Rate for CMR.

PrescriptionDrugCovGenIn/PerformanceData.html. The decision criteria used to select measures for adjustment was (1) a median absolute difference between LIS/DE and non-LIS/DE beneficiaries of 5% or more and/or (2) the LIS/DE subgroup performed better or worse than the non-LIS/DE subgroup in all contracts.

The measures for adjustment for the 2018 Star Ratings include the following three Part C measures for MA (MA-only and MA-PD) and 1876 contracts: Breast Cancer Screening, Osteoporosis Management in Women Who had a Fracture, and Diabetes Care – Blood Sugar Controlled. Similar to last year, in order to apply consistent adjustments across MA-PDs and PDPs, the Part D measures were selected by applying the selection criteria to MA-PDs and PDPs independently and, then, selecting measures that met the criteria for either delivery system. For the 2018 Star Ratings program, the two Part D measures: Medication Adherence for Hypertension (RAS antagonists) and Medication Therapy Management (MTM) Program Completion Rate for CMR are included for adjustment for MA-PDs and PDPs.

2018 Categorical Adjustment Index (CAI) Values

MA contracts have up to three mutually exclusive and independent adjustments – one for the overall Star Rating and one for each of the summary ratings (Part C and Part D). PDPs have one adjustment for the Part D summary rating. Tables 3 – 14 provide the rating-specific categories for classification of contracts based on the percentage of LIS/DE and disabled beneficiaries along with the final adjustment categories.

Table 1 provides the range for the percentages that correspond to the LIS/DE categories determined by dividing the distribution of MA contracts LIS/DE percentages into twelve equal-sized groups. Table 2 provides the range of the percentages that correspond to the disability quintiles for the categorization of MA contracts for the CAI for the overall Star Rating.

The upper limit for each category is not included in that category, but rather the next higher category. For example, if a contract's percentage of LIS/DE beneficiaries is 8.110160%, the contract's LIS/DE initial category is L3 (Table 1). The exceptions for the upper limit exclusion for a class are the 12^{th} initial category for LIS/DE and the 5^{th} quintile for disabled (Table 1 and 2, respectively). Table 3 provides the description of each of the final adjustment categories for the overall Star Rating for MA contracts and the associated values of the CAI for each final adjustment category.

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

LIS/DE Initial Group	Percentage of Contract's LIS/DE Beneficiaries
L1	0.000000 to less than 6.188617
L2	6.188617 to less than 8.110160
L3	8.110160 to less than 10.344828
L4	10.344828 to less than 12.224661
L5	12.224661 to less than 15.456919
L6	15.456919 to less than 19.752043
L7	19.752043 to less than 24.168883
L8	24.168883 to less than 33.968268
L9	33.968268 to less than 51.805150
L10	51.805150 to less than 76.665433
L11	76.665433 to less than 99.831252
L12	99.831252 to less than or equal to 100.000000

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

Disability Quintile	Percentage of Contract's Disabled Beneficiaries
D1	0.000000 to less than 15.160537
D2	15.160537 to less than 19.602284
D3	19.602284 to less than 26.769989
D4	26.769989 to less than 38.698266
D5	38.698266 to less than or equal to 100.000000

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

Final Adjustment Category	LIS/DE Initial Group	Disability Quintile	CAI Value
A	L1 - L2	D1	−0.020980
B	L3 - L7 L1 - L2	D1 - D3 D2 - D3	−0.009289
C	L8 - L10	D1 - D3	0.001019
D	L1 - L9	D4 - D5	0.011701
E	L11 - L12 L10	D1 - D4 D4	0.037323
F	L10 - L11	D5	0.060366
G	L12	D5	0.085606

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

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

LIS/DE Initial Group	Percentage of Contract's LIS/DE Beneficiaries
L1	0.000000 to less than 5.983054
L2	5.983054 to less than 8.039216
L3	8.039216 to less than 10.242867
L4	10.242867 to less than 12.184512
L5	12.184512 to less than 15.386761
L6	15.386761 to less than 19.691642
L7	19.691642 to less than 23.623793
L8	23.623793 to less than 33.865945
L9	33.865945 to less than 51.765486
L10	51.765486 to less than 76.665433
L11	76.665433 to less than 99.831252
L12	99.831252 to less than or equal to 100.000000

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

Disability Quintile	Percentage of Contract's Disabled Beneficiaries
D1	0.000000 to less than 14.987446
D2	14.987446 to less than 19.397330
D3	19.397330 to less than 26.688919
D4	26.688919 to less than 38.496072
D5	38.496072 to less than or equal to 100.000000

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

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

Final Adjustment Category	LIS/DE Initial	Disability Quintile	CAI Value
A	L1 - L2	D1	−0.034597
B	L3 - L5 L1 - L2 L3	D1 - D2 D2 - D3 D3	−0.008463
C	L6 - L12 L6 - L9 L4 - L9 L1 - L9	D1 D2 D3 D 4- D5	0.000971
D	L10 - L11 L12	D2 - D5 D2	0.038593
E	L12	D3 - D5	0.060840

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

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

LIS/DE Initial Group	Percentage of Contract's LIS/DE Beneficiaries
L1	0.000000 to less than 6.188617
L2	6.188617 to less than 8.189398
L3	8.189398 to less than 10.554205
L4	10.554205 to less than 13.047285
L5	13.047285 to less than 15.695174
L6	15.695174 to less than 20.120593
L7	20.120593 to less than 25.628787
L8	25.628787 to less than 37.247228
L9	37.247228 to less than 57.692308
L10	57.692308 to less than 83.018448
L11	83.018448 to less than 99.905110
L12	99.905110 to less than or equal to 100.000000

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

Disability Quintile	Percentage of Contract's Disabled Beneficiaries
D1	0.000000 to less than 15.274769
D2	15.274769 to less than 20.230934
D3	20.230934 to less than 27.548509
D4	27.548509 to less than 40.446927
D5	40.446927 to less than or equal to 100.000000

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

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

Final Adjustment Category	LIS/DE Initial Group	Disability Quintile	CAI Value
A	L1 - L2 L3 - L4	D1 - D3 D1 - D2	−0.013576
B	L5 - L9 L3 - L4	D1 - D3 D3	−0.002877
C	L1 - L7 L8	D4 - D5 D4	0.007977
D	L10 - L12 L9 - L11	D1 - D3 D4	0.037128
E	L8 - L9	D5	0.048750
F	L10	D5	0.080788
G	L11	D5	0.104590
H	L12	D4 - D5	0.123372

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

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

LIS/DE Quartile	Percentage of Contract's LIS/DE Beneficiaries
L1	0.000000 to less than 1.861410
L2	1.861410 to less than 6.885402
L3	6.885402 to less than 29.506059
L4	29.506059 to less than or equal to 100.000000

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

LIS/DE Quartile	Percentage of Contract's LIS/DE Beneficiaries
D1	0.000000 to less than 8.159247
D2	8.159247 to less than 14.153052
D3	14.153052 to less than 30.526888
D4	30.526888 to less than or equal to 100.000000

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

Please note that the CAI values for the Part D summary rating for PDPs are different from the CAI values for the Part D summary rating for MA contracts. Categories were chosen to enforce monotonicity and to yield a minimum of 10 contracts per final adjustment category. There are four final adjustment categories for PDPs for the Part D summary rating.

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

Final Adjustment Category	LIS/DE Quartile	Disability Quartile	CAI Value
A	L1	D1	−0.157338
B	L2 - L4 L1	D1 - D2 D2	−0.108075
C	L1 - L3 L4	D3 - D4 D3	−0.019559
D	L4	D4	0.098544

Categorization of Puerto Rico Contracts for LIS/DE for CAI Determination

Puerto Rico has a unique health care market with a large percentage of low-income individuals in both Medicare and Medicaid. Puerto Rican beneficiaries are not eligible for LIS. The categorization of contracts into final adjustment categories for the CAI relies on both the use of a contract's percentages of LIS/DE and disabled beneficiaries. Since the percentage of LIS/DE is a critical element in the categorization of contracts to identify the contract's CAI, an additional adjustment is done for contracts that solely serve the population of beneficiaries in Puerto Rico to address the lack of LIS. The adjustment results in a modified percentage of LIS/DE

beneficiaries that is subsequently used to categorize the contract in its final adjustment category for the CAI.

For the 2017 Star Ratings, CMS applied an additional adjustment for contracts that solely serve the population of beneficiaries in Puerto Rico to address the lack of LIS to make the application of the CAI equitable for contracts in Puerto Rico. (The details of the methodology can be found in the Announcement of Methodological Changes for Calendar Year (CY) 2017 for Medicare Advantage Capitation Rates, Part C and Part D Payment Policies and 2017 Call Letter Attachment VII, Section I, pages 135-136 and in Attachment O in the 2017 Medicare Part C & D Star Rating Technical Notes.)

For the 2018 Star Ratings, CMS will continue to employ the methodology developed for the additional adjustment for Puerto Rico using the 2015 data from the American Community Survey and CY 2016 Medicare Enrollment data. CMS continues to explore alternative data sources for Puerto Rico to provide both resource and income information for the determination of the additional adjustment.

CMS recognizes the additional challenge unique to Puerto Rico related to the medication adherence measures used in the Star Ratings Program due to the lack of LIS. For the 2017 Star Ratings, CMS implemented a different weighting scheme for the Part D medication adherence measures in the calculation of the overall and summary Star Ratings for contracts that solely serve the population of beneficiaries in Puerto Rico.

For the 2018 Star Ratings, CMS will continue to reduce the weights for the adherence measures to zero (0) for the summary and overall rating calculations and maintain the weight of three (3) for the adherence measures for the improvement measure calculations for contracts that solely serve the population of beneficiaries in Puerto Rico.

Next Steps

CMS is firmly committed to building the foundation for a long-term solution that appropriately addresses the issue at hand and aligns with our policy goals. CMS remains steadfast that any policy response must delineate the two distinct aspects of the LIS/DE and/or disability issue - quality and payment - as well as prevent distortion of the quality ratings and their meaning. Further, the long-term solution must recognize the unique challenges of serving vulnerable populations. While the measure stewards including the National Committee for Quality Assurance (NCQA) and the Pharmacy Quality Alliance (PQA) continue their work, CMS will consider all feasible options appropriate over the long term.

Our work closely aligns with the research agenda of the Office of the Assistant Secretary for Planning and Evaluation (ASPE), as outlined in the Improving Medicare Post-Acute Care

Transformation Act of 2014 (IMPACT Act, P.L. 113-185).[7] In December 2016, ASPE released the first in a two-part series of Reports to Congress (RTC) mandated by the IMPACT Act.[8] In it, ASPE analyzes the effect of social risk factors on health outcomes of Medicare beneficiaries. ASPE reviewed a number of CMS programs, including Medicare Advantage. We are carefully considering the feasibility of the considerations presented in ASPE's RTC for MA contracts and sponsors, as well as the impact on our use of the ratings for beneficiaries. In addition, we will engage in continued dialogue and collaboration directly with ASPE, our other HHS partners, and stakeholders. See Appendix 2 for summary of comments received on this topic.

2018 CMS Display Measures

Display measures on CMS.gov are not part of the Star Ratings. These may include measures that transitioned from the Star Ratings, new measures that are being tested before inclusion into the Star Ratings, or measures displayed solely for informational purposes. Organizations and sponsors will have the opportunity to preview the data for their display measures prior to release on CMS' website. Data for measures moved to the display page continue to be collected and monitored; poor scores on display measures may reveal underlying compliance and performance issues that are subject to enforcement actions by CMS. All 2017 display measures will continue to be shown as display measures on CMS.gov in 2018 unless noted below.

CMS will continue to provide advance notice regarding measures considered for implementation as future Star Ratings measures. Other display measures may be provided as information only. Below are the changes to the measures for the 2018 display page.

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

  In the 2017 Call Letter, CMS committed to shortening the 2017 MA CAHPS survey by removing some questions that are not used in current Star Ratings measures. We

[7] ASPE, as instructed the IMPACT ACT, is conducting a study that examines the effect of individuals' socioeconomic status on quality measures, resource use, and other measures for individuals in the Medicare program.

[8] ASPE's first Report to Congress: Social Risk Factors and Performance under Medicare's Value-Based Purchasing Programs can be accessed using the link that follows: https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.

removed items from the CAHPS survey that were previously reported on the display page. Display items related to Reminders for appointments, Reminders for immunizations, Reminders for screening tests, Computer used during office visits, Computer use by provider helpful, Computer use made talking to provider easier, and Getting information from drug plan are not included on the 2017 MA & PDP CAHPS surveys and will not be reported on the 2018 display page.

- **Pneumococcal Vaccination Status for Older Adults (Part C).** The Pneumococcal Vaccination Status for Older Adults (PNU) measure, currently collected through the Medicare CAHPS survey, assesses the percentage of Medicare members 65 years of age and older who have ever received a pneumococcal vaccination. The 2014 Advisory Committee on Immunization Practices pneumococcal vaccination guideline supports administration of a sequential series of two vaccines for adults age 65 and older. Recent stakeholder and public comment feedback indicates there is significant interest in finding alternative non-survey based methods to assess pneumococcal vaccination status and guideline adherence. Alternative data sources of interest include claims, case management systems, medical records, registries and electronic health records. CMS is exploring potential non-survey based methods of collecting this information.

  In the meantime, NCQA recommended the following wording changes to the existing CAHPS measure: "Have you ever had one or more pneumonia shots? Two shots are usually given in a person's lifetime and these are different from a flu shot. It is also called the pneumococcal vaccine." As previously announced, the new wording will be utilized for 2017 CAHPS implementation. This measure is on the CMS display page. CMS shared all comments received on this measure with NCQA.

- **Hospitalizations for Potentially Preventable Complications (Part C).** This measure is a risk-adjusted measure that assesses the rate of hospitalization for complications of chronic and acute ambulatory care-sensitive conditions. The measure is therefore an important indicator of care coordination. CMS first included this measure on the 2017 display page, with plans to move it into the 2018 Star Ratings. Due to concerns from NCQA, the measure developer, we will continue this as a display measure for 2018, and plan to move it into the 2019 Star Ratings. The consensus process used by NCQA raised some concerns, which were significant enough to warrant a delay. Among these concerns were a large number of outlier plans—that is, those that performed much better or worse than other plans and for unknown reasons. Also, there was some interest in studying the potential bias that might occur when hospitals use observation stays instead of inpatient admissions. NCQA will be studying and reviewing their findings with stakeholders during the coming year and CMS will follow their activities. CMS shared all comments received with NCQA. Please refer to the NCQA HEDIS 2017 Technical Specifications for Health Plans Volume 2 for measure construction and technical specifications.

- **Statin Therapy for Patients with Cardiovascular Disease (Part C).** The Statin Therapy for Patients with Cardiovascular Disease measure was developed by NCQA as part of HEDIS. It focuses on the percentage of males 21 to 75 years of age and females 40 to 75 years of age who were identified as having clinical atherosclerotic cardiovascular disease and were dispensed at least one high or moderate-intensity statin medication during the measurement year. NCQA allows for the exclusion of certain conditions and symptoms that may indicate statin intolerance (e.g., myalgia, myositis, myopathy or rhabdomyolysis). Please refer to the NCQA HEDIS 2017 Technical Specifications for Health Plans Volume 2 for measure construction and technical specifications. Since the HEDIS statin measures overlap with the measures developed by the PQA, CMS included only one of the HEDIS measures on the 2017 display page and will retain it on the 2018 display page. After gaining experience with the new treatment guidelines and metric, we plan to include this measure in the 2019 Star Ratings. CMS shared all comments received on this measure with NCQA.

- **Asthma Measures (Part C).** The NCQA measure, Medication Management for People with Asthma, captures the percentage of members 5 to 85 years of age who were identified as having persistent asthma and were dispensed appropriate medications on which they remained during the treatment period (i.e., first prescription date through end of measurement year). The measure, Asthma Medication Ratio, captures 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. Stakeholders expressed concerns that asthma and COPD might be difficult to distinguish among those age 65 and older. CMS and measure developers will consider the utility of prescription drug event and encounter data to solve these concerns before moving forward with implementing these measures. For this reason, Medication Management for People with Asthma will not be reported on the 2018 display page, nor on the 2018 Star Ratings. CMS shared all comments received on this measure with NCQA.

- **Non-Recommended PSA-Based Screening in Older Men (Part C).** This NCQA measure (PSA) reflects the percentage of men age 70 and older who were screened unnecessarily for prostate cancer using the prostate-specific antigen (PSA) based screening. It excludes men in hospice, and men with a prostate cancer diagnosis or dysplasia of the prostate. It also excludes those with a prior-year PSA test that was elevated (that is, a PSA in the current year is needed for monitoring) and excludes those who were dispensed prescriptions for 5-alpha reductase inhibitor (5-ARI) during the measurement year. CMS has decided not to report the PSA measure on the 2018 display page (see Appendix 2 for summary of comments received). CMS has shared all comments received with NCQA and will review the inclusion of this measure in the future after reviewing results from the current 2017 U.S. Preventive Services Task Force investigation of PSA testing among adult men.

- **Formulary Administration Analysis measure (Part D)**. We will adopt a new display measure using the results of the Formulary Administration Analysis (FAA) used by CMS to evaluate whether Part D sponsors are appropriately adjudicating drug claims consistent with Part D requirements and sponsors' CMS-approved benefits. For this study, Part D sponsors submit all point-of-sale rejected claims relating to non-formulary status, Prior Authorization, Step Therapy, and Quantity Limits for a specified time period. CMS then selects a targeted sample of rejected claims for further analysis. Each rejected claim is reviewed by the Part D sponsor to verify whether the rejection is consistent with the approved formulary status. CMS next assigns a pass or fail to each sample claim depending on the appropriateness of the rejection. The percentage of failures will be displayed for each Part D sponsor. Since 2015, CMS has produced two display measures using results of the Transition Monitoring Program Analysis (TMPA). We are considering ways in which to expand TPMA and FAA monitoring to allow the inclusion in the Star Ratings as important beneficiary access measures. At the earliest, these measures may be proposed for the 2020 Star Ratings.

- **High Risk Medication (Part D).** As described earlier, we will transition the HRM measure from the Star Ratings to the display page for 2018 (based on 2016 data). The PQA, the measure steward, revised the criteria to calculate the average dose for doxepin, reserpine, and digoxin. We implemented this change in the 2016 measure reports through the Patient Safety Analysis website, which will be used for the 2018 display measure.

  Additionally, the PQA revised the HRM measure drug list to reflect the updated 2015 American Geriatrics Society (AGS) Beers Criteria. The intent of this measure has not changed. The specifications, other than the list of medications, have not changed. Per the PQA, the updated measure is effective for use in performance measurement beginning in January 2017. We plan to use the updated HRM drug list for the 2019 display measure (using 2017 data).

  In summary, the revised PQA HRM drug list excludes three drugs (i.e., thioridazine, trimethobenzamide and chloral hydrate), and adds fourteen new HRM drugs. We evaluated the impact of the revised PQA's HRM drug list on the HRM rate calculations at the contract-level. We generated HRM rate calculations for the CY 2015 participating contracts, and used the final 2015 HRM rates as a baseline. Using the revised list, the HRM rate increased by 3.3 percentage points (3.5 and 3.3 percentage point increase for MA-PD and PDP contracts, respectively). The estimated revised year of service 2015 HRM rates were 10.9% overall, 8.4% for MA-PD contracts and 12.6% for PDP contracts.

  Avoiding potentially inappropriate medications in older adults remains important for Medicare beneficiaries' quality of care. This measure will be reconsidered for the Star

Ratings again in the future once analyses and specification changes, if any, are completed by the PQA. Any changes will be proposed or implemented with sufficient lead-time.

- **Drug-Drug Interactions (Part D).** The drug-drug interactions (DDI) measure is the percent of Part D beneficiaries who received a prescription for a target medication during the measurement period who were dispensed a prescription for a contraindicated medication with or subsequent to the initial prescription. An expert panel convened by the PQA conducted an extensive review of the drug-drug pairs included in its DDI measure, which resulted in a revised list of approved drug-drug interactions effective for the 2017 measurement year. The intent and specifications of the measure were not changed.

  We performed an evaluation of the PQA's revised drug list on the DDI rate calculations at the contract-level. We generated DDI rate calculations for the CY 2015 participating contracts, using 2015 PDE data as of 6/30/16 for both the revised DDI NDCs and the final 2015 rates. The NDC list used for the final 2015 rates was updated in February 2016. Overall, the DDI rate decreased by 2.1 percentage points (1.9 and 2.1 percentage point decrease for MA-PD and PDP contracts, respectively). The new estimated DDI rates were 3.8% overall, 3.1% for MA-PDs and 4.2% for PDPs. We plan to implement the PQA's revised DDI measure drug list for the 2019 display measure based on 2017 data.

- **Chronic Use of Atypical Antipsychotics by Elderly Beneficiaries in Nursing Homes (Part D).** In 2013, CMS began to calculate a general atypical antipsychotic utilization rate in nursing homes for inclusion in the Part D display measures. We will remove this measure from the 2018 display measure set and replace with the PQA Antipsychotic Use in Persons with Dementia (APD) measure (discussed below).

- **Antipsychotic Use in Persons with Dementia (APD) (Part D)**. The PQA APD measure is the percentage of Part D beneficiaries 65 years or older with dementia who received prescription fills for antipsychotics without evidence of a psychotic disorder or related condition.

  Part D sponsors began to receive 2016 APD measure reports on a monthly basis through the Patient Safety Analysis website. In addition to the overall APD rates, sponsors also receive rates across three population subgroups:

  - APD-COMM: Community-only residents (never a nursing home resident),
  - APD-STNH: Short-term nursing home residents (100 cumulative days or less in a nursing home based on the Long Term Care Minimum Data Set (MDS)), and
  - APD-LTNH: Long-term nursing home residents (greater than 100 cumulative days in a nursing home).

As discussed in the final CY 2017 Call Letter, we proposed to add the APD measure (plus the three population subgroup rates) to the 2018 display measures using 2016 data. We are adding only the overall APD measure to the 2018 display page. We observed unexpected variability in the population breakouts (APD-COMM, APD-STNH, and APD-LTNH) in the monthly 2016 patient safety reports distributed to date. Although a beneficiary is assigned to one of the population breakouts based on the number of days that he or she spent in a nursing home during the measurement period, there is no requirement that he or she meet the measure inclusion criteria while residing in a nursing home. Therefore, we will improve the precision of the stratification rate calculations beginning with the 2017 reports; beneficiaries must have an antipsychotic claim (meet the numerator criteria) while residing in the community or nursing home. We also will report only two population subgroups: APD-COMM and APD-LTNH. This stratification will be applied to the 2017 data for the 2019 display measures at which time we plan to display the overall APD rate as well as the rates for the two population breakouts. We will assess adding the APD measure to the Star Ratings in the future.

- **Use of Opioids from Multiple Providers and/or at High Dosage in Persons without Cancer (Part D).** PQA's opioid measures examine multi-provider and/or high dosage opioid use among individuals 18 years and older without cancer and not in hospice care. These three measures were included in the Patient Safety reports starting in 2016.

  The PQA's Measure Update Panel and Quality Metrics Expert Panel recently approved non-substantial changes to the measures. First, each rate will have a separate title and the term "morphine equivalent dose" will be changed to "morphine milligram equivalents."

  Measure 1: Use of Opioids at High Dosage in Persons without Cancer (OHD): The proportion (XX out of 1,000) of individuals from the denominator receiving prescriptions for opioids with a daily dosage greater than 120 mg morphine milligram equivalents (MME) for 90 consecutive days or longer.

  Measure 2: Use of Opioids from Multiple Providers in Persons without Cancer (OMP): The proportion (XX out of 1,000) of individuals from the denominator receiving prescriptions for opioids from four (4) or more prescribers AND four (4) or more pharmacies.

  Measure 3: Use of Opioids at High Dosage and from Multiple Providers in Persons without Cancer (OHDMP): The proportion (XX out of 1,000) of individuals from the denominator receiving prescriptions for opioids with a daily dosage greater than 120 mg morphine milligram equivalents (MME) for 90 consecutive days or longer, AND who received opioid prescriptions from four (4) or more prescribers AND four (4) or more pharmacies.

  Additional changes made by the PQA to these measures include:

1. The opioid treatment period for Measures 1 and 3 must be 90 days or more.
2. ICD-9 and ICD-10 codes will be changed to align with the American Medical Association (AMA) Physician Consortium for Performance Improvement (PCPI) cancer value set.
3. All buprenorphine products indicated for medication-assisted treatment (MAT) will be excluded.

We will implement these changes beginning with the 2017 Patient Safety reports. All three measures will continue to be reported through the Patient Safety Analysis website. During the comment period, we received several comments to align the measures publicly reported with CMS' opioid policy. More specifically, commenters felt that Measure 3 mirrored the opioid overutilization criteria that CMS currently used for the Overutilization Monitoring System, whereas the other two measures did not. Therefore, we plan to add the OHDMP measure only to the 2019 Part D display page (using 2017 data). Some commenters suggested that PQA lower the threshold in the measures to align with CDC guideline and the revised OMS criteria thresholds. We will share this feedback with the PQA for their consideration for future measure specification updates. At this time, we do not plan to add any of these three measures to the Star Ratings.

- **Statin Use in Persons with Diabetes (SUPD) (Part D).** This PQA measure is the percentage of patients between 40 and 75 years old who received at least two diabetes medication fills and also received a statin medication during the measurement period. Beneficiaries in hospice according to the Enrollment Database (EDB) are excluded from the denominator of the SUPD measure for the entire year. The SUPD measure will remain on the display page for 2018 using 2016 data.

  The PQA revised the SUPD measure specifications to exclude beneficiaries with end-stage renal disease (ESRD). Beginning with the 2017 measurement year, we will exclude beneficiaries with a positive ESRD indicator in Medicare Enrollment Database (EDB) anytime during the year. We plan to add the SUPD measure to the 2019 Star Ratings (using 2017 data).

Forecasting to 2019 and Beyond

The following describes changes to existing measures and potential new measures. CMS will also monitor any additional measures developed by NCQA or PQA for potential incorporation into the Star Ratings for 2019 or later. As we add new measures, CMS will consider which measures are topped out or have little variation across contracts to transition them to the display page.

Patient Safety Report Frequency

Currently, Part D contracts are provided both their Star Rating and display patient safety measure rates on a monthly basis through reports on the Patient Safety website. Most of the rates are calculated using PQA measure specifications and national drug code (NDC) lists updated by the PQA bi-annually, usually in January and July. We observed that the monthly measure rates might be affected by both the time between NDC updates as well as a lag in PDE data submissions. Beginning with the 2017 reports, we proposed to generate the patient safety measures reports (and outlier notices) quarterly instead of monthly to reduce the variability due to data lags. In response to the draft CY 2018 Call Letter, sponsors expressed how valuable the reports are for their performance improvement and monitoring activates. Therefore, CMS will continue to provide the reports on a monthly basis and send outlier notices on a quarterly basis. In between updates, sponsors may observe some differences between their internal monitoring reports and the patient safety reports especially if they are applying more real-time NDC changes or capturing PDE data not yet submitted to or processed by CMS. CMS will continue to explore ways to improve the processes to implement updated PQA NDC lists in the reports as soon as possible.

Changes to existing measures

- **Colorectal Cancer Screening (Part C).** The Colorectal Cancer Screening (COL) measure assesses the percentage of adults 50-75 years of age who had appropriate screening for colorectal cancer. This NCQA measure is based on the U.S. Preventive Services Task Force (USPSTF) guideline on colorectal cancer screening in adults age 50-75. In June 2016, the USPSTF released a new clinical recommendation statement and NCQA updated the measure specifications so that computed tomography colonography and FIT-DNA are recognized as screening test options, as well as screening via fecal occult blood test, flexible sigmoidoscopy and colonoscopy. These changes have been implemented in the HEDIS 2017 measure specification, but as they expand screening options, this measure will not be removed from Star Ratings. CMS shared comments received on this measure with NCQA.

Potential changes to existing measures

- **Initiation and Engagement in Alcohol or Drug Dependence (AOD) Treatment (Part C).** The Initiation and Engagement in Alcohol or Other Drug Dependence Treatment (IET) measure assesses the percentage of adolescent and adult members with a new episode of alcohol or other drug dependence who: 1) initiated AOD treatment within 14 days of the diagnosis and 2) had two or more additional services for AOD treatment within 30 days of the initiation visit. CMS is considering including data on the use of Medication-Assisted Treatment (MAT) in the denominator and numerator components of the measure. CMS shared comments received on this measure with NCQA. These

changes are being considered for data collection in 2018, which would lead to reporting of this measure on the display page in 2020.

- **Telehealth and Remote Access Technologies (Part C).** CMS solicited feedback on the appropriateness of including telehealth and/or remote access technology encounters, as allowed under the current statutory definition of Medicare covered telehealth services and/or as a provided by the MAO as a MA supplemental benefit, as eligible encounters in various Part C quality measures.

  For example, some HEDIS measures require a visit for the denominator, numerator, or exclusion, and we sought comment on whether telehealth and/or remote access technology encounters should be counted as eligible encounters for the relevant portion of the measure, that is whether for counting as part of a measure, such telehealth and/or remote access technology visits are equivalent (reasonable replacements) for in-person visits for relevant clinical areas. NCQA is interested whether this inclusion might be appropriate, for example, for certain behavioral health services.

  Feedback from the draft Call Letter was shared with NCQA. If NCQA makes any changes to include such encounters, data from 2018 would reflect this change and could be included on the 2020 display page.

- **Cross-Cutting Exclusions for Advanced Illness (Part C).** CMS solicited feedback on the clinical appropriateness and feasibility of excluding individuals with advanced illness from selected Part C measures. While many Part C measures are designed to compare the quality of care provided to general populations or disease-specific care provided to individuals with a chronic condition, these measures may not be clinically appropriate for certain individuals with advanced illness and may overlook the quality issues that are specific to these patients. NCQA is therefore considering the need for exclusions for selected measures for patients with advanced illness where providing certain treatments and services may not be appropriate. CMS appreciates feedback we received about whether specific illnesses and health care utilization (e.g., use of palliative care services) may warrant an exclusion, and to which measures the exclusion should be applied. We are concerned about any changes to measures that result in lessened incentives for providing high-quality care to such beneficiaries. CMS shared all comments received with NCQA.

- **Care Coordination measures (Part C).** A critical reason Medicare Advantage plans exist is to coordinate care and ensure good transitions between care settings. Therefore, CMS proposed to treat measures of such activities as intermediate outcomes since they reflect actions taken which can assist in improving a beneficiary's overall health status. Based on feedback received from the draft Call Letter, we are not moving forward with a change in weights to the care coordination measures at this time.

- **Center for Medicare and Medicaid Innovation Model Tests.** The MA Value-Based Insurance Design (MA-VBID) model test is an opportunity for MAOs to offer supplemental benefits or reduced cost sharing to enrollees with CMS-specified chronic conditions, focused on the services that are of highest clinical value to them. The Part D Enhanced Medication Therapy Management (MTM) model tests whether providing Part D sponsors with additional payment incentives and regulatory flexibilities will engender enhancements in the MTM program, leading to improved therapeutic outcomes, while reducing net Medicare expenditures. We note that some stakeholders have expressed concern regarding the potential for the improvements in quality resulting from these tests to adversely influence the Star Ratings of contracts that are ineligible to participate (or that include some PBPs ineligible to participate). CMS' goal is to not penalize participants or non-participants in either model.

  For the MA-VBID Model test, CMS is considering the option of exclusion of VBID-participants' data when calculating the cut points for relevant measures. CMS has waived the MTM requirements under Section 1860D–4(c)(2) and 42 CFR 423.153(d) and the Part D Reporting Requirements for MTM for Part D plans participating in the Part D Enhanced MTM Model. However, Part D sponsors with plans participating in this model must establish MTM programs in compliance with current requirements and reporting data for the remaining plans under each Part D contract. Therefore, the MTM Program CMR Completion Rates will be calculated using available plan-reported data from the remaining plans under the Part D contract. CMS plans to analyze if this approach significantly advantages or disadvantages Enhanced MTM model participants and evaluate potential adjustments as necessary, including the establishment of different cut points for model participants or to case-mix adjust scores for the purpose of determining cut points.

Temporary removal of measures from Star Ratings

- **Reducing the Risk of Falling (Part C).** This measure, collected through the Medicare Health Outcomes Survey (HOS), assesses the percentage of beneficiaries who discussed falls or problems with balance or walking with their provider and received fall risk intervention(s) from their provider. NCQA made two changes to this measure. First, NCQA changed the denominator of both indicators to include all beneficiaries age 65 and older, as opposed to limiting the denominator to those age 75 and older or age 65-74 with a balance or walking problem or fall in the past year. This action removes a potential bias toward sampling only patients who were treated unsuccessfully. Second, NCQA updated the list of example interventions by removing the phrase "Check your blood pressure lying down or standing" and adding "Suggest you take Vitamin D." This aligns the list of interventions with current USPSTF recommendations. These changes required revising

the underlying survey questions in HOS. The measure will remain in the Star Ratings for 2018. The revised questions will be first collected in 2018. As a result of these changes, there will be no data for this measure for the 2019 and 2020 Star Ratings.

- **Plan All-Cause Readmissions (Part C).** NCQA is exploring several revisions to the HEDIS Plan All Cause Readmissions measure based on feedback they have received from the field and stakeholders. These revisions may impact the definition of the denominator, numerator and risk adjustment model for data collected in 2018. The specific revisions they are exploring include 1) Inclusion of observation stays in the denominator and numerator; 2) revising the measure denominator to be the overall plan population as opposed to index hospital admissions; and 3) adding death in the measurement year as a possible factor in the risk adjustment model. CMS shared all comments received with NCQA.

Potential new measures for 2019 and beyond

- **Care Coordination Measures (Part C).** Effective care coordination, including care transition, contributes to improved health outcomes (http://www.qualityforum.org/News_And_Resources/Press_Releases/2012/NQF_Endorses_Care_Coordination_Measures.aspx). CMS believes that 5-star MA contracts perform well on our Star Ratings measures because they understand how to effectively coordinate care for their enrollees. Our assumption about plan care coordination activities, however, is based largely on anecdotes and discussions with high performing plans, as well as on data from CAHPS surveys, which reflect enrollees' experiences with the care they receive.

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

- **Transitions of Care (Part C).** CMS appreciates feedback received about a new HEDIS Transitions of Care measure with four indicators:

1. *Notification of Inpatient Admission:* Documentation of primary care practitioner notification of inpatient admission on the day of admission or the following day.
2. *Receipt of Discharge Information:* Documentation of primary care practitioner receipt of specific discharge information on the day of discharge or the following day.
3. *Patient Engagement After Inpatient Discharge*: Documentation of patient engagement (e.g., office visits, visits to the home, or telehealth) provided by primary care practitioner within 30 days after discharge.
4. *Medication Reconciliation Post-Discharge* (which is currently a HEDIS measure): Documentation of medication reconciliation within 30 days of discharge.

The intent of the measure is to improve the quality of care transitions from an inpatient setting to home. The measure would be collected in calendar year 2018 for use on the display page in 2020. CMS appreciates feedback received about the components of the measure, about data collection options, and about the ability of such a measure to contribute to better assessment of care coordination for Medicare Advantage enrollees. All comments were shared with NCQA.

- **Follow-up after Emergency Department Visit for Patients with Multiple Chronic Conditions (Part C).** CMS is considering use of a new HEDIS measure assessing follow-up care provided after emergency department visit for patients with multiple chronic conditions. Patients with multiple chronic conditions are more likely to have complex care needs and follow-up following an acute event, like an emergency department visit, can help to prevent the development of more severe complications. The developer, NCQA, is evaluating what timeframe (e.g., 7, 14, or 30 days post-ED visit) and what types of follow-up (e.g., face- to-face office visits, telephone or web interactions, or visits to the home) are appropriate. CMS appreciates feedback received on these questions as well as on the utility and importance of this measure as a care transitions measure. We shared all comments with NCQA.

- **Opioid Overuse (Part C).** Additionally, NCQA approved the PQA's three opioid measures (discussed above) in 2016 but is considering two additional measures of opioid overuse including:

  Multiple Prescribers: The percentage of members receiving prescriptions for opioids from four or more prescribers during the measurement year.

  Multiple Pharmacies: The percentage of members receiving prescriptions for opioids from four or more pharmacies during the measurement year.

  Once developed, we will consider future testing or collection which could begin in calendar year 2018 for use on the 2020 display page. CMS shared comments received with NCQA.

- **Depression Screening and Follow-Up for Adolescents and Adults (Part C).** CMS and measure developers are exploring a provider-level measure for use in measuring plan performance. This NCQA measure assesses the percentage of patients age 12 and older who were screened for depression using a standardized assessment tool, such as the PHQ-9, and if positive, received appropriate follow-up care within 30 days of the positive screen. This measure would be collected in 2018 for use on the display page in 2020. CMS appreciates the feedback received on the measure, the best range of standardized assessment tools to be used in primary care settings for screening, and the measure's reliance on electronic clinical data systems. We shared all comments with NCQA.

- **Alcohol Screening and Follow-Up (Part C).** CMS aims to adapt a provider-level NCQA measure, Unhealthy Alcohol Use: Screening & Brief Counseling (NQF 2152), for health plan reporting. The intent of this measure is to increase the use of alcohol screening and brief intervention, which is recommended by the USPSTF for adults 18 and older. A number of health plans have been helping to test and evaluate performance for the adapted measure and to gather information on feasibility of implementation at the health-plan level. CMS appreciates the feedback received on the implementation of data collection in 2018 for reporting on the display page in 2020. We shared all comments with NCQA.

- **Appropriate Pain Management (Part C).** CMS appreciates feedback received on ways to measure appropriate management of chronic and acute pain, especially among patients with particular specific conditions such as chronic medical illnesses, substance use disorder, and depression. We thank commenters for feedback about different settings, such as inpatient, emergency department, and primary care settings, and about the value of a wide range of pharmacologic and nonpharmacologic approaches. Finally, CMS appreciates the comments received on the applicability and feasibility of implementing such measures at the plan level versus at the medical group or individual practitioner level. All comments have been shared with NCQA.

- **Plan Makes Timely Decisions about Appeals (Part C).** CMS will consider if cases dismissed by the IRE because the plan has subsequently approved coverage/payment should be included in this measure starting with the 2019 Star Ratings (using 2017 data). Currently, we exclude all cases dismissed/withdrawn by the IRE from this measure. However, plans' performance may be artificially improved as a result, especially if the dismissal was directly related to the plans' (untimely) approval. Inclusion of certain cases that are dismissed or withdrawn at the IRE level could provide a more accurate assessment of plans' timeliness in their Part C appeals processing.

- **New PQA-endorsed measures in development for future testing/consideration (Part D).**

- Concurrent Use of Opioids and Benzodiazepines: The percentage of individuals 18 years and older with concurrent use of opioids and benzodiazepines.

- Adherence to Non-infused Disease Modifying Agents Used to Treat Multiple Sclerosis: The percentage of individuals 18 years and older who met the Proportion of Days Covered (PDC) threshold of 80% during the measurement period for disease-modifying agents treating multiple sclerosis.

Measurement and Methodological Enhancements

CMS is committed to continuing to improve the Part C and D Star Ratings by identifying new measures and methodological enhancements. We appreciate the feedback we received to the draft CY 2018 Call Letter since it helps CMS' continuing analyses, as well as our collaboration with measurement development entities such as NCQA and PQA. We will continue to analyze measures to determine if measure scores are "topped out" or showing high performance across all contracts. In making decisions to transition these measures to the display page, CMS does not have a strict formula. Although some measures may show uniform high performance across contracts and little variation between them, we want to balance how critical the measures are to improving patient care, the importance of not creating incentives for a decline in performance after the measures transition out of the Star Ratings, and the availability of alternative related measures. If plans have only recently achieved uniformly high performance, for example, or if no other measures capture a key focus in Star Ratings, a "topped out" measure may be retained in Star Ratings.

- In light of recent USPSTF updates related to breast cancer screening, CMS solicited feedback about the current evidence for age and appropriate methods for primary screening for breast cancer. CMS and the steward for the Breast Cancer Screening HEDIS measure, NCQA, are reviewing the feedback to assess whether or not changes are needed to the measure.

- Effective processing of Part C organization determinations and reconsiderations and Part D coverage determination and redeterminations by sponsors are critical areas of the Medicare Advantage and Part D program. CMS requirements for these processes provide key beneficiary protections for access to health care and prescription drugs. We have featured appeals measures in the Star Ratings since 2007 because they are such important indicators of beneficiary access. We continue to be interested in developing new or enhanced measures of beneficiary access, especially with the industry-wide collection of data from all sponsors as described earlier. In addition to the current measures of sponsors' timeliness and reliable decision-making, we remain interested in potentially evaluating sponsors' compliance with effectuating appeals and provider outreach requirements, as well as appropriate clinical-decision making and notification to beneficiaries.

Innovations in Health Plan Design

The CMS Innovation Center is responsible for developing and testing new payment and service delivery models intended to lower costs while preserving or enhancing quality of care for Medicare, Medicaid, and CHIP beneficiaries. In the 2016 Call Letter, CMS indicated its intention to partner with private payers to test innovations in health plan design for CMS beneficiaries.

Since the 2016 Call Letter, CMS has announced the Medicare Advantage Value-Based Insurance Design (MA-VBID) and the Part D Enhanced Medication Therapy Management (MTM) model tests; both began operations on January 1, 2017. Each of these model tests is described below.

Potential means of adjustment to account for the impact of these models on Star Ratings are discussed above under the section, Enhancements to the 2018 Star Ratings and Beyond.

CMS continues to work on the development of potential new innovations in health plan design. We welcome stakeholder suggestions and input.

We received suggestions for potential model tests for CMS to conduct under Innovation Center authority. CMS appreciates these suggestions, and looks forward to continuing to engage stakeholders in the model test development.

Medicare Advantage Value-Based Insurance Design Model Test

The MA-VBID model test is an opportunity for MAOs to offer supplemental benefits or reduced cost sharing to enrollees with CMS-specified chronic conditions, focused on the services that are of highest clinical value to them. Only those MAOs expressly authorized by CMS to participate in the model may do so, and only within PBPs accepted into the model test. The model will test whether the additional flexibility provided to MAOs to develop and offer interventions can improve health outcomes and lower expenditures for Medicare Advantage enrollees.

CMS is testing the model in Arizona, Indiana, Iowa, Massachusetts, Oregon, Pennsylvania, and Tennessee. Beginning in CY 2018, CMS will also test the MA-VBID model in Alabama, Michigan, and Texas.

CMS has authorized eleven MAOs from nine parent organizations in Indiana, Massachusetts, and Pennsylvania to participate in the model test in CY 2017, and released a Request for Applications for CY 2018 participation.

For more information, including a description of other changes to the model test's design for CY 2018, please visit: https://innovation.cms.gov/initiatives/vbid/.

We received comments supportive of the MA-VBID model test, with suggestions for improvement in future model years. We appreciate receiving this feedback. We also believe

there are lessons learned from the VBID model test and will review those to consider possible improvements prior to any national implementation or other next steps.

Part D Enhanced MTM Model

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

Six Part D Sponsors encompassing 22 PBPs are participating in CMS' Part D Enhanced MTM model for 2017. These plans will offer MTM programs subject to the terms and conditions of the model test in the selected regions. All other Part D plans, including any ineligible plans offered by the PDP sponsors of participating plans, will remain subject to the current regulatory requirements for MTM programs. For more information, please visit: https://innovation.cms.gov/initiatives/enhancedmtm/.

Several commenters expressed support for the Part D Enhanced MTM model test. CMS also received comments suggesting improvements to the model test, specifically to allow pharmaceutical manufacturers to collaborate with participants and to further emphasize pharmacist involvement. CMS appreciates this feedback and will take all suggestions under consideration when evaluating potential model enhancements going forward.

Section II – Part C

Overview of CY 2018 Benefits and Bid Review

Portions of this guidance apply to cost-based plans and MA plans (including EGWPs, Dual-Eligible Special Needs Plans (D-SNPs), Chronic Care Special Needs Plans (C-SNPs), and Institutional Special Needs Plans (I-SNPs)). CMS does not evaluate whether employer group plans, D-SNPs, and 1876 Cost Plans are duplicative under 42 C.F.R. §422.256(b)(4) for our "meaningful difference" evaluation. Similarly, employer group plans and 1876 Cost Plans are not evaluated for low enrollment under 42 C.F.R. §422.506(b)(1)(iv) and (b)(2). CMS reserves the right to review employer group plans for low enrollment and/or meaningful difference in future years.

Medicare-Medicaid Plans in capitated financial alignment model demonstrations are not subject to the review criteria summarized in the table below and benefits and benefit review guidance for these plans are 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 5, 2017 deadline. Any organization whose bid fails the Part C Service Category Cost Sharing, PMPM Actuarial Equivalent Cost Sharing, Meaningful Difference, Total Beneficiary Cost (TBC), and/or Optional Supplemental Benefit requirements at any time prior to final approval will receive a compliance notice, even if the organization is allowed to correct the deficiency. The severity of compliance notice may depend on the type and/or severity of error(s).

The following table displays key MA bid review criteria and identifies the criteria that are used to review the bids of the various plan types identified in the column headings.

Table 13: Plan Types and Applicable Bid Review Criteria

Bid Review Criteria	Applies to Non-Employer Plans (Excluding Dual Eligible SNPs)	Applies to Non-Employer Dual Eligible SNPs	Applies to 1876 Cost Plans	Applies to Employer Plans
Low Enrollment 42 C.F.R. §422.506(b)(1)(iv) and (b)(2)	Yes	Yes	No	No
Meaningful Difference 42 C.F.R. §422.254(a)(4)	Yes	No	No	No
Total Beneficiary Cost section 1854(a)(5)(C)(ii) of the Act 42 C.F.R. §422.254	Yes	No	No	No
Maximum Out-of – Pocket (MOOP) Limits 42 C.F.R. §422.100(f)(4) and (5) and §422.101(d)(2) and (3)	Yes	Yes	No	Yes
PMPM Actuarial Equivalent Cost Sharing 42 C.F.R. §422.254(b)(4)	Yes	Yes	No	Yes
Service Category Cost Sharing 42 C.F.R. §§417.454(e), 422.100(f) and 422.100(j)	Yes	Yes	Yes[1]	Yes
Part C Optional Supplemental Benefits 42 C.F.R. §422.100(f)	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 C.F.R. §§417.454(e) and 422.100(j)).

CMS has interpreted and applied the regulatory standards for service category cost sharing standards and amounts, PMPM Actuarial Equivalence factors, and Total Beneficiary Cost (TBC) requirements for CY 2018 and has provided guidance on these requirements in each applicable section below. MAOs must also continue to comply with statutory requirements, 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, CMS is not making specific adjustments or specific allowances for these changes in the benefits review requirements.

Plans with Low Enrollment

At the end of March, CMS sent affected MAOs a list of non-SNP plans that have fewer than 500 enrollees or fewer than 100 enrollees for SNP plans and that have been in existence for three or more years [as of March 2017 (three annual election periods)]. The notification represents CMS' decision not to renew these plans under 42 C.F.R. §422.506(b)(1)(iv) and (b)(2). Plans with low enrollment located in service areas that do not have a sufficient number of competing options of the same plan type (such that the low enrollment plan still represents a viable plan option for beneficiaries), as determined by CMS, will not receive this notification.

Through return e-mail, MAOs must either (1) confirm each of the low enrollment plans identified by CMS will be eliminated or consolidated with another of the organization's plans for CY 2018, or (2) provide a justification for renewal. If CMS does not find a unique or compelling reason the low enrollment plan is a viable plan option for beneficiaries, CMS will instruct the organization to eliminate or consolidate the plan. Instructions and the timeframe for submitting justifications 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 led 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 applicable CMS renewal/non-renewal guidance issued prior to bid submission 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 42 C.F.R. §422.254(a)(4), MAOs offering more than one plan in a given service area must ensure 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. CMS will continue to use plan-specific per member per month (PMPM) out-of-pocket cost (OOPC) estimates to identify meaningful differences in beneficiary costs among the same plan types. For CY 2018, benefits and the reduction in cost sharing offered as part of the Value-Based Insurance Design (VBID) model test will not be included in the meaningful difference evaluation as in CY 2017. Documentation and instructions for the OOPC model are available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/OOPCResources.html.

In the CY 2018 draft Call Letter, CMS discussed our evaluation of meaningful difference. CMS requested comments on how differences in the provider network could constitute a meaningful difference and how plans could work with us to make such network differences both transparent to beneficiaries and consistent throughout the plan year.

We received comments recommending the inclusion of provider network and premium in the meaningful difference evaluation. For example, a commenter suggested we incorporate Provider Specific Plans (PSP) in the evaluation as a separate plan type. A commenter encouraged CMS to use rulemaking if we consider narrower provider networks as part of the meaningful difference evaluation. Commenters also opposed evaluating meaningful difference at the legal entity or parent organization level.

CMS will consider the inclusion of premium in the meaningful difference evaluation for future years. We agree with commenters that there is merit in evaluating differences in provider networks in this context, as well as in weighing the previously expressed concerns. As a first step, for CY 2018, organizations may offer similar benefit packages through a plan that uses the contract-level network and another plan that uses the PSP-network. Therefore, in CY 2018, PSPs are excluded from our meaningful difference evaluation.

Over the next year, we will consider additional ways to measure differences in provider networks in our overall review of meaningful difference. We hope to issue sub-regulatory guidance outlining our approach as soon as possible.

PSPs are MA plans designed to offer enrollees benefits through a subset of the overall contracted network in a given service area. PSPs will be subject to existing crosswalk guidance and organizations should clearly identify and describe PSPs and their networks in their Annual Notice of Change (ANOC), Evidence of Coverage (EOC), and provider directories so that beneficiaries understand these network differences.

For CY 2018, CMS required all new and existing MA contracts offering or planning to offer a PSP to submit their contract-level networks to CMS by early-March for review and approval (see HPMS Memo titled "Review and Approval of Provider Specific Plans for Contract Year 2018" issued February 15, 2017). Organizations that did not submit their contract-level networks to CMS for review and approval cannot offer a PSP for CY 2018.

Based on Network Adequacy Guidance (Section 7), CMS expects organizations to test the adequacy of their PSP-specific network prior to bid submission in June. CMS will deny any PSP failing to meet network adequacy criteria. The organization cannot resubmit a revised bid or adjust assumptions in the previously submitted bid even if their PSP fails our network adequacy evaluation. For this reason, we encourage organizations to proactively request technical assistance or ask clarifying questions regarding the relevant criteria as they work through that process. CMS will be responsive to such inquiries. To maintain the integrity of the bidding process, the organization may: (1) remove the PSP indicator from the bid, but may not re-upload

the bid to adjust for the network change; or (2) terminate the plan. CMS notes that termination of the PSP may have other consequences with contract and SNP service areas, particularly if the county (ies) in the PSP service area are not included in any other PBPs.

CMS will continue to evaluate meaningful differences among CY 2018 non-employer, non-dual eligible SNPs, and non-cost contractor plans offered by the same MAO in the same county and under the same contract. Consistent with past years, we will consider a difference of at least $20.00 PMPM between the OOPC for each plan offered by the same MAO in the same county to be meaningful for purposes of applying the meaningfully different standard.

CMS considers HMO and HMO-POS as one plan type, unless the HMO-POS plan covers all Parts A and B services outside the network, in which case the HMO-POS plan is considered meaningfully different from the HMO plan. Consistent with CY 2017, this standard for evaluating meaningful difference will not include geographic or provider limitations on the out-of-network benefits.

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. As previously stated, we do not apply the meaningful difference evaluation to PSPs.

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(s) served and Institutional SNPs will be separated into the following three categories: Institutional (Facility); Institutional Equivalent (Living in the Community); and a combination of Institutional (Facility) and Institutional Equivalent (Living in the Community). We currently do not apply the meaningful difference evaluation to D-SNPs.

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

4. The OOPC (Part C and Part D) PMPM estimate will be calculated for each plan. CMS considers a difference of at least $20.00 PMPM between the OOPC for each plan offered by the same MAO in the same county to be meaningful for purposes of applying the meaningfully different standard.

CMS notes meaningful difference will be evaluated based on the "as submitted formulary" prior to rebate reallocation, and "first approved formulary" following rebate reallocation. MAOs must follow the CY 2018 renewal/non-renewal guidance issued prior to bid submission to determine if their plans may be consolidated with other plans.

If CMS provides an opportunity to correct CY 2018 meaningful difference issues following the submission deadline, we will not prescribe how the MAOs should redesign benefit packages to achieve the differences. The MAO is not permitted to change its formulary (e.g., adding drugs, etc.) as a means to satisfy this requirement. The formulary review process has multiple stages and making changes that are unrelated to CMS identified formulary review concerns negatively affects the formulary and bid review process. For example, portions of the annual formulary review process are based on outlier analyses. If an MAO were permitted to make substantial formulary changes after the initial reviews, these analyses could be adversely impacted. In addition, significant formulary changes would necessitate additional CMS review, outside of the normal review stages, may jeopardize the approval of a sponsor's formulary and as a result could affect approval of its contract. To avoid meaningful difference issues, MAOs are strongly encouraged to make sure all Part C and Part D benefit and formulary changes are considered as part of their meaningful difference evaluation prior to submitting their final bids and formularies to CMS. We make all of the necessary tools and information available to MAOs in advance of the bid submission deadline, and therefore expect all MAOs to submit bids that satisfy our requirements.

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 make sure enrollees who continue enrollment in the same plan are not exposed to significant cost increases. As in past years, CMS will evaluate TBC for non-employer plans (excluding D-SNPs). For CY 2018, benefits and cost sharing that are offered as part of the Value-Based Insurance Design (VBID) model test will not be included in the TBC evaluation. The MA plans participating in the VBID model test will be evaluated under the TBC calculation, including plan premium and non-VBID benefits and cost sharing.

Under 42 C.F.R. §422.254, CMS reserves the right to further examine and request changes to a plan bid even if a plan's TBC is within the required amount. This approach not only protects enrollees from significant increases in cost sharing or decreases in benefits, but also confirms enrollees have access to viable and sustainable MA plan offerings.

We received comments recommending an adjustment for the health insurance providers fee. MAOs must comply with requirements under current law, including the health insurance providers fee and are expected to do so independently of CMS requirements for benefits and bid

review. Some commenters suggested CMS eliminate the TBC requirement, while others suggested we modify the calculation to reflect increases in medical and pharmacy inflation. To provide flexibility for CY 2018 plans in addressing the factors discussed in the comments, CMS is increasing the TBC threshold from $32.00 PMPM to $34.00 PMPM for most plans as described below.

In mid-April 2017, as in past years, CMS will provide plan specific CY 2018 TBC values and incorporate the following adjustments 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 ($4.10 for CY 2018).

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

The TBC change threshold for CY 2018 is $34.00 PMPM for most plans. Therefore, a plan experiencing a net increase in adjustments must have an effective TBC change amount below the $34.00 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 $34.00 PMPM threshold. In an effort to support plans that improve quality compensation and experience large payment adjustments, along with holding plans accountable for lower quality, CMS will apply the TBC evaluation as follows.

For CY 2018, 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 $34.00 PMPM will have a TBC change threshold of $0.00 PMPM (i.e., −1 times the TBC change limit of $34.00 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 -$34.00 PMPM will have a TBC change threshold of $68.00 PMPM (i.e., 2 times TBC change limit of $34.00 PMPM) plus applicable technical adjustments. That is, plans would not be allowed to make changes that result in greater than $68.00 worth of decreased benefits or increased premiums.

- Plans with a star rating below 3.0 and an overall payment adjustment amount less than −$34.00 PMPM will have a TBC change threshold of $68.00 PMPM (i.e., 2 times TBC change limit of $34.00) plus applicable technical adjustments.

- Plans not accounted for in the three specific situations above are evaluated at the $34.00 PMPM limit, similar to CY 2017.

We received comments expressing concern about the TBC evaluation for Special Needs Plans for End Stage Renal Disease (ESRD), which are subject to larger increases and/or decreases in payment amounts. Organizations noted our OOPC model does not address plans that only enroll ESRD patients and we should create a new model or not apply the TBC requirement to ESRD plans. We understand concerns related to this limitation when payments are decreasing. However, consistent with last year, CMS will maintain the CY 2017 evaluation process but reflect the increase in the overall TBC change threshold:

- ESRD SNPs with an increase in the overall payment adjustment amount greater than $34.00 PMPM will have a TBC change threshold of $0.00 PMPM (i.e., −1 times the TBC change limit of $34.00 PMPM) plus applicable technical adjustments.

- ESRD SNPs with a decrease in the overall payment adjustment amount less than -$34.00 PMPM will have a TBC change threshold of $68.00 PMPM (i.e., 2 times TBC change limit of $34.00 PMPM) plus applicable technical adjustments. That is, plans are not allowed to make changes that result in greater than $68.00 worth of decreased benefits or increased premiums.

If CMS provides an opportunity to correct CY 2018 TBC issues following the submission deadline, the MAO cannot change its formulary (e.g., adding drugs etc.) as a means to satisfy this requirement. The requirements under this section are the same as those under Meaningful Difference section in this Call Letter. Detailed TBC information and examples will be provided in mid-April 2017 via the HPMS Memorandum titled "CY 2018 MA Bid Review and Operations Guidance."

We received comments from several organizations expressing concerns about our proposal to exclude adjustments from the TBC calculation for CY 2017 plan(s) that are consolidated into a continuing CY 2018 plan. Commenters provided information indicating that certain situations would produce inconsistent evaluation results and that consolidating plans would be treated differently than continuing plans in the calculation. We appreciate the comments and will maintain the TBC evaluation used during CY 2017 for consolidating plans. CMS will include the operational details of this process in the annual HPMS Memo titled "CY 2018 Medicare Advantage Bid Review and Operations Guidance," issued in mid-April.

As in the past, CMS received comments requesting an earlier release of the TBC data posted on HPMS. CMS releases the estimated beneficiary out-of-pocket cost (OOPC) model in early-April. Similarly, CMS finalizes and releases the PBP software in early-April. Therefore, CMS is limited in its ability to release the TBC data posted on HPMS any earlier than mid-April.

Maximum Out-of-Pocket (MOOP) Limits

As codified at 42 CFR §422.100(f)(4) and (5) and §422.101(d)(2) and (3), all MA plans, including employer group plans and SNPs, must establish limits on enrollee out-of-pocket spending that do not exceed the annual maximum amounts set by CMS. Although the MOOP

requirement is for Parts A and B services, an MAO can include supplemental benefits as services subject to the MOOP. MA plans may establish as their MOOP any amount within the ranges shown in the table.

Table 14 below displays the CY 2018 mandatory and voluntary MOOP amounts and the combined (catastrophic) MOOP amount limits applicable to Local PPOs and Regional PPOs. A plan's adoption of a MOOP limit that qualifies as a voluntary MOOP ($0 - $3,400) results in greater flexibility for individual service category cost sharing. The possible ranges of the MOOP amount within each plan type are displayed 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. As clarified in the CY 2017 Call Letter, the in-network MOOP amount dictates the combined MOOP range for PPOs (i.e., PPOs are not permitted to offer a combined MOOP amount within the mandatory range, while having an in-network MOOP amount within the voluntary range).

Table 14: CY 2018 Voluntary and Mandatory MOOP Range Amounts by Plan Type (Values may be updated at a later date)

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

As explained in the CY 2012 Call Letter, MOOP limits are based on a beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Original Medicare. The mandatory MOOP amount represented approximately the 95th percentile of projected beneficiary out-of-pocket spending. Stated differently, five percent of Original Medicare

beneficiaries are expected to incur approximately $6,700 or more in Parts A and B deductibles, copayments and coinsurance. The voluntary MOOP amount of $3,400 represents approximately the 85th percentile of projected Original Medicare out-of-pocket costs.

The Office of the Actuary conducts an annual analysis to help CMS determine the proposed MOOP amount. Since the MOOP requirement was finalized in 42 C.F.R. §422.100(f)(4) and (5), a strict application of the 95th and 85th percentile would have resulted in MOOP limits fluctuating from year-to-year. CMS has exercised discretion to maintain stable MOOP limits from year-to-year, if the beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Original Medicare is approximately equal to the appropriate percentile. This approach avoids enrollee confusion, allows plans to provide stable benefit packages, and does not discourage the adoption of the lower voluntary MOOP amount if the limit increases one year and then decreases the next. CMS expects to increase MOOP limits if a consistent pattern of increasing costs emerges over a period of time.

Although it may be rare that a dual-eligible enrollee would be responsible for paying cost sharing (because the State Medicaid program is making those payments on his/her behalf), all MA plans must track enrollees' 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, certain dual-eligible enrollees for whom cost sharing is allowed may incur cost sharing and any enrollee losing his/her Medicaid eligibility may be responsible for cost sharing. D-SNPs have the flexibility to establish $0 as the MOOP amount, thereby guaranteeing there is no cost sharing for plan enrollees, including those who are liable for Medicare cost sharing. Otherwise, if the D-SNP does charge cost sharing for Medicare Part A and Part B covered benefits, it must track enrollees' out-of-pocket spending and it is up to the plan to develop the process and vehicle for doing so.

We received comments suggesting changes to encourage MAOs to offer voluntary MOOP limits as part of their plan designs. For example, some suggested changes, include increasing the amount of the voluntary MOOP limit; increasing the number service categories that provide cost sharing flexibility; and offering enrollment throughout the year. CMS will continue to conduct research and evaluate potential future changes to the MOOP limits, based on Medicare FFS, MA encounter data, and general benefit analyses.

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 and must not be discriminatory. In order to ensure that cost sharing is consistent with both 42 C.F.R. §422.254(b)(4) and §422.100(f)(2), CMS will evaluate actuarial equivalent cost sharing limits separately in the following service categories for CY 2018: Inpatient, Skilled Nursing Facility (SNF), Durable Medical Equipment (DME), and Part B drugs. Please note that CMS has updated factors for Inpatient and SNF in

Column 4 of the table below (Part B Adjustment Factor to Incorporate Part B Cost Sharing) for CY 2018. As described in the Part C Cost Sharing Standards section of this Call Letter, CMS will permit cost sharing for the first 20 days of the Skilled Nursing Facility (SNF) benefit for CY 2018 if the plan includes a voluntary MOOP. Therefore, SNF will be included in the AE evaluation process and is included in the chart below.

Whether in the aggregate, or on a service-specific basis, CMS identifies excess cost sharing by comparing two values found in Worksheet 4 of the BPT. Specifically, CMS compares a plan's PMPM cost sharing for Medicare covered services (BPT Worksheet 4, Section IIA, column l) to Original Medicare Actuarially Equivalent Cost Sharing (BPT Worksheet 4, Section IIA, column n). For Inpatient and SNF services, the AE Original Medicare cost sharing values, unlike plan cost sharing values, do not include Part B cost sharing; therefore, CMS applies an adjustment factor 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 table below uses illustrative values to demonstrate the mechanics of this determination.

Table 15: Illustrative Comparison of Service-Level Actuarial Equivalent Costs to Identify Excessive Cost Sharing

	#1	#2	#3	#4	#5	#6	#7
BPT Benefit Category	**PMPM Plan Cost Sharing (Parts A&B)** ***(BPT Col. l)***	**Original Medicare Allowed** ***(BPT Col. m)***	**Original Medicare AE Cost sharing** ***(BPT Col. n)*** [1]	**Part B Adjustment Factor to Incorporate Part B Cost Sharing (Based on FFS data)**	**Comparison Amount** ***(#3 × #4)***	**Excess Cost Sharing (#1 − #5, min of $0)**	**Pass/Fail**
Inpatient	$33.49	$331.06	$25.30	1.410	$35.67	$0.00	Pass
SNF	$10.83	$58.19	$9.89	1.067	$10.56	$0.27	Fail
DME	$3.00	$11.37	$2.65	1	$2.65	$0.35	Fail
Part B-Rx	$0.06	$1.42	$0.33	1	$0.33	$0.00	Pass

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

NOTE: In CY 2017, CMS waived the requirement for MA employer plans to submit a Bid Pricing Tool (BPT), which affects our ability to evaluate the PMPM Actuarial Equivalent Cost Sharing discussed in this section. MA employer plans (EGWPs) continue to be subject to all unwaived MA regulatory requirements regardless of whether CMS affirmatively evaluated these plans as part of bid review or in connection with other oversight. CMS may take compliance actions against EGWPs in connection with failure to comply with unwaived regulatory and statutory requirements.

Part C Cost Sharing Standards

For CY 2018, CMS will continue the current policy of affording MA plans greater flexibility in establishing Parts A and B cost sharing by adopting a lower voluntary MOOP limit than is available to plans that adopt the higher, mandatory MOOP limit. Table 16 below summarizes the standards and cost sharing amounts by MOOP type (e.g., mandatory or voluntary) for MA plans that we will not consider discriminatory or in violation of other applicable standards. CY 2018 bids must reflect enrollee cost sharing for in-network services no greater than the amounts displayed below. CMS applies these standards only to in-network Parts A and B services unless otherwise indicated in the table. All standards and cost sharing are inclusive of applicable service category deductibles, copayments and coinsurance, but do not include plan level deductibles. Inpatient standards are updated to reflect estimated changes in Original Medicare cost for CY 2018.

Table 16: CY 2018 In-Network Service Category Cost Sharing Requirements

Cost Sharing Limits			
Service Category	**PBP Section B data entry field**	**Voluntary MOOP**	**Mandatory MOOP**
Inpatient Hospital – Acute - 60 days	1a	N/A	$4,235
Inpatient Hospital – Acute - 10 days	1a	$2,495	$1,996
Inpatient Hospital – Acute - 6 days	1a	$2,271	$1,817
Inpatient Hospital Psychiatric - 60 days	1b	$2,677	$2,142
Inpatient Hospital Psychiatric - 15 days	1b	$2,025	$1,620
Skilled Nursing Facility – First 20 Days[1,2]	2	$20/day	$0/day
Skilled Nursing Facility – Days 21 through 100[1]	2	$167.50/day	$167.50/day
Emergency Care/Post Stabilization Care[3]	4a	$100	$80
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%

Cost Sharing Limits			
Service Category	**PBP Section B data entry field**	**Voluntary MOOP**	**Mandatory MOOP**
DME-Diabetes Monitoring Supplies	11c	N/A	20% or $10
DME-Diabetic Shoes or Inserts	11c	N/A	20% or $10
Dialysis Services[1]	12	20% or $30	20% or $30
Part B Drugs-Chemotherapy[1,4]	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 that establish a voluntary MOOP 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. The dollar amount included in the table represents the maximum cost sharing permitted per visit (copayment or coinsurance).

[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.

MA plans may not charge enrollees higher cost sharing than is charged under Original Medicare for chemotherapy administration, skilled nursing care and renal dialysis services (42 CFR §422.100(j)). Although CMS has not established a specific service category cost sharing limit for all possible services, MA plans may not pay less than 50% of the contracted (or Medicare allowable) rate and cost sharing for services cannot exceed 50% of the total MA plan financial liability for the benefit. If a plan uses a copayment method of cost sharing, then the copayment for an in-network Original Medicare service category cannot exceed 50% of the average contracted rate of that service (Medicare Managed Care Manual, Chapter 4, Section 50.1).

Copayments are expected to reflect specific benefits identified within the PBP service category or a reasonable group of benefits or services provided. Some PBP service categories may identify specific benefits for which a unique copayment would apply (e.g., category 3 includes specific benefits for cardiac rehabilitation, intensive cardiac rehabilitation and pulmonary rehabilitation services), while other categories include a variety of services with different levels of costs which may reasonably have a range of copayments based on groups of similar services (e.g., category 8b includes outpatient diagnostic radiological services). It is expected that organizations typically have much lower cost sharing for enrollees than our requirements due to effective managed care principles, effective negotiations between organizations and providers, and competition.

MAOs with benefit designs using a coinsurance or copayment amount for which CMS does not have an established amount (e.g., coinsurance for inpatient or copayment for durable medical equipment) must submit documentation with their initial bid that clearly demonstrates how the coinsurance or copayment amount satisfies CMS service category requirements for each applicable plan. This documentation may include information for multiple plans and must be identified separately from other supporting documentation submitted as part of the BPT. The documentation must be submitted for each plan through the supporting documentation upload section titled "Cost Sharing Justification" in HPMS. The upload will be available to all MA plan types (both employer and individual market), but not for stand-alone PDPs. The navigation path for uploading cost sharing justification files will be located at Plan Bids > Bid Submission > CY 2018 > Upload > Cost Sharing Justification.

CMS annually evaluates available Medicare data and other information to apply MA requirements in accordance with applicable law. Organizations are afforded the flexibility to design their benefits as they see fit so long as they satisfy Medicare coverage requirements.

The following summarizes changes in cost sharing requirements that were considered and described in the draft Call Letter for CY 2018:

- As indicated in the draft CY 2018 Call Letter, CMS considered whether to permit cost sharing for the first 20 days of the SNF benefit for CY 2018. We received comments supporting the proposal because SNF and home health cost sharing should replicate original Medicare. CMS received comments recommending that we allow flexibility in applying cost sharing to SNF during the first 20 days as in CY 2017. Commenters indicated that as long as the overall SNF benefit is actuarially equivalent to original Medicare, the flexibility to impose cost-sharing in the first 20 days provides MAOs the opportunity to increase the number of plans they offer with a lower, voluntary MOOP amount. As a result, we are not finalizing the change for CY 2018 and will maintain the same SNF cost sharing limit permitted in CY 2017 for MA plans that use a voluntary MOOP. Please note plans are not permitted to apply a service category deductible or a per stay amount to the SNF benefit.

- Per our authority at 42 C.F.R. §422.113(b)(2)(v), the Emergency Care/Post Stabilization Care limit for plans has been increased for CY 2018 to better align cost sharing with actual costs and as an incentive to use primary and specialty care services for routine care and avoid using the emergency room for non-emergent routine services. The voluntary MOOP amount increased from $75 to $100, while the mandatory MOOP amount increased from $75 to $80. CMS expects having different limits based on the plan's MOOP amount will encourage organizations to offer benefit packages with a lower voluntary MOOP amount, while maintaining beneficiary protection. We received comments in support of this increase, although some commenters thought the increase should be the same regardless of the MOOP amount. One organization suggested

increasing the limit above $100 and allow coinsurance in this category that can exceed the limit (similar to original Medicare). Other commenters expressed their concern over the increase and that it may result in lower income enrollees being deterred from using emergency room services. CMS is finalizing our proposal for CY 2018 and will consider increasing the limit for plans offering a mandatory MOOP amount. In addition, we will consider potential rulemaking to address the limit on coinsurance for this service.

- CMS considered whether to use additional cost sharing thresholds for cardiac rehabilitation services ($50), intensive cardiac rehabilitation services ($100), and pulmonary rehabilitation services ($30). Cost sharing amounts for these services have been an area of concern for CMS as we learned of benefit designs that CMS believed were not fully transparent to enrollees. CMS has worked with these organizations to successfully address these issues and ensure these organizations comply with our benefits policy as described above. CMS is not finalizing the addition of these cost sharing categories for CY 2018, but plan designs must continue to satisfy CMS benefits policy.

In response to questions about how certain health care services are defined and entered into the PBP software, MAOs are reminded that PBP services are defined in both the PBP software and HPMS reports (navigation path: HPMS > Plans Bids > Bid Reports > 2018 > "Service Category Report").

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. CMS will continue to consider a plan to be non-discriminatory when the total value of all optional supplemental benefits offered to non-employer plans under each contract meets the following thresholds: (a) the enrollment-weighted contract-level projected gain/loss margin, as measured by a percent of premium, is no greater than 15% and (b) the sum of the enrollment-weighted contract-level projected gain/loss margin and non-benefit expenses, as measured by a percent of premium, is no greater than 30%.

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

Employer Group Waiver Plans

In CY 2017, CMS waived the requirement for MA employer plans to submit a MA or Part D Bid Pricing Tool (BPT), but employer plans must complete and submit the MA portion of the Plan Benefit Package (PBP) in accordance with CMS requirements. Organizations should make a good faith effort in projecting CY 2018 member months for each plan and place the amount in

Section A-2 of the PBP. The following question must be completed for all MA and 1876 Cost Plan organizations: "Indicate CY 2018 total projected member months for this plan."

Medical Services Performed in Multiple Health Care Settings

CMS will continue its efforts to avoid duplication of medical services categories in the PBP and provide guidance on how to properly place services that can be performed in different health care settings (e.g., physician office, outpatient hospital, and free standing facility) in the appropriate service category to correctly complete data entry within the PBP.

CMS aims to improve transparency and streamline data entry so cost sharing associated with those PBP service categories reflects the services provided across a variety of healthcare settings. CMS is concerned that including the same service in multiple locations throughout the PBP may result in confusing marketing materials and that CMS cost sharing requirements may 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 artificially 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).

Most individual PBP service categories reflect cost sharing for services provided in different places of service. The two service categories below generated the most questions because they reflect a specific place of service. Based on bid review activities, MAOs requested examples of services that may be included by plans:

- Outpatient Hospital (9a): Some examples include, outpatient surgery, observation services, and palliative care services.

- Outpatient Diagnostic/Therapeutic Radiological Services (8b): Some examples include, magnetic resonance imaging (MRI), positron emission tomography (PET) and single-photon emission computed tomography (SPECT) services.

These examples are provided in the service category descriptions in HPMS documentation and the PBP screens.

We received comments requesting clarification on how to enter services into the PBP for the outpatient hospital services category. For example, therapeutic radiological services may be offered in an outpatient hospital setting, but has its own PBP category. Services that have their own PBP category (e.g., therapeutic radiological services) must be entered into that particular category (8b). The plan should use the minimum and maximum data fields to vary the cost sharing based on the different places of service.

Tiered Cost Sharing of Medical Benefits

For CY 2018, MAOs will continue to submit tiering requests through an electronic mailbox. Organizations must submit the benefit design to CMS prior to bid submission to help make sure benefits are acceptable and communications are transparent for beneficiaries. Organizations also are permitted to modify proposed cost sharing amounts in their actual bid submission. Further details regarding the process will be provided in an HPMS memorandum in mid-April.

We received comments supporting the tiering of medical benefits, while others expressed concerns about beneficiary confusion. Plan marketing materials must describe benefits in a clear and transparent manner so that beneficiaries can make informed purchase and health care decisions.

CMS Monitoring and Compliance Activities Regarding Encounter Data

Under 42 C.F.R. § 422.310 MAOs are required to submit encounter data for each item and service provided to an MA plan enrollee. The Medicare Advantage Encounter Data System (EDS) was implemented to receive encounter data beginning in 2012 and has collected over 2 billion encounter data records to date. PACE organizations are also required to submit encounter data.

Pursuant to 42 C.F.R. § 422.310(d), for PY 2015 CMS initiated the transition to Encounter Data based risk scores for MA and PACE enrollees by using diagnoses from encounter data records as an extra source of data when calculating beneficiary risk scores. For PY 2016, CMS blended two risk scores, one calculated using diagnoses from the RAPS, and the other risk score calculated using diagnoses from encounter data records; the RAPS and ED-based risk scores are weighted 90 percent and 10 percent, respectively. For PY 2017, the RAPS and ED-based risk scores will be weighted 75 percent and 25 percent, respectively. See Attachment III, Section J of this CY 2018 Rate Announcement for additional information.

Additionally, as a prudent purchaser of medical care for Medicare enrollees, CMS needs to ensure the collection of complete and accurate encounter data for a range of program purposes beyond risk adjustment, such as analysis of service utilization in the MA program. For example, a recent CMS analysis of encounter data was used by the Department of Health and Human Services to locate and assist MA enrollees requiring respiratory services during the disaster relief efforts in Louisiana this summer. Ensuring the completeness and accuracy of encounter data is also important as a growing community of analysts starts to use these data for a range of research projects.

As required under § 422.310(b) and (d), MAOs must submit risk adjustment data that characterize the context and purpose of each item and service provided to a Medicare enrollee, and must also conform to CMS' requirements for submitting this data and to all relevant national standards. In addition, at § 422.504(l), CMS requires MAOs to certify to the accuracy,

completeness, and truthfulness of their encounter data (based on best knowledge, information, and belief). Thus, CMS expects that MAOs are conducting self-assessments regarding the accuracy and completeness of their encounter data submissions for each contract they have with CMS, and that each year MAOs apply the findings from their self-assessments to improve the accuracy and completeness of their encounter data submissions. We also note that CMS is conducting site visits with a sample of MAOs to understand different approaches to and issues with encounter data processing and to identify areas where CMS can improve technical assistance and guidance.

The monitoring measures described in this Call Letter will be used to review and evaluate whether an MAO's encounter data submissions meet the regulatory standards applicable to CMS-specified abbreviated formats (also known as RAPS data) and data that is equivalent to FFS data (also known as encounter data). CMS expects that over time new monitoring measures will be developed and introduced.

CMS has been conducting basic monitoring of MAOs' encounter data submissions since 2012 and will now be using performance measures related to encounter data submission to guide oversight and enforcement in this area, with the goal of further ensuring complete and accurate submissions. CMS is implementing compliance actions for some failures to comply with the regulatory submission standards set forth at § 422.310(b) and (d) and at § 422.504(l). CMS will include MMPs in these efforts as appropriate.

CMS is focusing monitoring and compliance activity in these areas:

- Operational Performance: Refers to submitters' performance related to encounter data submission requirements such as certification to submit, non-submission, and frequency of submission.

- Completeness Performance: Refers to both the overall volume of encounter data records (e.g., whether encounter data records are being submitted for all services rendered) as well as to the completeness of data within an encounter data record (e.g., whether key fields are populated as expected).

- Accuracy Performance: Refers to the reasonableness of ED patterns. Measures addressing the reasonableness of specific data elements or reasonable patterns in submitted data would be considered under the area of accuracy (e.g., reasonable patterns of HCPCs and diagnosis codes).

CMS will communicate its measures and acceptable performance thresholds (benchmarks) via the Call Letter, HPMS memos, or other guidance communications.

CMS has identified the following measures, relating to operations and completeness, to use to guide its evaluation and oversight of MAO data submission under 42 C.F.R. §422.310:

- (Operational Performance O1) **Failure to complete end-to-end certification**

  CMS will assess certification status to identify contracts that have failed to complete end-to-end certification.

- (Operational Performance O2) **Failure to submit any encounter data records**

  CMS will assess failure to submit any encounter data records for a given calendar year.

- (Operational Performance O3) **Failure to submit encounter data records on a timely basis**

  CMS' encounter data systems must accommodate submissions from all MAOs of data on each item and service provided to each enrollee. To handle submissions for millions of enrollees each year, CMS and MAOs need to manage system loads in an efficient and cost-effective manner. To this end CMS has communicated to submitters the need for routine, timely submissions of encounter data records (EDRs) since 2012, expressed as the standards described in Table 17.

  Therefore, CMS will assess the frequency of submitters' file submissions each quarter, based on the most recently completed three quarters. CMS will count whether an MAO has submitted files on a timely basis and as frequently as necessary. The frequency standards are based on the enrollment size of a contract as shown in the table below.

Table 17: Plan Size Submission Frequency Requirements

Number of Medicare Enrollees in the Contract	EDR Minimum Submission Frequency
Greater than 100,000	Weekly
50,000 – 100,000	Bi-Weekly (every 2 weeks)
Less than 50,000	Monthly

- (Operational Performance O4) **Excessive encounter data submission at the end of the risk adjustment data submission window**

  Submission of an excessive number of records at the end of the submission window indicates that encounter data records have not been submitted timely throughout the year. The denominator of the measure will be the total number of encounter data records submitted with dates of service in the calendar year for which the most recent risk adjustment submission window has passed, and the numerator of the measure will be the

subset of encounter data records for the applicable calendar year submitted in the last two months of the submission window.

- (Completeness Performance C1) **Extremely low volume of overall encounter data record submissions.**

  The regulation at §422.310(b) requires submission of encounter data for all items and services provided to an MA enrollee; a low volume of submissions indicates that encounter data is not being submitted for all items and services on a timely basis. CMS will assess submitters' overall volume of encounter data records (those records making it through the front-end of the EDS) each quarter, based on the most recently completed three quarters. CMS will use as a guide whether a submitter's overall volume of encounter data records is at or below a percentage of the benchmark for two consecutive quarters within a rolling three quarter period. The benchmark for comparison will be the average overall front-end volume of encounter data records for all MA contracts within the enrollment size category (small contracts are those under 50,000 enrollees, medium contracts are those with enrollment between 50,000 and 100,000, and large contracts are those with greater than 100,000 enrollees).

- (Completeness Performance C2) **Extremely low volume of accepted encounter data records by service type.**

  The regulation §422.310(b) requires submission of encounter data for all items and services provided to an MA enrollee; a low volume of submissions indicates that encounter data is not being submitted for all items and services on a timely basis in the required format. CMS will assess submitters' volume of accepted encounter data records in the aggregate as well as by service type (inpatient, outpatient, professional, DME). CMS will assess whether a submitter's aggregate or service level volume of encounter data records is at or below a region-specific percentage of the benchmark for two consecutive quarters. The benchmark for comparison will be the aggregate and service level volume of encounter data records for all MA contracts within a region.

- (Completeness Performance C3) **Low matching rate of inpatient encounter data records to inpatient no-pay records.**

  The regulation §422.310(b) requires submission of encounter data for all items and services provided to an MA enrollee; a low matching rate to inpatient no-pay records received from hospitals by CMS may indicate that encounter data is not being submitted for all items and services. Certain inpatient hospitals must submit "informational-only" bills (also known as "No Pay" claims) for MA enrollee discharges, under FFS payment policies. These bills are submitted to CMS in order to capture the number of MA inpatient days, which are utilized in calculations of medical education and disproportionate share (DSH) payments to the hospitals. For information on requirements

for informational-only bills, see Chapter 3 of the Medicare Claims Processing Manual (e.g., Sections 20.3 and 140.2.5.3) on the CMS website at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf.

CMS will continue to provide the matching rate of inpatient encounter data records to inpatient no-pay records to contracts in the report cards. This measure will be used for informational purposes and to help contracts identify potential issues with inpatient encounter data submissions. CMS will use the Encounter Data Report Cards or other means to communicate a contract's performance on these measures to the appropriate contacts.

In future years, CMS expects to revise existing performance measures or include additional measures as they are developed as part of CMS' on-going evaluation and oversight of MAO compliance with the standards set forth at § 422.310(b) and (d) and at § 422.504(l). The measures and benchmarks discussed here will be used to evaluate MAO compliance with the regulatory and statutory requirements related to risk adjustment data submission. These evaluations will inform and provide direction for CMS oversight and compliance actions with regard to the applicable regulations.

CMS will continue monitoring and assessment of contractor performance, using these measures. CMS will identify contracts failing to meet the performance thresholds for follow up communication, technical assistance, and tracking, and will conduct monitoring and compliance activity, including but not limited to notices of non-compliance, warning letters, and corrective actions plans as needed to improve performance.

CMS thanks those who submitted comments on the monitoring and compliance approach presented here and appreciates stakeholders' general support for performance standards for encounter data submission, completeness and accuracy. CMS recognizes the primary concern stated by commenters that compliance activity for encounter data is premature at this time. CMS notes the primary recommendation from commenters to take into account stakeholders' feedback on proposed measures and that CMS improve transparency and communication of measures to the industry. CMS also appreciates the detailed feedback on specific measures included in the Call Letter.

With regard to next steps:

Timeline for Monitoring and Compliance Activity. CMS appreciates the need to phase-in monitoring and compliance activity and intends to continue taking an incremental approach to implementing monitoring and compliance action relating to encounter data submission, completeness, and accuracy. The three measurement areas set forth in this Call Letter present a general framework. In starting this process, CMS will consider monitoring and compliance related to the most rudimentary performance measures, such as failure to complete end-to-end certification and failure to submit any encounter data records (assuming the contract has enrollees). CMS will work on further development of additional measures over time and

appreciates the measure specific feedback from respondents. CMS will take this feedback into consideration.

CMS expects to continue promoting complete and accurate encounter data submissions through expanded validation and feedback activities on the encounter data submitted. Recent related activities include report cards, user group calls, on-site visits and various other methods of technical assistance.

Collaboration and Transparency for ED Compliance. CMS developed the CY 2018 Call Letter discussion of the measures in order to solicit feedback from stakeholders on encounter data monitoring and compliance. CMS will continue to seek and listen to valuable feedback from stakeholders and to be transparent in the monitoring and compliance process.

Clarifications and Updates

Benefit Period Clarification for PBP

An organization may structure its hospital and skilled nursing facility (SNF) benefits to define 'benefit periods' differently than in Original Medicare. Such a benefit period typically starts the day inpatient care begins and ends when an enrollee has not received any inpatient care for a defined period of time. For example, in Original Medicare, the beneficiary must have 60 days without inpatient care to begin a new benefit period for inpatient care. CMS provides organizations with the four options listed below when choosing a benefit period for inpatient hospital acute, inpatient hospital psychiatric and SNF (referred to as inpatient facility hereinafter) benefits in the PBP. All benefit periods (including "Other") must not limit the number of inpatient days it covers to less than the number that would be covered by Original Medicare during a contract year and must be actuarially equivalent to Original Medicare's benefit and should be easily understood by the enrollee.

PBP Options:

(1) Original Medicare's benefit period for inpatient facilities, begins the day an enrollee is admitted to the inpatient facility. The benefit period ends when the enrollee has not received any inpatient care, for 60 days in a row. If the enrollee goes into a hospital or a SNF after one benefit period has ended, a new benefit period begins. The enrollee must pay cost sharing for each benefit period. There's no limit to the number of benefit periods.

(2) Annual benefit period begins the day an enrollee is admitted to an inpatient facility but there is no end of the period. The enrollee is charged cost sharing only once a year, no matter how many times the enrollee is admitted or discharged from an inpatient facility throughout the year.

(3) Per Admission benefit period (also may be referred to as "per stay") begins the day an enrollee is admitted to an inpatient facility and ends when the enrollee is discharged. The enrollee is charged the cost sharing each time he/she is admitted to an inpatient facility.

(4) "Other" benefit period is an option for plans to select if the Original Medicare, Annual or Per Admission alternatives do not describe the benefit period the organization is providing. The organization must provide a description of the benefit period in the notes section of the PBP so CMS can review and understand how their benefit period is being provided to their enrollees.

Based on previous bid review activities, CMS discovered some plans have chosen "Other" for the benefit period and the description used by the plan to describe the benefit period more appropriately fell into the a "Per Admission" or "Per Stay" benefit period category. It is important plans select the appropriate benefit period and only select "Other" for the benefit period if no other options provided in the PBP appropriately characterize the benefit period.

We received one comment expressing appreciation for our clarification on different benefit period options, but expressed concern about marketing materials being transparent for enrollees. CMS is issuing this guidance without change to make sure plans understand the need for enrollee transparency in marketing materials.

Reinsurance

CMS indicated in the draft CY 2018 Call Letter that quota share reinsurance is not permissible under the Section 1855(b) requirement for MA organizations to assume full financial risk. Quota share is a form of proportional (pro rata) reinsurance where the insurer and the reinsurer share risk based upon an agreed percentage, in some cases from the first dollar of expenses. We also noted that this section of the statute does not apply to Part D plans, including the Part D portion of an MA-PD plan. See section 1860D-12(a)(2) for provisions applicable to Part D plans and sponsors.

Section 1855(b) of the Act (42 U.S.C. 1395w-25) states:

> (b) ASSUMPTION OF FULL FINANCIAL RISK.—The [MA] organization shall assume full financial risk on a prospective basis for the provision of the health care services for which benefits are required to be provided under section 1852(a)(1), except that the organization—
>
> (1) may obtain insurance or make other arrangements for the cost of providing to any enrolled member such services the aggregate value of which exceeds such aggregate level as [CMS] specifies from time to time,

> (2) may obtain insurance or make other arrangements for the cost of such services provided to its enrolled members other than through the organization because medical necessity required their provision before they could be secured through the organization,
>
> (3) may obtain insurance or make other arrangements for not more than 90 percent of the amount by which its costs for any of its fiscal years exceed 115 percent of its income for such fiscal year, and
>
> (4) may make arrangements with physicians or other health care professionals, health care institutions, or any combination of such individuals or institutions to assume all or part of the financial risk on a prospective basis for the provision of basic health services by the physicians or other health professionals or through the institutions.

The draft Call Letter also requested comments to assist in developing a proposal to establish the aggregate value specified in the first statutory exception, which would be adopted in future rulemaking.

In response to the draft Call Letter, several organizations expressed concerns about CMS's interpretation of Section 1855(b). MA organizations were concerned they would not be able comply with a prohibition on quota share arrangements for contract year 2018 and about potential enforcement actions against those with existing arrangements. One commenter stated that Section 1855(b) does not specifically use the term "reinsurance" and that MA plans continue to be responsible to enrollees for full risk of the MA services when the organization has reinsurance arrangements. Organizations indicated that quota share reinsurance is a common market practice that reduces financial exposure to changes in health care costs, helps manage capital requirements, and allows organizations to grow enrollment responsibly. Comments indicated organizations that may benefit from using quota share reinsurance could be located in areas with fewer beneficiary choices and that preventing MA organizations from using this form of reinsurance may negatively impact competition and consumer choice, especially in small and mid-sized market areas. Several comments suggested CMS should address the permissibility of any and all reinsurance arrangements through formal rulemaking at the same time we establish the aggregate value in the first statutory exception and provide sufficient implementation time.

As the comments clarified for CMS that a quota share structure could be used in connection with the risks identified in section 1855(b)(1) through (4), CMS is not proceeding with the interpretation that quota share reinsurance itself is not permitted by the statute. CMS acknowledges that the details of an arrangement (whether reinsurance or otherwise) for an MAO to share, transfer, or otherwise shift the risks identified in the exceptions listed in the statute are generally not limited by the statutory text. The statute permits MA organizations to share risk proportionally, so long as the risk (the type and amount) is in the exceptions.

CMS anticipates continuing to consider this issue, and the comments received, as it decides on future guidance and rulemaking. The limit for exception (1) could be established by CMS and

set at a level that would permit greater reinsurance protection for smaller MA plans if the limit is based on the number of plan enrollees (i.e., limit is lower for smaller plans and higher for larger plans).

We are not finalizing the CY 2018 draft Call Letter position regarding quota share reinsurance. CMS has not thus far provided regulatory guidance interpreting or applying this provision to specific arrangements. CMS may provide further clarifying guidance and/or potential future rulemaking to which MAOs would be held accountable at that time. To the extent any issues are identified we would work with MAOs to address concerns.

SNP-Specific Networks

CMS has increasingly taken steps to make certain that Medicare Advantage (MA) networks provide adequate access to covered services to meet enrollees' healthcare needs in accordance with 42 C.F.R. §422.112(a)(1)(i). We currently assess MA network adequacy at the contract level; however, many Medicare Advantage organizations (MAOs) offer a variety of plans under a contract. These include special needs plans (SNPs), which are MA coordinated care plans specifically designed to provide targeted care to special needs individuals who are either (1) institutionalized (I-SNPs), (2) dually eligible for both Medicare and Medicaid (D-SNPs), or (3) have a specific severe or disabling chronic condition (C-SNPs). All SNPs are required to limit enrollment to beneficiaries who meet the eligibility criteria for the type of SNP and to follow the same rules as non-SNP MA plans, but the key difference is that SNPs provide focused care to special target populations based on their unique health care needs. Given the different needs of SNP populations, CMS is interested in exploring the potential benefits of establishing separate network adequacy evaluations of SNP-specific networks.

We sought comment from SNP enrollee advocates, professional organizations, and sponsors on how and whether SNP-specific networks do and should differ from non-SNP MA plan networks in order to provide adequate access to covered services in light of the needs of the SNP covered population. For example, C-SNP networks might have or need more providers in certain specialties related to the chronic condition(s) of the given C-SNP. CMS asked commenters to consider what SNP-specific networks currently look like, how they are different from other MA networks, what would be desirable in SNP-specific network adequacy evaluation, and any suggested modifications to our current network adequacy evaluation and oversight relative to SNP-specific networks. We were also interested in how SNP-specific network adequacy evaluation would improve patient health or the quality of care. Our goal was to understand current SNP-specific networks and to make appropriate changes to ensure adequate access for some of our most vulnerable MA enrollees in need of enhanced care coordination.

We received many comments in support of the idea of SNP-specific network adequacy evaluations. Most commenters asked that any new SNP-specific standards allow for flexibility so that networks can be appropriately tailored for SNP enrollees with complex, unique health

care needs. Commenters recommended that SNP standards not be more restrictive than current MA network adequacy criteria. Many commenters also requested that CMS work collaboratively and transparently with stakeholders in developing network adequacy evaluations specific to SNPs. Detailed suggestions about time and distance standards, provider types, and exceptions were also submitted. For D-SNP network standards, some suggested that CMS consult with states and build on the experience of MMPs under the Medicare-Medicare Financial Alignment Initiative, in support of CMS's Medicare-Medicaid integration efforts. In addition, commenters noted that D-SNP networks need providers that accept both Medicare and Medicaid.

Based on the feedback from SNP stakeholders, CMS will move forward on developing SNP-specific network adequacy evaluations. We thank commenters and will consider these suggestions as we progress in our research and future development of SNP-specific network adequacy evaluations. CMS looks forward to working with MAOs, providers, and other key stakeholders to better understand SNP networks and improve SNP enrollee health care experiences.

Decreasing Health Disparities in the Quality of Care that Vulnerable Populations Receive

A high priority for CMS is addressing disparities in health and health care between the population groups our agency serves. Furthermore, this supports the Health and Human Services (HHS) Strategic Goals for ensuring access to quality, culturally competent care for vulnerable populations. HHS Strategic Goal 1 (Strengthen Health Care) aims to reduce racial and ethnic disparities by providing culturally and linguistically appropriate health information, empowering individuals and their families through education and outreach strategies, and targeting environmental health initiatives in lower-income and minority communities. [9]

We are taking this opportunity to reinforce the importance of providing health care to enrollees in a nondiscriminatory way and to clarify our policies to assist MAOs in identifying ways to eliminate disparities. 42 C.F.R. §422.110 prohibits discrimination on the basis of race, color, national origin, sex, age or disability in health programs and activities that receive Federal financial assistance provided or made available by the Department. CMS reminds MAOs of their obligation to ensure that all enrollees receive high quality and necessary care without discrimination.

To improve health equity among vulnerable populations – racial and ethnic minorities, people with disabilities, sexual and gender minorities, and rural populations – MAOs are expected to promote access to high-quality and culturally competent health care services. CMS believes that some MAOs have interpreted the regulations at 42 C.F.R. §422.110, which prohibits discrimination, to preclude the MAO from conducting outreach that targets a portion of the

[9] https://www.hhs.gov/about/strategic-plan/

population or providing targeted interventions to a specific subset of enrollees. In fact, MAOs may target groups of enrollees for specialized services based on the enrollees' health conditions, as illustrated by the Enhanced Disease Management supplemental benefit described in Chapter 4 of the Medicare Managed Care Manual. CMS also expects MAOs to analyze enrollee data to identify disparities among their enrollees and undertake quality improvement and outreach activities to increase enrollee engagement so that appropriate care, including preventive services, can be provided to enrollees who have been identified as having worse health outcomes. To assist in the identification and prioritization of disparities, in 2016 CMS launched Part C and D Performance Data Stratified by Race and Ethnicity for HEDIS and CAHPS measures at the contract and national level, which can be found at this link: https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.html.

In alignment with the above-referenced law and HHS strategic goals, CMS sought comment from the industry regarding their experiences related to identifying and engaging enrollees in order to provide appropriate services, especially to vulnerable enrollees. CMS was particularly interested in learning about MAOs' collection of information about enrollees' race, gender, ethnicity and languages and how that information is used to eliminate disparities through quality improvement and outreach activities. All comments received on this topic were supportive of efforts to identify and reduce health disparities, especially among vulnerable and underserved populations. Many of the commenters applauded CMS for discussing this topic and felt that addressing health disparities would help to improve overall health outcomes and functionality, especially in SNPs. We thank the industry for their comments.

Section III – Part D

Formulary Submissions

CY 2018 Formulary Submission Window

The CY 2018 HPMS formulary submission window will open this year on May 15, 2017 and close at 11:59 PM PDT on June 5, 2017. CMS must be in receipt of a successfully submitted and validated formulary submission by the deadline of June 5, 2017 in order for the formulary to be considered for review. The Part D formulary is part of the plan's complete bid and therefore a failure to submit and link a formulary to each plan that uses a formulary by the June 5th deadline will result in denial of that bid submission.

CY 2018 Formulary Reference File

CMS released the first CY 2018 Formulary Reference File (FRF) in March 2017. 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 2017, 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 2017, CMS is planning to provide a subsequent release of the 2018 FRF prior to the June 5th formulary submission deadline. The May FRF will be released in mid to late May in order to allow for sufficient time to evaluate and add new Part D drugs that become available in our datasets. Since the OOPC model incorporates Medicare Current Beneficiary Survey (MCBS) data from 2011 and 2012, new Part D drugs cannot be included in the OOPC model since they would not have appeared in the survey. Further, given the limited timeframe between the May release of the 2018 FRF and the June 5th deadline, CMS is unable to accommodate an updated version of the 2018 OOPC model to incorporate the new generics that may be added to the May FRF. Therefore, CMS cautions plan sponsors that any newly added drugs on the May release of the 2018 FRF will not be included in the 2018 OOPC model.

CMS will offer a summer formulary update window that will allow for the following formulary changes: 1) the addition of drugs that are new to the summer release of the FRF, and 2) the submission of negative changes on brand drugs, only if an equivalent generic or therapeutically similar drug is added to the summer FRF and corresponding formulary file within the same category and class, at the same tier or lower, and with no more restrictive utilization management than what was applied to the existing brand. Thus, plan sponsors need to carefully consider any newly added drugs to the May release of the 2018 FRF, since additional restrictions will be imposed on the summer formulary update window.

Part D sponsors are reminded that they may enhance their formularies by adding Part D drugs (with or without utilization management restrictions), reducing beneficiary cost-sharing, or removing utilization management edits between the summer update window and the first HPMS submission of the upcoming plan year. These enhancements must be included in the Part D sponsor's marketing materials and must be submitted during the next available HPMS formulary submission window. Sponsors are encouraged to notify beneficiaries of formulary additions in a timely manner since in some cases, such as new generics, an earlier conversion could lead to better value for the beneficiary and potentially reduce program costs.

Changes for CY 2018 Formulary Submissions

Historically, CMS has collected the drug type label for each RxCUI on the formulary file submission. Similarly, this information is collected on the PBP to indicate which types of drug will be placed on each tier. For CY 2018, we have proposed that the formulary file submission format will no longer contain a field for drug type label, and the options on the PBP will be streamlined to two options: brand and generic. To see our proposal, which is pending OMB approval (OMB control number 0938-0763), please refer to the Paperwork Reduction Act (PRA) listing CMS-R-262, titled "CY 2018 Plan Benefit Package (PBP) Software and Formulary Submission" for complete file layouts and PBP screenshots, available at: https://www.cms.gov/

Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-R-262.html.

United States Pharmacopeia (USP) Convention Medicare Model Guidelines

Version 7.0 of the USP Medicare Model Guidelines is available on usp.org. Part D sponsors that utilize the Model Guidelines for their formulary classification are expected to use this version in their formulary development and submission processes. In addition, CMS intends to utilize this version in its review process.

Medication Therapy Management (MTM) Annual Eligibility Threshold

Targeted beneficiaries for a Part D sponsor'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 42 C.F.R. §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 42 C.F.R. §423.104(d)(5)(iv). The 2017 MTM program annual cost threshold is $3,919. The 2018 MTM program annual cost threshold is updated for 2018 using the annual percentage increase of 1.22% as specified in the Announcement of Calendar Year (CY) 2018 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies. Therefore, the 2018 MTM program annual cost threshold is $3,967.

Annually, Part D plan sponsors must submit an MTM program description to CMS through the Health Plan Management System (HPMS) for review and approval. CMS evaluates each program description to verify that it meets the current minimum requirements for the program year. The Annual Calendar in this Call Letter highlights key dates for the submission of MTM programs and attestations, as applicable. Of note, the attestation deadline is two weeks after the deadline for submission of CY 2018 MTM programs in HPMS.

A memo containing MTM program guidance and submission instructions is released each year by CMS and is available on the CMS.gov MTM page at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html. The guidance memo for CY 2018 will be released approximately one month before the 2018 MTM program submission deadline. The CY 2018 guidance memo will include the MTM program submission template. Questions regarding the MTM submission process or policy may be sent via email to partd_mtm@cms.hhs.gov.

Tiering Exceptions: Policy Clarifications, Additional Operational Guidance, and Solicitation for Stakeholder Feedback

Consistent with statute and regulations, plan sponsors offering prescription drug benefits for Part D drugs through the use of a tiered formulary must establish and maintain reasonable and complete exceptions procedures. These procedures must permit enrollees to obtain a drug in a higher cost-sharing tier at the more favorable cost-sharing applicable to alternative drugs on a lower cost-sharing tier of the plan sponsor's formulary when the plan sponsor determines that the non-preferred drug is medically necessary based on the prescriber's supporting statement.

As noted in the draft 2018 Call Letter, changes in the prescription drug landscape, including the considerable impact of high-cost drugs on the Part D program, have resulted in increasingly complex plan benefit packages and more variation in type and level of cost-sharing. In response, CMS has made a number of changes to Part D formulary tier models for non-defined standard benefit plans, including changes to tier labeling, which has resulted in brand and generic drugs being placed on the same tiers more frequently. However, some of these changes, along with the prevalence of multiple brand and generic drug tiers on formularies, have resulted in confusion about CMS policies related to tiering exceptions.

CMS believes that the policy clarifications on tiering exceptions in this final 2018 Call Letter will make the process more accessible for enrollees and less cumbersome for plan sponsors to administer. Tiering exceptions are an important beneficiary protection that allows Part D plan enrollees with a medical need for a non-preferred drug to manage out of pocket costs. Our expectation is that these clarifications will give sponsors a better understanding of CMS policy related to tiering exceptions and will promote alignment between Part D sponsor's policies and CMS requirements. In addition, we believe these clarifications will help reduce IRE overturns for these cases. CMS expects plans to ensure that their policies and procedures for tiering exceptions comply with CMS requirements.

Preferred and Non-Preferred Drugs

In the draft CY 2018 Call Letter, we provided clarifying guidance regarding the meaning of "preferred" and "non-preferred" drug in the context of multi-tier and mixed-tier formularies. Several plan sponsors and PBMs disagreed with the clarification that eligibility for a tiering exception should be based on the regulatory definitions of "preferred" and "non-preferred" drug as opposed to plan formulary tier labels. A number of commenters stated that the clarification circumvents tier structures. Advocacy groups and pharmaceutical manufacturers were supportive of the clarification and noted that plan enrollees should have access to information regarding tiering exceptions given the importance of this beneficiary protection in managing out-of-pocket costs.

As stated in the draft 2018 Call Letter, when plans design their tiering exceptions criteria and adjudicate requests for tiering exceptions, CMS expects sponsors to apply the correct definitions

for preferred and non-preferred drugs. Our regulations at 42 C.F.R. §423.100 define a preferred drug as "a covered Part D drug on a Part D plan's formulary for which beneficiary cost-sharing is lower than for a non-preferred drug in the plan's formulary." The statute at §1860D-4(g)(2) plainly contemplates that a preferred drug is a drug with more favorable cost-sharing for the beneficiary. Therefore, we are proceeding with clarifying in this final 2018 Call Letter that plan sponsors should base eligibility for a tiering exception on whether the alternative drug is on a formulary tier that has lower cost-sharing than the tier on which the requested drug resides, thereby making it a "preferred" drug. Eligibility should not be based on the label of the tier containing the alternative drug(s). CMS plans to make corresponding changes to the manual guidance in Chapter 18 of the *Prescription Drug Benefit Manual*.

Approval of Tiering Exception Requests

Chapter 18, §30.2.1.4 states that, "When a tiering exception is approved, the plan sponsor must provide coverage for the drug in the higher cost-sharing tier at the cost-sharing level that applies to the drug in the applicable lower cost-sharing tier." In the draft 2018 Call Letter, CMS proposed to clarify that, in situations where the requested drug has alternatives in multiple lower tiers and the plan sponsor has approved the request for a tiering exception, the plan must apply the cost-sharing for the *lowest* applicable cost-sharing tier that contains alternatives for the requested drug. Consistent with the manual provision, the lowest cost-sharing tier is the "applicable lower cost-sharing tier."

A number of plan sponsors and PBMs commented that they believe this clarification is a change in policy. Advocacy groups and pharmaceutical manufacturers expressed support for this clarification. When we have received this question from plan sponsors in the past, we have provided a response consistent with this clarification. Even though CMS has provided this clarification on an ad hoc basis, we believe a program-wide clarification is necessary to promote consistent application of this approach for approved tiering exceptions. Accordingly, for this 2018 final Call Letter, CMS is clarifying that approval of a tiering exception is to the lowest applicable tier when alternative drugs are in multiple lower tiers. Plan sponsors that do not currently do so are expected to comply with this approach no later than the beginning of the 2018 plan year. CMS plans to make corresponding changes to the manual guidance in Chapter 18 of the *Prescription Drug Benefit Manual*.

Several commenters requested clarification on what criteria to apply when determining what drugs should be considered "alternatives for treating the enrollee's condition" for purposes of tiering exceptions. We thank commenters for their input; CMS will continue to explore whether and how we can provide further clarity on this issue either through rulemaking or sub-regulatory guidance.

In the draft CY 2018 Call Letter, CMS also clarified that, consistent with regulations, a tiering exception is granted when the Part D plan sponsor determines that the requested drug is

medically necessary. Therefore, it is incumbent upon the plan to determine, in light of the supporting statement, whether there is another alternative to the prescribed drug that is in a lower tier than the preferred drug(s) addressed in the prescriber's supporting statement. As described in Chapter 18, §30.2 of the Prescription Drug Benefit Manual, if the prescriber's supporting statement does not sufficiently demonstrate the medical necessity of the requested drug and the plan determines it needs more information to make the decision, the plan must contact the prescriber and clearly identify what is needed.

We expect that this clarification, as it relates to the impact of an exception and not whether it should be granted, should not impact the rate of approvals or denials of tiering exceptions. We will approach the monitoring of plans' tiering exceptions processes with that expectation in mind.

Authorized Generics

Current tier labels for non-defined standard Part D plans allow plans to label a tier as "generic" when that tier may contain brand drugs. The regulation at 42 C.F.R. §423.578(a)(6) states that a plan sponsor is not required to cover a non-preferred drug at the generic cost-sharing if the plan maintains a separate tier dedicated to generic drugs. Chapter 18, §30.2.1.4 currently states that the limitation on approval of tiering exceptions at the cost-sharing that applies to generic drugs refers to tiers that include only generic drugs, not mixed tiers (that contain both brand and generic drugs) that are labeled generic.

In response to the draft CY 2018 Call Letter, several commenters requested that plan sponsors be able to treat "authorized generics" as generic drugs for purposes of tiering exceptions. CMS collects Part D plan formularies based on the National Library of Medicine RxNorm concept unique identifier (RXCUI), and not at the more specific National Drug Code (NDC) level. This process doesn't allow us to clearly identify whether the tier includes authorized generics.

We believe that the concept of a tier "dedicated to generic drugs" can be interpreted to mean a tier dedicated to generics and other drugs that are comparable to generics such as authorized generics. In this final CY 2018 Call Letter, we are revising our interpretation of the regulatory term "dedicated to generic drugs" to include authorized generics. We believe this is consistent with how such drugs are treated under current formulary structures and will not disrupt how plans administer their formularies. As such, to the extent a formulary tier is made up of only generic drugs or authorized generics, such a tier is considered dedicated to generics whether or not specific authorized generic drug products are adjudicated at the cost sharing applicable to such tier and a plan sponsor may exclude that tier from the tiering exception process.

Request for Information on Tiering Exceptions

In the draft CY 2018 Call Letter, CMS requested information related to tiering exceptions from plan sponsors, PBMs, and other interested stakeholders. We noted that, while tiering exception

requests constitute a small percentage of overall case volume, they are consistently associated with significantly lower approval rates than all other types of coverage and exception requests. Requested information included data on tiering exception request volume, approval and denial rates, beneficiary complaints and areas of confusion or concern.

While we received very limited data on tiering exceptions, we wish to thank commenters for the information that was provided. As stated in the draft Call Letter, in addition to the clarifications described above, CMS intends to use available data to close information gaps related to tiering exception policy and inform potential future rulemaking in this area.

Access to Preferred Cost-Sharing Pharmacies

In the CY 2016 Call Letter, CMS announced the policies we would implement during 2016 to address low access to preferred cost-sharing pharmacies (PCSPs). CMS then stated in the CY 2017 Call Letter that we would continue to implement policies for that year. Because we believe that the policies first announced for CY 2016 have afforded beneficiaries improved beneficiary access to PCSPs and clearer information about PCSP networks offered by Part D plans, we will continue to apply them in CY 2018 and in succeeding plan years.

For each plan year, CMS will take the following steps related to PCSP access for beneficiaries. First, we will post information about the current year's PCSP access levels on the CMS website. Second, we will require plans who were outliers with respect to access to PCSPs to disclose that their plan's PCSP network offered lower access than other plans. Finally, we will work with plans that are extreme outliers to address concerns about beneficiary access and marketing representations relating to preferred cost-sharing. We will work with extreme outlier plans to either improve access or develop targeted marketing strategies to ensure that beneficiaries selecting these plans are aware of their status as extreme outliers.

The current policy has improved access to PCSPs since it was first implemented, and we will continue to apply the same outlier thresholds that have been in place since CY 2016. Therefore, plans that provide PCSP pharmacy access within 2 miles of less than 40% of beneficiaries' residences in urban areas, within 5 miles of less than 87% of beneficiaries' residences in suburban areas, and within 15 miles of less than 70% of beneficiaries' residences in rural areas will be identified as outliers in 2018 and succeeding years, unless CMS notifies sponsors of a change in the thresholds in a future Call Letter. Outlier plans will be required to disclose in marketing materials, including websites, that their plans' PCSP networks offer lower access. The required disclaimer language was first announced in the June 24, 2015, HPMS memo "Marketing Disclaimer Language for Plans with Limited Access to Preferred Cost-Sharing Pharmacies" and was reissued in an August 16, 2016, HPMS memorandum. CMS continues to expect that plans will analyze their own 2017 and 2018 networks to determine whether they are below outlier thresholds. CMS will analyze preferred cost-sharing pharmacy access on a quarterly basis and will remind plans of their outlier status periodically.

CMS will also continue to work with extreme outliers to address concerns about beneficiary access and marketing representations related to preferred cost-sharing. CMS will notify these plans in or around April of each year that we intend to address with them during bid negotiations PCSP access issues for the upcoming plan year. In 2016 and 2017, most plans identified as extreme outliers opted to improve access rather than develop marketing plans to better inform beneficiaries of low PCSP access. We anticipate plans will take similar steps during negotiations for 2018 and future plan years.

We will continue to publish information about PCSP access levels annually on the CMS website at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/index.html. We will also explore the feasibility of incorporating this information into the Medicare Plan Finder in the future.

Sponsors that fail to include required marketing disclosure language and/or do not meet the terms of bid negotiation agreements will be subject to compliance and/or enforcement actions.

Part D Benefit Parameters for Non-Defined Standard Plans

Each year, 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 C.F.R. §423.104(d)(2)(iii), tiered cost-sharing for non-defined standard benefit designs may not exceed levels annually determined by CMS to be discriminatory. The benefit parameters for CY 2018 are set forth in Table 18 below.

For purposes of determining whether coverage gap cost-sharing thresholds specified in Table 18 have been met, we will continue to rely on the FDA Application Type to identify formulary drugs as applicable or non-applicable. The maximum coinsurance of 55% applies to tiers that contain only applicable drugs. If only non-applicable drugs or a combination of both non-applicable and applicable drugs are on a tier, then the maximum coinsurance of 24% 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, as noted in Table 18 below, to determine whether the coinsurance values are discriminatory. 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.

We remind sponsors that we expect Drug Tier Labels to be representative of the drugs that make up that tier. Sponsors will continue to have the option of selecting a non-preferred *brand* tier or non-preferred *drug* tier, but not both. CMS will continue to evaluate the brand/generic composition of the non-preferred *brand* tier as part of the bid review process and communicate concerns based on an outlier analysis. While we continue to believe a coinsurance structure is preferable for the non-preferred *drug* tier, CMS will continue to afford Part D sponsors the flexibility to determine the cost-sharing structure that is most appropriate for their benefit design, with the goal of maintaining transparency and a meaningful benefit offering for enrollees in a plan with non-preferred drug tiers that also balances a sponsor's ability to mix brand and generic drugs within the tier. We intend to conduct outlier tests for those Part D sponsors who choose a copay structure for the non-preferred drug tier. In order to demonstrate that the cost-sharing structure chosen provides a value for beneficiaries, we expect sponsors to evaluate and be prepared to provide written justification upon request. Sponsors may be asked to make modifications to their benefit structure or formulary tiering if the submitted justification is not accepted.

Please note that the PBP tool has been modified for CY 2018 with respect to Drug Type Labels. The options have been simplified to include either "brand" or "generic." Please refer to "Changes for CY 2018 Formulary Submissions," of this Call Letter for additional information.

In the draft CY 2018 Call Letter, we proposed a minimum monthly cost-sharing out-of-pocket costs (OOPC) difference between basic and enhanced PDP offerings of $20, and a minimum monthly cost-sharing OOPC difference between enhanced PDP offerings of $37. The values were based on the 50th percentile of the November CY 2017 Bid Data run through the new CY 2017 OOPC MPF model that incorporates CY 2017 Formulary Data, 2011/12 MCBS Data, and FDA Application Type for applicable/non-applicable determinations related to coverage gap cost-sharing estimates.

CMS received a number of comments in support of and opposing our proposed increase to the threshold between enhanced PDP offerings. Those in favor of CMS' proposal believed that the increase helps to ensure that sponsors are offering meaningfully different plans and minimizes beneficiary confusion. Commenters opposed to the proposal argued that the increase leads to more expensive plans and effectively limits plan choice. The commenters who did not support the increase asked CMS to lower the OOPC differentials between plan offerings, or at a minimum, lower the differential between enhanced plan offerings so that sponsors can give beneficiaries more choices.

CMS appreciates the importance of ensuring adequate plan choice for beneficiaries and the value of multiple plan offerings with a diversity of benefits, now and in the future as the coverage gap closes. CMS recognizes that the current OOPC methodology is only one method for evaluating whether the differences between plan offerings are meaningful, and will investigate whether the current OOPC model or an alternative methodology should be used in future years to evaluate meaningful differences between PDP offerings. Based on comments received, CMS recognizes that the proposed CY2018 OOPC percentile applicable to enhanced alternative (EA) plans could result in too few plan choices for beneficiaries. CMS will therefore maintain the 50th percentile for the basic to enhanced PDP offerings for CY 2018 (i.e., the minimum monthly cost-sharing OOPC difference between basic and enhanced PDP offerings will be $20), but will apply the 25th percentile instead of the 50th percentile to evaluate the difference between EA plans offered by the same sponsor (i.e., the minimum monthly cost-sharing OOPC difference between enhanced PDP offerings will be $30). We expect that, for CY 2018, our application of the meaningful difference standard will still allow us to approve up to 3 plan benefit packages (1 basic, and at most, two enhanced plans). We also believe that applying the 25th percentile may result in more stable formularies because plan sponsors would not need to make formulary changes for the sole purpose of meeting the meaningful difference standard.

As in the past, meaningful difference requirements apply to all stand-alone PDPs. We also continue to expect that the additional enhanced PDPs within a service area will have a higher value than the first enhanced plan and will include additional gap cost-sharing reductions for at least 10 percent of their formulary brand drugs.

CMS makes all of the necessary tools and information available to sponsors in advance of the bid submission deadline, and therefore expects all PDPs to submit bids that satisfy our standards. If CMS provides an opportunity to correct CY 2018 meaningful difference standards following the submission deadline, the PDP will not be permitted to change its formulary (e.g., adding drugs, etc.) as a means to satisfy this requirement. The formulary review process has multiple stages and making changes that are unrelated to CMS-identified formulary review concerns negatively affects the formulary and bid review processes. For example, portions of the annual formulary review process are based on outlier analyses. If a Part D sponsor were to be permitted to make substantial formulary changes after the initial reviews, these analyses could be adversely impacted. In addition, significant formulary changes will necessitate additional CMS review, outside of the normal review stages, and may jeopardize the approval of a sponsor's formulary. To avoid meaningful difference issues, PDPs are strongly encouraged to make sure all Part D benefit and formulary changes are considered as part of their meaningful difference evaluation prior to submitting their final bids and formularies to CMS.

The methodology for developing the CY 2018 out-of-pocket costs (OOPC) model is consistent with last year's methodology. F or more information, please reference the HPMS memorandum dated December 22, 2016 titled "Medicare Plan Finder (MPF) Plan Version of Out-of-Pocket

Cost (OOPC) Model for CY 2017." Customary updates for utilization data, as well as PBP and formulary data used for CY 2018 bid submissions, are also included in the 2018 model.

Table 18: Benefit Parameters for CY 2018

	CY 2018 Threshold Values
Minimum Meaningful Differences (PDP Cost-Sharing OOPC)[1]	
Enhanced Alternative Plan vs. Basic Plan	$ 20
Enhanced Alternative Plan vs. Enhanced Alternative Plan	$ 30
Maximum Copay: Pre-ICL and Additional Cost- Sharing Reductions in the Gap (3 or more tiers)	$[2,3]$
Preferred Generic Tier	<$20[4]
Generic Tier	$20
Preferred Brand/Brand Tier	$47
Non-Preferred Drug Tier	$100
Non-Preferred Brand Tier	$100
Injectable Tier	$100
Select Care/Diabetic Tiers[5]	$11
Vaccine Tier	$0
Maximum Coinsurance: Pre-ICL (3 or more tiers)	$[2,3]$
Preferred Generic Tier	25%
Generic Tier	25%
Preferred Brand/Brand Tier	25%
Non-Preferred Drug Tier	50%
Non-Preferred Brand Tier	50%
Injectable tier	33%
Select Care/Diabetic Tiers[5]	15%
Vaccine Tier	0%
Maximum Coinsurance: Additional Cost-Sharing Reductions in the Gap for Applicable Beneficiaries (all tier designs)[6]	$[3]$
Preferred Generic Tier	24%
Generic Tier	24%
Preferred Brand/Brand Tier	55%
Non-Preferred Drug Tier	55%
Non-Preferred Brand Tier	55%
Injectable Tier	55%
Select Care/Diabetic Tiers[5]	55%
Vaccine Tier	0%
Minimum Specialty Tier Eligibility	
1-month supply at in-network retail pharmacy	$670

[1] The Enhanced Alternative Plan to Basic Plan meaningful difference minimum threshold is based on the 50th percentile of the November CY 2017 Bid Data run through the CY 2017 OOPC MPF model which incorporates CY 2017 Formulary Data, 2011/12 MCBS Data, and FDA Application Type for applicable/non-applicable determinations related to coverage gap cost-sharing estimates. This threshold excludes plans that were waived of the meaningful difference requirements due to the transition period afforded during consolidation. 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 2017 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] A separate maximum cost-share threshold for the Preferred Generic Tier has not been established. Cost-sharing for the Preferred Generic Tier need only be lower than that for the cost-sharing of the Generic Tier. Equivalent cost-sharing for the Preferred Generic and Generic tiers will not be accepted, except in the case when a sponsor buys down the cost-sharing to $0 for both generic tiers.

[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. 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 24% applies. Injectable, Specialty, Select Care and Select Diabetic Drug labeled tiers for which additional gap coverage is offered, if any, will be analyzed in the same manner as brand labeled tiers with respect to beneficiary coinsurance maximums. Note, the beneficiary coinsurance maximums for the coverage gap reflect the plan liability, but exclude the 50% manufacturer discount for applicable drugs.

Specialty Tiers

Per 42 C.F.R. §423.578 (a)(7), if a Part D plan sponsor maintains a formulary tier (the specialty tier) in which it places very high cost and unique items, such as genomic and biotech products, the sponsor may design its exception process so that very high cost or unique drugs are not eligible for a tiering exception. Only Part D drugs with sponsor-negotiated prices that exceed an established dollar-per-month threshold are eligible for specialty tier placement. The current cost threshold of $670 was established for CY 2017 as a result of applying the annual percentage increase used in the Part D benefit parameter updates to the previous threshold of $600.

In the final CY 2017 Call Letter, we noted that the cost threshold may or may not be increased on an annual basis moving forward, and that we would test increased thresholds and continue to perform other analyses to assess whether threshold adjustments are necessary. Further, we stated that we would investigate whether the inclusion of Part D drugs on a specialty tier adversely affects drug utilization or enrollment decisions by certain types of beneficiaries, and the impact of tiering exceptions for specialty tier drugs.

Given that CY 2017 is the first year for the increased specialty tier threshold, CMS is continuing to collect data to support future policy making. Initial analyses were performed utilizing CY 2016 prescription drug event (PDE) data and the drugs identified as generally being eligible for specialty tier inclusion based on the $670 threshold. The vast majority of 30-day equivalent PDEs – nearly 99% – are for drugs that are below the threshold. However, we are concerned that

the percentage of FRF drugs eligible for the specialty tier continues to increase, and is now near 20%, in spite of the increased cost threshold. The proportion of Part D expenditures for specialty tier eligible drugs is also increasing and is now near 20%. CMS will maintain the $670 threshold for CY 2018, but we will continue to investigate these and other trends in order to shape future analyses involving the specialty tier.

Improving Drug Utilization Review Controls in Medicare Part D

Background on the Current Part D Opioid Overutilization Policy

Opioid medications ("opioids"), particularly when used to treat pain in patients without active cancer or who are not in hospice care, have serious risks such as increasing tolerance, addiction, overdose, and death. In response to the growing national opioid epidemic, over time CMS has implemented a two-prong approach to specifically address opioid overuse in Medicare Part D from a medication safety perspective:

1. Retrospectively perform drug utilization review to identify potential opioid overutilizers and provide appropriate case management aimed at coordinated care.
2. Prospectively implement real-time safety alerts at the time of dispensing as a preventive step to ensure prescribers are aware that potentially high risk levels of opioids will be dispensed to their patients.

In the CY 2013 Call Letter and supplemental guidance, CMS described an opioid overutilization policy that focuses on cases that have the highest risk of adverse events, by which sponsors are expected to reduce beneficiary overutilization of opioids and maintain access to needed medications.[10] In July 2013, CMS launched the Overutilization Monitoring System (OMS) to help oversee sponsors' compliance with this CMS overutilization guidance.

CMS' approach has successfully given sponsors, pharmacists, and physicians the tools needed to identify potential opioid overutilizers in the Part D program and take appropriate steps to minimize risk for those beneficiaries. From 2011 through 2016, there was a 61% decrease (over 17,800 beneficiaries) in the number of Part D beneficiaries identified as potential very high risk opioid overutilizers (i.e., beneficiaries with at least 90 consecutive days with greater than 120 mg morphine equivalent dose (MED) daily with more than 3 prescribers and more than 3 pharmacies contributing to their opioid claims). (Table 19.)

[10] An excerpt from the Final 2013 Call Letter, the supplemental guidance and additional information about the OMS are available on the CMS webpage, Improving Drug Utilization Controls in Part D (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html).

Table 19: OMS Part D Potential Opioid Overutilization Rates, 2011 – 2016*

Year	Total Part D Enrollees	Total Part D Enrollees Utilizing Opioids	% Part D Enrollees Utilizing Opioids	Total Beneficiaries with at Least 90 Consecutive Days >120 mg MED Daily AND > 3 Prescribers & > 3 Pharmacies for Opioid Claims	Difference Year-to-Year	Share of Opioid Utilizers Flagged as Outliers	Difference in Share Year-to-Year
2011	31,483,841	10,049,914	31.9%	29,404		0.29%	
2013	37,842,632	11,794,908	31.2%	25,347	− 4,057	0.21%	−0.08%
2014	39,982,962	12,308,735	30.8%	21,838	− 3,509	0.18%	−0.04%
2015	41,835,016	12,510,448	29.9%	15,651	− 6,187	0.13%	−0.05%
2016	43,569,035	12,885,620	29.6%	11,594	− 4,057	0.09%	−0.04%

61% decrease

69% decrease

*Table 19 includes partial year inactive contracts, and hospice and cancer patients are excluded from utilizer and potential overutilizer counts. For these opioid utilization comparisons, CMS used OMS methodology and prescription drug event (PDE) TAP Data processed with cut-off dates in the early January of the following year.

CMS included proposals in the draft 2018 Call Letter to enhance both aspects of CMS' current Part D opioid overutilization policy; 1) to retrospectively better identify potential opioid overutilizers who may need case management; and 2) to increase focus on real-time safety alerts at the pharmacy. In addition, the Enhancements to the 2018 Star Ratings and Beyond section of the 2018 Call Letter discusses implementation of PQA-endorsed opioid overutilization measures.

Additional Background on Part D Retrospective Drug Utilization Review and Case Management and OMS

CMS currently expects Part D sponsors to implement retrospective drug utilization review criteria to identify patients who are at risk of adverse events due to opioids, so that their cases may be further reviewed clinically. These criteria, established by the sponsors' Pharmacy and Therapeutics (P&T) committees within CMS guidance, should identify potential, non-borderline opioid overutilizers who may warrant case management and exclude beneficiaries with cancer or in hospice where the benefit may outweigh the risk associated with high opioid doses.

Once beneficiaries are identified, the Part D sponsors' clinical staff work with prescribers and beneficiaries to assess the potential risks. If medical necessity cannot be established due to unresponsive prescriber(s), or if misuse is verified with prescribers, sponsors may implement a beneficiary-specific claim edit at all network pharmacies that will result in the rejection of claims or rejection of quantities in excess of the opioid dosing deemed medically necessary.

The sponsor is expected to send a written notice to the beneficiary and prescriber(s) at least 30 days prior to implementing a beneficiary-specific claim edit. This allows time for the beneficiary and prescribers to request a coverage determination prior to the edit being implemented; however, a coverage determination may be requested at any time.

CMS developed specific criteria for retrospective drug utilization review and case management as part of its opioid overutilization guidance because the FDA – approved labeling for opioids generally do not contain maximum daily doses. Consequently, when developing the initial guidance in 2013, CMS also developed a comprehensive MED approach to assist CMS and Part D sponsors in identifying potentially unsafe doses in Medicare beneficiaries. We will

address later in this section how these criteria are now used by Part D sponsors for retrospective review and case management and focus here on the criteria used by OMS since its launch in July 2013, which are:

> Use of opioids with cumulative daily MED exceeding 120 mg for at least 90 consecutive days with more than 3 prescribers and more than 3 pharmacies contributing to their opioid claims, during the most recent 12 months, excluding beneficiaries with cancer diagnoses and beneficiaries in hospice.

In the draft 2017 Call Letter, CMS announced its intention to modify the OMS criteria to improve the identification of inappropriate opioid use (i.e., reduce "false positives" related to overutilization that resolved recently and to better identify the most egregious cases of overuse). We proposed to reduce the measurement period to 6 months, use average MED rather than a count of 90 consecutive days of high MED, and group prescribers within the same practice. We received support for the proposed changes.

In response to the draft 2017 Call Letter, several stakeholders commented that CMS should revise the OMS criteria to align with the new CDC guideline issued in March 2016. Primarily due to timing constraints, CMS did not adopt the CDC guideline in the final 2017 Call Letter (issued in early April 2016), but stated that we would consider the suggestion for 2018.

It is important to note that the purpose of the CDC guideline for opioid prescribing is to assist primary care providers in delivering safer, more effective chronic pain management for patients with pain outside of active cancer treatment, palliative care, and end-of-life care. In the guideline, CDC identifies 50 MME[11] daily dose as a threshold for increased risk of opioid overdose, and to generally avoid increasing the daily dosage to 90 MME. Thus, the guideline is not intended as an absolute prescribing limit.

Nevertheless, the guideline is helpful to CMS in establishing policy guidance, as it is the first national guideline developed by expert clinicians and researchers that identifies potentially dangerous levels of opioid prescribing. Therefore, after its publication, CMS commenced data analysis to assess if the additional caseload associated with any revisions to our targeting criteria would still be manageable for Part D sponsors.

Changes to the OMS Opioid Overutilization Criteria for 2018

Based on this analysis, CMS proposed in the draft 2018 Call Letter the following modifications to CMS' opioid overutilization criteria beginning in 2018:

[11] Note: CDC's terminology, morphine milligram equivalents (MME), is equal to morphine equivalent dose (MED) in milligrams as used by CMS. Often calculated as a daily dose.

Modification	Rationale
Shorten the measurement period from 12 months to 6 months	A shortened measurement period better identifies current potential overutilization, reduces the number of repeat cases reported by the OMS, and reduces the number of false positives.
Use average MED rather than a count of 90 consecutive days of high MED	By allowing gaps between prescription fills and days' supply in the calculation, the average MED methodology improves identification of beneficiaries who are chronic users of high opioid doses compared to evaluating consecutive days, and reduces false positives.
Lower the MED mg threshold (90 mg)	A lower MED threshold aligns the CDC guideline (amount generally suggested to avoid increasing above) and may capture additional beneficiaries with egregious patterns of potential overutilization who may need additional monitoring or case management.
Group providers, such as physicians, within the same practice	Grouping providers reduces false positives by eliminating beneficiaries managed in the group practice setting.

The full proposed criteria in the draft 2018 Call Letter was:

- During the most recent 6 months,
    - Use of opioids with an average daily MED greater than 90 mg for any duration; and
    - Received opioids from more than 3 prescribers and more than 3 pharmacies, OR from more than 4 prescribers regardless of the number of opioid dispensing pharmacies.
- Beneficiaries with cancer diagnoses and beneficiaries in hospice are excluded.
- Prescribers associated with the same single Tax ID Number (TIN) are counted as a single prescriber.

We estimated that 33,223 beneficiaries would meet the revised criteria using 2015 data (0.27% of all Part D opioid users; 0.08% of all Part D enrollees) The estimates are comparable to the number of beneficiaries identified in 2013 when the policy began (25,347 beneficiaries; 0.21% of all opioid users; 0.07% of all Part D enrollees).

We discovered an error with the estimates provided in the draft 2018 Call Letter. We had estimated that 33,223 beneficiaries would meet the revised criteria, which included beneficiaries who received opioids from more than 4 prescribers. Instead, this estimate is associated with the

inclusion of beneficiaries who received opioids from more than 5 prescribers. We find that over 52,000 beneficiaries would meet the criteria as proposed in the draft 2018 Call Letter.

CMS also solicited comments in the draft 2018 Call Letter for a more significant revision to target beneficiaries with more than 3 prescribers regardless of the number of opioid dispensing pharmacies (we estimated over 114,000 beneficiaries would be identified).

Most commenters on the draft 2018 Call Letter supported the proposed changes to the OMS criteria listed in the table above. A few commenters opposed lowering the MED threshold to 90 mg citing lack of evidence to support the CDC guideline on opioid prescribing. Generally, there was no support for the additional proposal to further expand the criteria to include beneficiaries who received their opioids from more than 3 prescribers regardless of the number of pharmacies citing concerns about caseload.

Based on the feedback we received which considered the caseload (over 33,000), CMS will implement these revised OMS criteria beginning in 2018:

- During the most recent 6 months,
    - Use of opioids with an average daily MED greater than 90 mg for any duration; and
    - Received opioids from more than 3 prescribers and more than 3 pharmacies, OR from more than 5 prescribers regardless of the number of opioid dispensing pharmacies.
- Beneficiaries with cancer diagnoses and beneficiaries in hospice are excluded.
- Prescribers associated with the same single TIN are counted as a single prescriber.

After the 2018 Call Letter is published, we will post a revised analysis summary at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html

We wish to provide a point of clarification on the OMS criteria: Some commenters on the draft 2018 Call Letter asked for more information on the calculation of the average MED. As noted in the analysis summary document posted on CMS.gov (link provided above), average MED is defined as the summation of total MED taken during the measurement period divided by the number of days between the first and last day of the opioid episode. An opioid episode is the number of days between the first opioid claim's date of service (DOS) and the last opioid claim's DOS plus the day supply of the last opioid claim within the measurement period. If the days supply extends the episode past the measurement period, the episode length is truncated to the measurement period end date and the quantity dispensed is prorated for the same period. For example, if an opioid claim's quantity is 120 tablets with a day supply of 30 days (or 4 tablets

per day) and the opioid episode extends past the measurement period by 10 days, a prorated quantity of 80 tablets is included in the MED calculation. The denominator for the MED calculation is the opioid episode length.

We will continue to monitor the number and percent of potential opioid overutilizers based on the revised OMS criteria and the initial criteria (for historical purposes). Our goal was and continues to be a continued reduction in opioid overuse in the Medicare Part D program. In the absence of FDA dosing limits on opioids, we are using the CDC guideline to establish a threshold to identify potentially high risk beneficiaries who may benefit from closer monitoring, creating alignment between Government programs.

Background and Changes to Part D Sponsors' Internal Opioid Criteria for Retrospective Identification of Opioid Overutilization and Subsequent Case Management

Through the OMS, sponsors receive quarterly reports of Part D enrollees who may be potentially overutilizing opioids based on the criteria described above. In accordance with CMS guidance to date, CMS expects sponsors' clinical staff to work with the prescribing physician(s) and beneficiary to address the risks associated with overuse, and update CMS on actions taken.

CMS also gives sponsors some flexibility in developing their internal criteria for retrospective identification of opioid overutilization for case management, as sponsors should not merely rely on OMS which is a compliance tool. Beginning in 2018, Part D sponsors are expected to lower their internal criteria to be no less restrictive than use of opioids with an average daily MED exceeding 90 mg for any duration during the measurement period. Sponsors may use a lower MED threshold and may vary other criteria including the number of prescribers and pharmacies. Sponsors also have flexibility to apply other methods to group prescribers within the same practice or not. As some commenters noted in response to the draft 2018 Call Letter, some sponsors do not have access to the TIN.

Background on Real-Time Safety Alerts at the Pharmacy

Although Part D sponsors' retrospective case management and CMS oversight through the OMS reduced very high risk overutilization of opioids in the Part D program, given the continuing national opioid epidemic, CMS believes that there may be additional opportunity for Part D sponsors to reduce such risk through safety alerts at the time of dispensing. Part D sponsors commonly implement safety edits to prevent the unsafe dosing of drugs at the time of dispensing as part of their concurrent drug utilization review requirements for all Part D drugs, such as drug-drug interactions, therapeutic duplication, or an incorrect drug dosage (e.g., doses above the FDA approved maximum dosing).

Based on our previous guidance, beginning in 2017, sponsors were expected to implement additional soft or hard formulary-level safety edits[12] for opioids based on a cumulative MED, as outlined and finalized in the 2017 Call Letter. Note that PACE organizations are expected to comply with these expectations unless they do not adjudicate claims at point of sale (POS). Some sponsors implemented hard edits in 2017.

Changes to Real-Time Safety Alerts at the Pharmacy

In the draft 2018 Call Letter, we proposed that all sponsors implement a formulary-level hard opioid safety edit based on a cumulative MED. We received a significant number of comments, including many personal letters from prescribers and patients. While there was some support, many commenters raised concerns about access, member disruption, and the approval process. A large number of physicians commented that the hard edits presented as payer-mandated prescribing controls that are at odds with the underlying purpose of the CDC guideline. Several organizations and sponsors discussed operational concerns, and requested continued flexibility for implementing either a soft or hard edit. Commenters suggested that beneficiary and prescriber education about these edits needed improvement.

Based on this feedback, we are not finalizing the proposal for all sponsors to implement a hard edit. As in 2017, we continue to expect sponsors to implement formulary-level soft and/or hard cumulative MED opioid safety edits for 2018, but hard edits are not required, and we reiterate past guidance. We recommend that if a soft opioid safety edit is implemented, the threshold be set at levels greater than 90 mg MED. We also recommend that if a hard opioid safety edit is implemented, the threshold be set at 200 mg MED or more. The edits should include additional criteria to minimize false positives by accounting for known exceptions, such as hospice care, certain cancer diagnoses, reasonable overlapping dispensing dates for prescription refills or new prescription orders for continuing fills, and high-dose opioid usage previously determined to be medically necessary such as through case management or the coverage determination and appeals process. We also encourage sponsors to include criteria to identify beneficiaries whose opioid prescriptions are written by multiple prescribers. Part D sponsors will continue to submit information on their cumulative MED safety edits using a template through HPMS. We will continue to monitor 2017 experience with these edits to inform this policy in the future.

Based on the comments to the draft 2018 Call Letter, we are providing additional background and guidance on formulary-level soft and hard safety edits for opioids based on a cumulative MED. CMS expects Part D sponsors to implement a soft and/or hard edit but only as a safety edit.

Cumulative MED edits may identify and prevent opioid misuse in real-time and give information to prescribers who may not be aware their patients are receiving such high cumulative levels of

[12] Soft edit rejections can be overridden by the pharmacist, while the hard edit requires prescriber attestation through the coverage determination process.

opioids or opioids from other doctors. However, such edits are not intended to substitute for physician judgment or dictate a prescribing limit. Rather, through this process, physicians can receive important information about their patients, which helps them make decisions about the care they are providing to their patients. Ultimately, such safety edits may proactively address potentially unsafe cumulative opioid levels with prescribers at the time of dispensing to promote care coordination, and before beneficiaries are identified by the OMS. Thus, if the only issue in dispute is the MED, CMS expects the Part D sponsor to only rely on prescriber attestation that the higher MED is medically necessary to approve dosing that is higher than the hard edit when a coverage determination is requested, and to not require additional clinical criteria. Sponsors that cannot implement a hard opioid safety edit in a manner consistent with CMS' expectations or without appropriate controls in place to minimize access issues are expected to implement only a soft edit.

When a hard MED edit is triggered and the issue cannot be resolved at the pharmacy, the sponsor is required to notify their network pharmacy to distribute a written copy of the standardized CMS pharmacy notice to the enrollee. The pharmacy notice explains the enrollee's right to ask for a coverage determination from his or her plan, including an expedited coverage determination. CMS expects plan sponsors to ensure that appropriate staff are adequately trained to identify coverage determination requests, including verbal requests made by enrollees affected by hard MED edits. Plans are also reminded that the timeframe for expedited coverage determination requests applies when the prescriber indicates, or the plan decides, that applying the standard timeframe may seriously jeopardize the enrollee's life, health, or ability to regain maximum function. We generally expect coverage determinations related to the MED edit to meet the criteria for expedited review, which means the plan sponsor must issue a decision within 24 hours of receipt of the coverage determination request.

CMS expects to issue a HPMS memo that reiterates our expectations and this guidance, and that provides additional guidance for how existing and new hard MED edits are implemented and resolved. CMS will also do additional outreach to the physician community to ensure their awareness that the Part D sponsor should only rely on prescriber attestation and no additional clinical criteria should be used to approve the MED above the hard edit threshold. We are exploring opportunities to provide more information to beneficiaries about these edits, including via a note within the Medicare Plan Finder. We will also continue to monitor complaints and appeals related to these edits and take compliance actions as warranted.

CMS believes that Medicare Advantage Organizations and Part D sponsors, working with prescribing physicians, are in the best position to identify and employ best practices and the most appropriate care management interventions for enrollees using high dosage opioids. We expect all Part D sponsors to focus on improving the coordination of care among these beneficiaries using high dosage of opioids, and MA-PDs in particular should consider expanding the care management they provide enrollees.

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 and best practices for care management, such as the following information:

- ***CDC Guideline for Prescribing Opioids for Chronic Pain*** provides recommendations about the appropriate prescribing of opioid pain relievers and other treatment options to improve pain management and patient safety; provides other resources to facilitate communication between providers and patients (https://www.cdc.gov/drugoverdose/prescribing/guideline.html).

- ***Designing and Implementing Medicaid Disease and Care Management Programs: A User's Guide*** is designed to be a resource for decision makers involved with designing and implementing care management programs in Medicaid; these best practices could be useful for other health and drug plans. https://www.ahrq.gov/professionals/systems/long-term-care/resources/hcbs/medicaidmgmt/index.html

A Note about the Comprehensive Addiction and Recovery Act of 2016

Section 704 of the Comprehensive Addiction and Recovery Act of 2016 (CARA) (Pub. L. 114-198) includes provisions that permit Part D sponsors to establish drug management programs for at-risk beneficiaries under which Part D sponsors may limit such beneficiaries' access to frequently abused drugs to certain prescribers and pharmacies. CMS' implementation of Section 704 for plan year 2019 in accordance with the statutory provisions is underway. The effect of implementation on the Part D opioid overutilization policy will be addressed as soon as possible as we continue with the rulemaking process.

Addressing Chronic Use of Benzodiazepine Sedative-Hypnotics in the Medicare Part D Population

There continue to be concerns regarding the risks and benefits of benzodiazepine use, especially in the elderly due to an increased risk of falling.[13]

Therefore, we analyzed and tested the PQA measure, *Use of Benzodiazepine Sedative-Hypnotic Medications in the Elderly (BSH),* to assess the chronic use of these medications in the elderly enrolled in Part D.

The BSH rate measures the percent of Part D enrollees 65 years of age and older who received two or more prescription fills for any BSH medication for a cumulative period of more than 90 days. We calculated BSH rates across all Part D contracts using 2014 PDE data, adjusted for member-years.

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[13] Cumming RG, Miller JP, and Kelsey JL. et al. Medications and multiple falls in elderly people: the St. Louis OASIS study. Age Ageing. 1991 20:455–461.

We found that the average BSH measure rate across all Part D contracts was low (~1%) during 2014. The number of elderly Part D beneficiaries with chronic BSH use was about 300,000. Overall, 73% of Part D contracts' BSH rates did not exceed 0.97%, the aggregate average rate, and 10% had rates more than double the average, from 2% to more than 17%. BSH rates were lowest for community-only beneficiaries compared to long-term nursing home (NH) residents, 0.93% and 1.27%, respectively.

We do not plan to add the measure to the Star Ratings or display measures at this time since the overall use of BSH medications in the elderly is not an absolute contraindication per the Beers Criteria and the BSH rates were low for most Part D contracts. We will continue to monitor BSH rates, and we will consider outreach to outlier contracts in the future if necessary.

We strongly encourage Part D sponsors to evaluate their claims data and use drug utilization management tools to monitor beneficiaries' BSH use before it becomes chronic. We also recommend that sponsors assess prescriber rates to identify outliers for educational or administrative interventions.

Clarification of Part D "Reference-Based Pricing" Policy

In the CY 2010 Call Letter, CMS explained that reference-based pricing cost-sharing designs would no longer be permitted in Medicare Part D beginning in 2010. These cost-sharing designs require enrollees to pay a differential (i.e. penalty) based upon the difference between the negotiated price of the drug being dispensed and a lower-cost preferred reference drug. We explained that this prohibition was necessary to improve transparency with regard to expected enrollee cost-sharing. Since that time, we have learned that the term "reference-based pricing" or "reference pricing" is also used to describe payment arrangements between payers and pharmacies that do not involve enrollees paying a penalty based upon the negotiated price of the drug being dispensed and a lower-cost preferred reference drug. Such payment arrangements include maximum allowable cost (MAC) pricing of generic drugs and possibly other reference-based pricing of brand drugs by drug class. The Part D prohibition announced in the CY 2010 Call Letter applies only to the cost-sharing designs that require enrollees to pay a differential (i.e. penalty) based upon the difference between the negotiated price of the drug being dispensed and a lower-cost preferred reference drug. This policy does not otherwise prohibit reference-based payment arrangements negotiated between pharmacies and Part D sponsors (or their Pharmacy Benefit Managers) that establish the negotiated price.

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 2018 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 2018 bids.

In contract year 2018, we will use the COB user fees for activities including:

- Part D Transaction Facilitator operation and maintenance;
- The Benefit Coordination and Recovery Center (BCRC) operation and maintenance;
- Drug data processing system management, which is used to collect prescription drug event (PDE) data for Part D payment purposes and to produce invoices for the coverage gap discount program;
- Medicare Advantage and Prescription Drug System (MARx) management of COB data; and
- Review of Workers' Compensation settlement set-aside funds, which verify that medical services are paid for by the appropriate party

Part D Low Enrollment

CMS has the authority under 42 CFR §423.507(b)(1)(iii) to non-renew Part D plans (at the benefit package level) that do not have sufficient number of enrollees to establish that they are viable plan options. While we are particularly concerned with plans that have fewer than 500 enrollees, we urge sponsors to voluntarily withdraw or consolidate any standalone plan with less than 1,000 enrollees. Sponsors are strongly encouraged to view data on plan enrollment at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/index.html to determine if any of their plans meet this criterion. By April 2017, we will notify plans with less than 1,000 enrollees of available options for consolidation/withdrawal options. We reserve the right to require low enrollment plans to consolidate/withdraw in the future to ensure that all Part D plans offered in the marketplace are attractive to beneficiaries and do not add to their confusion in selecting a plan best suited to their prescription drug coverage needs.

Section IV – Medicare-Medicaid Plans

Medicare-Medicaid Plan Annual Requirements and Timeline for CY 2018

Contract Year (CY) 2018 will be the fifth contract year since the implementation of the first capitated model under the Medicare-Medicaid Financial Alignment Initiative. Since that time, CMS – in collaboration with our state partners – has implemented eleven capitated model demonstrations in ten states. While most initial implementation challenges and opportunities have been addressed, we will continue to build on the strong partnerships both CMS and the states have developed with participating Medicare-Medicaid Plans (MMPs) to provide high-

quality, seamless and integrated care to individuals dually eligible for Medicare and Medicaid in CY 2018 and beyond.

Prior to each contract year, CMS provides information about the Medicare requirements and timeframes for renewal of MMP contracts. This section of the Call Letter reminds MMPs of those requirements and their timeframes, as well as the policy regarding the use of past performance information for determining plan eligibility to receive passive enrollment. We will also provide guidance shortly after the issuance of the CY 2018 Final Call Letter about the applicability of the provisions in other sections of the Call Letter to MMPs.

As is the case for other Medicare Advantage (MA) and Part D plans, MMPs must submit a formulary, medication therapy management (MTM) program, and plan benefit package (PBP) each contract year, and annual submission timelines for MMPs are aligned with the standard MA and Part D schedule.

In addition to the requirements for MA and Part D plans, MMPs must also submit:

- On an annual basis, information to ensure the plan has a network adequate to provide enrollees with timely and reliable access to providers and pharmacies for Medicare drug and medical benefits based on requirements in the Medicare Parts C and D programs. In addition, states will evaluate networks for Medicaid service providers, including long-term supports and services.
- If applicable based on the approval period given to the most recent model of care (MOC) submission, a MOC that meets CMS's requirements for D-SNPs, as well as any applicable state requirements.
- The Additional Demonstration Drug (ADD) file to supplement the Part D formulary submission.

Table 20 below catalogues previously released guidance for MMPs or guidance that may be of particular interest to MMPs. CMS will release updated or new guidance as necessary; where more recent guidance exists or is released for topics that appear in previously released documents, MMPs should use the most recent document.

Table 20: Previously Released Guidance

Topic	Link to document
MMP Enrollment and Disenrollment Guidance	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/MMPEnrollmentManual090216.pdf
Additional State-specific Enrollment Guidance	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html
State-specific Marketing Guidance	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html
Waiver of Part D LIS Cost-Sharing Amounts	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Part_D_Cost_Sharing_Guidance.pdf
Past Performance Review Methodology Updates for CY 2018	https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PartCandPartDComplianceActions.html

In addition to comments on the topics in the draft CY 2018 Call Letter, one commenter supported guidance that CMS recently issued to state Medicaid agencies clarifying agency policy regarding DME access for individuals dually eligible for Medicare and Medicaid and urged CMS to create opportunities for flexibility in the Financial Alignment Initiative and other innovation models that would allow states to test further alignment of Medicare and Medicaid and improve DME access for dual eligible beneficiaries. We appreciate the comment and will continue our goal of better aligning Medicare and Medicaid DME policy through various mechanisms – both within and outside of the Financial Alignment Initiative.

Network Adequacy Determinations

The Medicare medical provider and facility portion of MMPs' network information will be due to CMS on the third Tuesday in September 2017. This submission will ensure that each MMP continues to maintain a network of providers that is sufficient in number, variety, and geographic distribution to meet the needs of the enrollees in its service area. MMPs may assess the Medicare portion of their networks at any time using the organization initiated upload functionality in the HPMS Network Management Module (NMM). The current reference file, as referenced in the three-way contracts, that provides the MMP standards is available at:

https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html as well as on the reference page within the NMM. CMS will release additional guidance on the submission process, including how MMPs will be able to submit exception requests, in the summer of 2017. The Medicare pharmacy portion of the network will be checked per the Part D reporting requirements.

We received feedback from commenters to expand our network adequacy determinations to include additional provider types and criteria beyond time, distance, and minimum number. Commenters suggested that CMS expand the providers reviewed to ensure that networks are diverse and represent a network trained in cultural competence and ADA compliance. Specifically, one commenter suggested that CMS check the Medicare portion of the MMP networks for qualified substance use disorder treatment providers and geriatric providers, including dementia care specialists. CMS thanks the commenters for these suggestions and will continue to consider ways to improve network standards, provider directories, and overall provider and health plan capacity to serve dual eligible beneficiaries.

Another commenter expressed their strong support for the annual MMP network reviews and urged CMS to require MMPs to update their provider directories and to expand its MMP network review to include a review of whether the providers listed in the provider directories speak additional languages, can accommodate persons with disabilities, and are currently accepting new patients. We note that the MMP annual Medicare network review is an assessment of minimum number, time, and distance of the MMPs' provider networks. However, CMS remains committed to working with MMPs to improve their directories to ensure that enrollees and prospective enrollees have the information they need to make informed decisions about their health care choices. CMS has conducted monitoring studies of CY 2016 and CY 2017 MMP provider and pharmacy directories, including whether the directories include information required in each state's three-way contract, including any non-English languages spoken in providers' offices, whether providers offer accommodations for individuals with physical disabilities, and whether providers are accepting new patients. CMS has provided MMPs with technical assistance in this area and intends to continue technical assistance and monitoring to address remaining gaps in information that is most critical to enrollees.

Another commenter appreciates CMS' ongoing efforts to ensure ADA competency among the MMPs and providers through the Disability-Competent Care webinar series. The commenter encourages CMS to add a webinar series for MMPs and other providers and provider organizations on topics related to cultural competence. CMS thanks the commenter for the suggestion. The cultural competence resources developed through HHS and CMS will soon be available and linked on MMCO's Provider Technical Assistance website at https://www.resourcesforintegratedcare.com/.

Model of Care (MOC)

MMPs with a model of care (MOC) expiring on December 31, 2017 were notified in the fall of 2016 regarding the need to submit a MOC for review and approval by February 15, 2017, for contract years beginning on or after January 1, 2018. MMPs with MOCs that are still within their period of approval in CY 2018 may make substantive changes to those MOCs through the off-cycle update process, as discussed in more detail in the January 14, 2016 HPMS memorandum, "Changes to Special Needs Plans and Medicare-Medicaid Plan Model of Care Submissions and Updates in the Health Plan Management System for CY 2017."

Formulary and Supplemental Drug Files

Each contract year, MMPs must submit and be approved to offer a demonstration-specific, integrated formulary that meets both Medicare Part D and Medicaid requirements. The required submissions for the integrated formulary are: (1) an updated base Part D formulary and supplemental Part D formulary files, as applicable, consistent with CY 2018 Part D formulary guidance; and (2) an updated Additional Demonstration Drug (ADD) file containing non-Part D drugs. Base formularies are due no later than June 5, 2017. Supplemental formulary files are due in HPMS on June 9, 2017 at 11:59 a.m. EDT.

MMPs must also submit an ADD file that includes non-Part D drugs. Non-Part D drugs include drugs in Medicare Part D excluded categories, over-the-counter drugs, and other products required by the state to be included on the integrated formulary. CMS will work with states to provide ADD file guidance to MMPs by May 2017. State guidance should include a list of the drugs the MMPs are required to include on the ADD file (by NDC and/or UPC). It is at the states' discretion whether to require MMPs to include one proxy NDC or multiple NDCs on the ADD file for each covered product.

State reviewers are solely responsible for reviewing and approving the ADD file. CMS will approve all other submitted formulary files. Reviews will begin immediately after the submission deadlines and will continue until all deficiencies have been resolved.

We received feedback from several commenters about the ADD file submission and review process, including concerns about whether CMS plays a sufficiently robust role, timing and scope state-specific guidance, and the availability and distribution of CMS' validation file for the ADD file submission. One commenter urged CMS to work toward the creation of integrated formulary submissions and concurrent, rather than separate, review of the Part D and Medicaid-covered drugs. This same commenter expressed concern about access issues for drugs that can be covered under Part D for some indications only but may be covered under Medicaid for other indications. Another commenter requested additional guidance on coverage requirements for ADD file drugs and noted that state-specific differences in formulary requirements and marketing materials are difficult to implement. This same commenter recommended development a forum for addressing MMP questions on the ADD file.

CMS continues to look for ways to further streamline the ADD file submission process and will look for opportunities to address commenters' concerns. While state staff review and approve ADD files, there is considerable involvement by CMS in creating a validation file for ADD file submissions. The validation file explicitly excludes drugs based on a variety of criteria, including whether specific drugs are current inactive. CMS will work to more closely coordinate with states to ensure Medicaid drug coverage requirements are appropriate. We also clarify that CMS annually produces and shares with states a validation file for the ADD file submission. We will evaluate whether additional efficiencies are possible but note that because CMS relies on an April data extract from NDC databases, timing of the validation file's completion prior to mid-May would be challenging.

We also clarify that drugs with both Part D and Part D-excluded indications) may be found on both the Part D Formulary Reference File (FRF), meaning they could be covered under Part D for Part D-covered indications, and on the ADD file for Part D-excluded indications. In these situations, it is the plan's responsibility to make appropriate coverage determinations. Exclusion of a drug from the FRF or plan's formulary does not preclude the plan from covering a drug under Part D for Part D-covered indications. Because each Financial Alignment Initiative capitated model demonstration is state-specific, it is not possible to standardize Medicaid drug coverage requirements or the member materials that convey drug coverage information. However, MMCO coordinates with both state and Part D pharmacy experts on MMP questions about drug coverage, and we encourage MMPs with any questions about ADD file requirements to send those to both MMCO and Part D benefits resource mailboxes, mmco@capsmodel@cms.hhs.gov and PartDBenefits@cms.hhs.gov.

In the draft Call Letter, we clarified that mid-year ADD file change submissions – that is, changes to the ADD file after the contract year has begun – are at the discretion of each state. CMS will work with states to open HPMS gates for ad hoc and/or regular ADD file resubmissions as necessary. Based on a comment about this process, we further clarify that an MMP requesting a mid-year ADD file update can contact either the state or CMS by sending an email to mmcocapmodel@cms.hhs.gov. CMS coordinates with each state to consider the request and open ADD file gates for mid-year changes as necessary.

Plan Benefit Package (PBP)

MMPs' plan benefit packages (PBPs) are reviewed annually to ensure that MMPs accurately describe the coverage details and cost-sharing for all Medicare, Medicaid, and demonstration-specific benefits. CMS will launch the HPMS PBP module on April 7, 2017, and we expect to provide further guidance at that time on MMP-specific updates to the PBP software for CY 2018. In addition, CMS will release an online training module on the CY 2018 PBP software for plans on April 7, 2017.

MMPs must submit their integrated PBPs to CMS no later than June 5, 2017 (11:59 p.m. PDT). Non-timely submission of a PBP is considered a plan notice of non-renewal. In addition, to the PBP, MMPs are required to submit the following as part of a complete bid submission:

- Service Area Verification
- Plan Crosswalk (NOTE: This is only for renewing contracts in CY 2018)
- Formulary Crosswalk

CMS will work with states to issue PBP guidance that clearly defines the state-required Medicaid benefits and supplemental demonstration benefits by the time the PBP module is launched in April 2017. The PBP review is conducted jointly between CMS and states to ensure the data entry is consistent with minimum coverage and cost-sharing requirements under Medicaid, Medicare Parts A, B, and D, and each state's demonstration.

MMPs are provided some degree of flexibility with respect to PBP revisions corrections after the time of final PBP approval. This flexibility is necessary to accommodate certain mid-year changes unique to MMPs, including but not limited to mid-year legislative changes to Medicaid benefits, as well as the timing of payment rate finalization.

CMS applies the following criteria to MMP requests to change or correct PBPs:

- PBP revisions to add or remove plan-offered supplemental benefits between the time of the release of the National Average Monthly Bid Amount in early August and sign-off of PBPs in HPMS in late August 2017 are permissible. This timeframe allows plans to accommodate any approved benefit changes in their required documents (including the Annual Notice of Change, Evidence of Coverage/Member Handbook, and Summary of Benefits) during the Annual Election Period.
- Rate-related PBP corrections are permissible during the Center for Medicare's annual correction window in September 2017 (see the calendar in this Call Letter for more information), but only for purposes of adding supplemental benefits to PBPs. MMPs that elect to correct their PBPs must work with their contract management team on an appropriate member communication strategy (e.g., issuance of corrected or revised information for materials that have already been mailed to members; corrections or updates of hard copy and online versions of other materials for prospective members). We clarify that there will be no compliance penalty for a PBP correction provided an MMP meets these conditions.
- PBP corrections unrelated to rates and supplemental benefits that are requested during the Center for Medicare's annual correction window in September 2017 (see the calendar in this Call Letter for more information) will be considered changes due to

plan error. As such, these PBP corrections (or any resultant corrections to MMPs' Annual Notice of Change and/or Evidence of Coverage/Member Handbook, which must be submitted in HPMS through the errata submission process in the Marketing Module) may be subject to compliance action, regardless of whether they are positive or negative changes.

- Any PBP corrections after the Center for Medicare's annual correction window in September 2017 will be considered on a case-by-case basis. In cases where a PBP correction is due to a midyear legislative change to Medicaid benefits (or a benefit change made in a three-way contract amendment) and an MMP's previously approved PBP submission included a more generous supplemental benefit than the new Medicaid or demonstration benefit, the MMP will be required to continue to provide the more generous supplemental benefit for the remainder of the contract year. PBP corrections (or any resultant corrections to MMPs' Annual Notice of Change and/or Evidence of Coverage/Member Handbook, which must be submitted in HPMS through the errata submission process in the Marketing Module) due to plan error may be subject to compliance action, regardless of whether they are positive or negative changes.

Past Performance Information and Eligibility for Passive and Opt-in Enrollment

As we noted in the draft CY 2018 Call Letter, our policy regarding the use of past performance information is articulated in previous guidance memoranda, including section 30.2.5 of the "Medicare-Medicaid Plan Enrollment and Disenrollment Guidance" (see https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/MMPEnrollmentManual090216.pdf for more information). MMPs should refer to that guidance for additional information regarding the impact of sanctions, treatment of new legal entities, and eligibility for passive enrollment after effectuation of the three-way contract.

One commenter noted that MMPs participating in the Financial Alignment Initiative capitated model demonstrations should be able to attain a certain level of maturity before being measured and that it is short-sighted and unfair to apply the same past performance standards to these projects as are applied to more mature products. Because it is a priority for both CMS and states to assess MMPs' capacity and experience in serving Medicare-Medicaid beneficiaries, both before and after the plan selection process, we intend to continue using previous and current performance in the Medicare program as one important source of data to determine organizations' eligibility for passive enrollment. At this time, we are not proposing changes to our current policy regarding the use of past performance information for MMPs in this final Call Letter. Another commenter expressed concerns about passive enrollment and requested that any ongoing passive enrollment include strong notification, outreach, and education components, and that CMS closely monitor continuity of care and MMP capacity. CMS agrees with the

commenter about the importance of beneficiary protections. These protections have been incorporated via notification requirements in section 30.2.5 of the National MMP Enrollment and Disenrollment Guidance and ongoing monitoring by CMS and states. CMS also encourages states to consult with beneficiary advocates and other stakeholders to develop and periodically update algorithms for passive enrollment.

Appendix 1 – Improvement Measures (Part C & D)

Part C or D	Measure	Measure Type	Weight	Improvement Measure
C	Breast Cancer Screening	Process Measure	1	Yes
C	Colorectal Cancer Screening	Process Measure	1	Yes
C	Annual Flu Vaccine	Process Measure	1	Yes
C	Improving or Maintaining Physical Health	Outcome Measure	3	No
C	Improving or Maintaining Mental Health	Outcome Measure	3	No
C	Monitoring Physical Activity	Process Measure	1	Yes
C	Adult BMI Assessment	Process Measure	1	Yes
C	Special Needs Plan (SNP) Care Management	Process Measure	1	Yes
C	Care for Older Adults – Medication Review	Process Measure	1	Yes
C	Care for Older Adults – Functional Status Assessment	Process Measure	1	Yes
C	Care for Older Adults – Pain Assessment	Process Measure	1	Yes
C	Osteoporosis Management in Women who had a Fracture	Process Measure	1	Yes
C	Diabetes Care – Eye Exam	Process Measure	1	Yes
C	Diabetes Care – Kidney Disease Monitoring	Process Measure	1	Yes
C	Diabetes Care – Blood Sugar Controlled	Intermediate Outcome Measure	3	Yes
C	Controlling Blood Pressure	Intermediate Outcome Measure	3	Yes
C	Rheumatoid Arthritis Management	Process Measure	1	Yes
C	Improving Bladder Control	Process Measure	1	No
C	Medication Reconciliation Post-Discharge	Process Measure	1	No
C	Plan All-Cause Readmissions	Outcome Measure	3	Yes
C	Getting Needed Care	Patients' Experience and Complaints Measure	1.5	Yes
C	Getting Appointments and Care Quickly	Patients' Experience and Complaints Measure	1.5	No
C	Customer Service	Patients' Experience and Complaints Measure	1.5	No
C	Rating of Health Care Quality	Patients' Experience and Complaints Measure	1.5	Yes

Part C or D	Measure	Measure Type	Weight	Improvement Measure
C	Rating of Health Plan	Patients' Experience and Complaints Measure	1.5	Yes
C	Care Coordination	Patients' Experience and Complaints Measure	1.5	No
C	Complaints about the Health Plan	Patients' Experience and Complaints Measure	1.5	Yes
C	Members Choosing to Leave the Plan	Patients' Experience and Complaints Measure	1.5	Yes
C	Beneficiary Access and Performance Problems	Measures Capturing Access	1.5	No
C	Health Plan Quality Improvement	Improvement Measure	5	No
C	Plan Makes Timely Decisions about Appeals	Measures Capturing Access	1.5	Yes
C	Reviewing Appeals Decisions	Measures Capturing Access	1.5	Yes
C	Call Center – Foreign Language Interpreter and TTY Availability	Measures Capturing Access	1.5	Yes
D	Call Center – Foreign Language Interpreter and TTY Availability	Measures Capturing Access	1.5	Yes
D	Appeals Auto–Forward	Measures Capturing Access	1.5	Yes
D	Appeals Upheld	Measures Capturing Access	1.5	Yes
D	Complaints about the Drug Plan	Patients' Experience and Complaints Measure	1.5	Yes
D	Members Choosing to Leave the Plan	Patients' Experience and Complaints Measure	1.5	Yes
D	Beneficiary Access and Performance Problems	Measures Capturing Access	1.5	No
D	Drug Plan Quality Improvement	Improvement Measure	5	No
D	Rating of Drug Plan	Patients' Experience and Complaints Measure	1.5	Yes
D	Getting Needed Prescription Drugs	Patients' Experience and Complaints Measure	1.5	Yes
D	MPF Price Accuracy	Process Measure	1	No
D	Medication Adherence for Diabetes Medications	Intermediate Outcome Measure	3	Yes
D	Medication Adherence for Hypertension (RAS antagonists)	Intermediate Outcome Measure	3	Yes

Part C or D	Measure	Measure Type	Weight	Improvement Measure
D	Medication Adherence for Cholesterol (Statins)	Intermediate Outcome Measure	3	Yes
D	MTM Program Completion Rate for CMR	Process Measure	1	Yes

Appendix 2 – 2018 Draft Call Letter Star Ratings Summary of Comments and Responses

Call Letter Section	Summary of Comments	CMS Final Course of Action
Medication Reconciliation Post Discharge (Part C)	Nearly all responders are in favor of this measure, but many express concerns about the weighting, terming this a process measure and not an intermediate outcome measure. The overwhelming majority of commenters want to retain a weight of 1. Many want to keep this measure on the display page for two years. One suggests that this measure would be appropriate for Part D as well.	CMS is withdrawing its proposal to weight this measure as an intermediate outcome measure. Medication Reconciliation Post Discharge will be weighted 1 as a process measure for the 2019 Star Ratings. CMS shared comments received with NCQA.
Improving Bladder Control (Part C)	Commenters are nearly split evenly on this measure: some are supportive, some want to retain this on the display page for a full two years, and some view the measure negatively. One association, while supportive, suggests the measure be applied to individuals who have experienced urine leakage, discussed their problem with their provider, and also discussed treatment options. Several support the use of alternative data sources and non-survey based methods of collecting this information.	Proceed as proposed. CMS shared comments received with NCQA.
Improvement measures (Part C & D)	Commenters support removing the three CAHPS measures from the 2018 Part C improvement calculation. One commenter asks why CMS did not propose to also move the three measures to the display page. A few commenters request that CMS include the Part C and D improvement measures if either one improves a contract's Star Rating, regardless of the overall Star Rating earned. Several commenters point out that the list of Improvement measures in Appendix 1 did not align with the text on pages 80-81.	Proceed as proposed to remove the three CAHPS measures from 2018 improvement calculations. The wording changes are minor and do not affect the denominator, so the measures will remain in the Star Ratings. CMS corrected the list of Improvement measures in Appendix 1 to align with the text.
Members Choosing to Leave the Plan (Part C & D)	Almost all commenters support CMS' proposed clarifications to the Technical Notes. One plan disagrees, recommending CMS retain the current language. Two plans raise issues beyond CMS' proposed changes, noting concerns with the measure's methodology, potential measurement bias and the short validation period.	Proceed as proposed. CMS is reviewing additional concerns.
SNP Care Management (Part C) and MTM Program Completion Rate for CMR Measure (Part D)	There was mixed feedback regarding this proposed change. A few commenters agree with the change. Several commenters also oppose this change. They cite that the decimal was easier to understand, the change diminished the meaningful and differentiated choice for Medicare beneficiaries, and the technical specifications should be updated to include members categorized as unreachable and member refusals. One commenter provides mixed feedback and is concerned that this topic suggested the use of inappropriate clustering is being used. Several comments are out of scope regarding additional data reported to CMS, or requests to break out reporting requirements using SNP types.	Proceed as proposed. This is consistent with CMS' rounding of other measures' data prior to star assignments, and simulations found contracts' star ratings in these two measures either increased or remained the same. We will reiterate that no other specification changes are being made for these measures.

Call Letter Section	Summary of Comments	CMS Final Course of Action
Call Center – Foreign Language Interpreter and TTY Availability (Part C & D)	The majority of commenters agree that CMS should allow interpreters an extra 60 seconds. Some note other concerns with the measure, including the languages CMS tests and limited variability of plan performance.	Proceed as proposed.
MPF Price Accuracy (Part D)	Commenters express concern with the frequency of point-of-sale (POS) price changes (PDE) versus the MPF price changes, and that this affects their ability to do well in the measure. This is not true because PDEs priced lower than MPF displayed pricing do not lower a contract's score in this measure. Some commenters suggest that CMS consider retiring this measure or moving to the display page.	Proceed as proposed.
Complaints about the Health Plan (Part C) and Complaints about the Drug Plan (Part D)	The majority of commenters support the change. A few commenters express concerns with applying mid-year data changes in the Star Rating and suggest delaying the use of the revised complaint categories until the 2020 Star Ratings. A couple of comments are about excluding certain complaints which are not within the control of or driven by the plan.	Proceed as proposed.
High Risk Medication (Part D)	The majority of commenters (sponsors and organizations) support removing the HRM measure from the Star Ratings, moving it to the display measures for 2018, and implementing the revised PQA HRM drug list for the 2019 display page. Some commenters are concerned that removing the measure would de-emphasize its importance and that CMS should add the measure back to the Star Ratings as soon as possible once the measure specifications are updated. Others reiterate that if the measure are moved back to the Star Ratings that sponsors should be provided ample notice. A few commenters suggest that CMS consider providing plans flexibilities in formulary design for HRM drugs.	Proceed as proposed.

Call Letter Section	Summary of Comments	CMS Final Course of Action
Adjusting Star Ratings for Audits and Enforcement Actions	Beneficiary Access and Performance Problems (BAPP) measure: The majority of the comments echo those received for the November 2016 Request for Comments. Many sponsors prefer the decoupling of audits and enforcement actions from Star Ratings, citing reasons that included: the differences in methodologies and goals, the subjective nature of audits, and the absence of audit information for each plan each year. Advocates, however, express concern about the increasing disconnect between the audit process and the Star Ratings Program and push CMS to reconsider the sanction reduction policy that was suspended in March 2016. Several commenters suggest an increase in the weight of the BAPP measure to accurately reflect the seriousness of the audit and enforcement actions. If CMS moves forward with the revised BAPP measure, many commenters prefer the current BAPP measure be used in the 2018 Star Ratings and the revised BAPP measure in the 2019 Star Ratings. Some commenters express concern about the proposed data timeframe because it goes across contract years, but others support the use of more recent data. There is widespread support for the proposed CMP deduction cap of 40 points, the revised CMP deduction methodology, and the revision of the BAPP cut points.	The current BAPP measure specifications will continue for the 2018 Star Ratings. In response to the comments to decouple audits and enforcement actions from Star Ratings, a revised BAPP measure will be on the display page for 2019, which removes all enforcement actions, including CMPs and the reduction for plans under sanction. We will engage stakeholders on additional discussions about this measure.
Data Integrity	Commenters generally support the need for this policy. Sponsors are divided if audit findings should be used to determine if the measure data are biased or incomplete. Information is requested about the methodology for identifying data integrity errors, and to confirm sponsors have the opportunity to resolve errors. Many sponsors request we delay applying the industry-wide appeals timeliness results for 2-3 years, treat this as a pilot, or post the results as a new display measure.	Proceed as proposed, with additional clarification about the potential application of industry-wide appeals timeliness monitoring tests.

Call Letter Section	Summary of Comments	CMS Final Course of Action
Impact of Socio-economic and Disability Status (CAI)	Many commenters express appreciation for the work that CMS continues to do regarding the research and development of a long-term response for the sensitivity of some of the Star Ratings measures to the composition of the beneficiaries enrolled in a contract. The majority of commenters support the continued use of the CAI until a long-term solution is developed and implemented. Some advocates urge CMS to delay a response until the research performed by the measure stewards, ASPE, and NQF is completed or not to adjust the ratings at all to avoid possible unintended consequences such as masking disparities or creating a double standard of care for vulnerable populations. A few commenters feel that the CAI did not adequately address the issue in the Star Ratings and cited the limited movement of the 2017 Star Ratings after its application. Several commenters suggest expanding the number of measures to be adjusted with some commenters specifically asking for the inclusion of the plan all-cause readmission measure. Several commenters suggest including social risks factors (such as age and gender) in the modeling for the CAI. Other comments include a request for a timeline for the development of the long-term solution; implementation of a hold harmless provision; and a half-star bonus for either SNPs that received a rating of 3.5 or above or plans serving high proportions of LIS/DE and disabled beneficiaries. Several commenters express their support for the continued use of the additional adjustment (LIS/DE indicator) for contracts operating solely in Puerto Rico.	The CAI will be implemented as proposed in the draft Call Letter, and CMS will continue to work with measure developers and ASPE on long-term solutions.
CAHPS measures (Part C & D)	Commenters support removing Reminders for appointments, Reminders for immunizations, Reminders for screening tests, Computer used during office visits, Computer use by provider helpful, Computer use made talking to provider easier, and Getting information from drug plan from the 2018 display page. Several expressed general comments about CAHPS surveys, especially for dual populations and those with disabilities.	Proceed as planned.
Pneumococcal Vaccination Status for Older Adults (Part C)	Almost all commenters support CMS' proposal to explore non-survey based methods for assessment, with many proposing alternative methods. They offer mixed opinions on claims data. Some support CMS' proposed wording for the CAHPS measure with others offering alternate language.	Proceed as proposed. CMS shared comments received with NCQA.
Hospitalizations for Potentially Preventable Complications (Part C)	All commenters support CMS' proposal to keep this measure on the display page for 2018 due to concerns with measurement instability or technical complexity. Several raised the hospital practice of observation stays as an issue.	Proceed as proposed. CMS shared comments received with NCQA.

Call Letter Section	Summary of Comments	CMS Final Course of Action
Statin Therapy for Patients with Cardiovascular Disease (Part C)	Several commenters are concerned that the measure duplicates the Statin Use in Persons with Diabetes (SUPD) Part D measure and want CMS to better align the two. Commenters want statin-intolerant members excluded from this measure, with confusion about whether this is already the case. Several comment on the appropriateness of this as a display or Star Ratings measure at all, with several asking CMS to keep as a display measure longer.	Proceed as proposed. CMS clarified exclusions and shared comments received with NCQA.
Asthma Measures (Part C)	The vast majority of commenters support CMS' decision not to report the asthma measures on the 2018 display page nor on the 2018 Star Ratings.	Proceed as proposed. CMS shared comments received with NCQA.
Non-Recommended PSA-Based Screening in Older Men (Part C)	The majority of providers do not agree with reporting this measure on the 2018 display page. In addition, there are requests from several associations that the PSA measure include additional exclusions such as for men age 70+ who are in excellent health. CMS also received many comments from individuals that PSA testing is still important for men over 70.	CMS has decided not to report the PSA measure on the 2018 display page. CMS will review the inclusion of this measure in the future after reviewing results from the current 2017 U.S. Preventive Services Task Force investigation of PSA testing among adult men. CMS shared comments received with NCQA.
Formulary Administration Analysis measure (Part D)	Most commenters, especially advocacy groups, support the measure. Some request information about the FAA methodology or other technical clarifications, and for CMS to keep this as a display page for at least 2 years before moving into Star Ratings.	Proceed as proposed. CMS will provide technical clarifications to the display measure specifications.
Drug-Drug Interactions (Part D)	Almost all commenters support the proposals to implement the revised PQA DDI drug list for the 2019 display page. One commenter opposed to the measure suggests that it be retired. And one commenter suggests that the measure be updated to reflect absolute contraindications.	Proceed as proposed.
Chronic Use of Atypical Antipsychotics by Elderly Beneficiaries in Nursing Homes (Part D)	See Antipsychotic Use in Persons with Dementia (APD) (Part D) summary below.	Proceed as proposed.

Call Letter Section	Summary of Comments	CMS Final Course of Action
Antipsychotic Use in Persons with Dementia (APD) (Part D)	Among the comments submitted to the proposals to remove the Chronic Use of Atypical Antipsychotics by Elderly Beneficiaries in Nursing Homes measure from the display page and replace it with the Antipsychotic Use in Persons with Dementia (APD) measure for the 2018 display page, almost all support the proposals, including sponsors, organizations, PBM, and patient advocates. There is also support to only display the overall APD rate for 2018, and revise the community and long term nursing home population breakouts for the 2019 display page (2017 reports). Only a couple of commenters oppose the proposals, including CMS ever considering the measure for the Star Ratings. One commenter raises potential denominator concerns for Puerto Rico plans. A commenter suggests that days supply be factored into the revised population breakouts.	Proceed as proposed.
Use of Opioids from Multiple Providers and/or at High Dosage in Persons without Cancer (Part D)	More than half of the commenters agree with the proposals to implement the PQA measure changes in the 2017 patient safety reports and add the three measures to the display page for 2019 based on 2017 data. There is also support not to add the measures to the Star Ratings at this time (although one commenter recommends that CMS consider adding these measures to the Star Ratings). Two commenters do not support the measures and suggest that CMS just focus on the policy. Other commenters raise other questions or concerns: to make additional changes to the measures to align with the proposed changes to the Overutilization Monitoring System changes (to lower the MED threshold to 90mg and move to an average methodology), about how these measures align with the CMS opioid overutilization policy (i.e., measure 1 and 2), and that many opioid related measures are being implemented in a short period of time. One commenter suggests that patient engagement measures should be developed in this area.	All three measures will continue to be reported through the Patient Safety Analysis website for 2017 reports. We plan to only add the OHDMP measure to the 2019 Part D display page (using 2017 data). At this time, we do not plan to add any of these three measures to the Star Ratings.
Statin Use in Persons with Diabetes (SUPD) (Part D)	Most of the commenters support including the SUPD measure on the display page for 2018 and adding to the 2019 Star Ratings (with new ESRD exclusion). Less than half oppose or have mixed comments on the proposals. Some commenters suggest that CMS delay adding to the Star Ratings or work on alignment with the Statin Therapy for Patients with Cardiovascular Disease (Part C) measure. Other commenters suggest that statin intolerant patients be excluded from the measure denominator or to exclude metformin due to its use in pre-diabetes, which we will share with the PQA.	Proceed as proposed.

Call Letter Section	Summary of Comments	CMS Final Course of Action
Patient Safety Report Frequency	All commenters oppose changing the frequency of the patient safety measure reports from monthly to quarterly. Despite acknowledging that there may be some differences due to data lag compared to their internal reports, commenters discuss how useful the reports are for their internal monitoring, performance improvement, and transparency. Some commenters recommend that CMS work with the industry to address these issues, including more frequent PQA NDC file updates.	Do not finalize as proposed. Continue to provide monthly reports and send outlier notices on a quarterly basis.
Colorectal Cancer Screening (Part C)	The majority of commenters support the continued inclusion of this measure in the Star Ratings, even with the expansion of the screening options. Some commenters remark that expanding the screening options will provide Medicare beneficiaries greater options and more access as well as assist health plans to increase compliance.	Proceed as proposed. CMS shared comments received with NCQA.
Initiation and Engagement in AOD Treatment (IET, Part C measure)	There is general support for addressing AOD health issues. However, there is concern about health plans' abilities to document when a diagnosis is first given and when treatment is received. Identifying when a patient is first diagnosed might be problematic when a patient is diagnosed in an emergency room visit or in a visit to a drug and alcohol treatment center. Further, since AOD services are often provided outside the traditional health care delivery system, a health plan might not be able to track the receipt of treatment.	CMS will further investigate the development of this measure and appreciates receiving comments. CMS has shared the comments with NCQA.
Telehealth and Remote Access Technologies	Providers are very cautious and concerned about too much use to save costs. Plans are in general supportive but express concern that regulations vary by state and some plans are not ready to use telehealth and so will be disadvantaged. Advocates are supportive. Pharmacy associations are supportive but thought pharmacists could play a greater role if they could have more access to EHRs and other electronic communications.	The comments were shared with NCQA to include in their work on measure development and revisions.
Cross-Cutting Exclusions for Advanced Illness	Nearly all plans support this approach as being patient-centered. Many have specific feedback, as CMS requested, and propose both extending exclusions to other measures and listing specific diagnoses and conditions that might be included in the specifications. One association cautions CMS to avoid exclusions based simply on the use of specialty palliative care services.	CMS appreciates the feedback received. CMS has shared the comments with NCQA for their consideration.
Care Coordination measures (Part C)	Advocates are supportive of increasing the weight of care coordination measures including CAHPS, while plans, plan associations and pharmacy associations are not supportive. There is near universal support to develop new clinical care coordination measures to replace the CAHPS one. Commenters express concern that we need to develop care coordination measures that address the unique coordination concerns of dual eligible beneficiaries and those with complex care needs.	Based on feedback received from the draft Call Letter, we are not moving forward with a change in weights to the care coordination measures at this time.

Call Letter Section	Summary of Comments	CMS Final Course of Action
Center for Medicare and Medicaid Innovation Model Tests	Most commenters support excluding model participants' data from calculating the cut points for relevant measures.	The model tests will not be implemented until 2017, so they will not affect ratings until 2019 Star Ratings. CMS will provide additional details about our approach for model participants' Star Ratings in a future Call Letter.
Reducing the Risk of Falling (Part C)	Nearly all commenters ask to retain this on the display page for the 2020 Star Ratings, since the revised questions will first be collected in 2018. A few respondents prefer that CMS obtain this data through non-survey means (i.e., electronic health records). One association, however, strongly urges CMS to retain the measure in the Star Ratings for 2019 and 2020.	CMS will further investigate the development of this measure and appreciates receiving comments. CMS has shared the comments with NCQA.
Plan All-Cause Readmissions (Part C)	Most plans are supportive of including observation stays in the PCR measure, but they and one association are very concerned that observation stays are not defined clearly or used consistently across the country. Two plans are opposed to observation stays because they are not consistently used across the country or defined.	This feedback has been shared with NCQA for their consideration.
Transitions of Care (Part C)	The majority of respondents support this measure but feel that there is much more work that needs to be done in the measure definition to overcome data transfer issues. Some respondents think the measure should be implemented as a provider/hospital-level measure.	CMS will further investigate the development of this measure and appreciates receiving comments. CMS has shared the comments with NCQA.
Follow-up after Emergency Department Visit for Patients with Multiple Chronic Conditions (Part C)	The majority of respondents support this measure but feel the severity of the patient's conditions should guide the follow-up timeframe. Some respondents pointed out that notification of emergency room visits are not always promptly communicated and wish for that to be taken into account in the measure specification.	CMS will further investigate the development of this measure and appreciates receiving comments. CMS has shared the comments with NCQA.
Opioid Overuse (Part C)	All of the respondents support the effort to fight opioid overuse. Many respondents point to the similarities with the Part D version of this measure and think CMS should focus on using that.	CMS will further investigate the development of this measure and appreciates receiving comments. CMS has shared the comments with NCQA.
Depression Screening and Follow-Up for Adolescents and Adults (Part C)	There is some support for this measure, but commenters want more choice and flexibility in the screening instrument(s) to be used and additional details about measure specification. Some commenters ask for more focus on outcomes rather than on screening processes. However, other commenters mention that with a shortage of mental health providers, ensuring follow-up could be a challenge. A few commenters remark that patient confidentiality could be problematic.	CMS will continue to follow development of this measure and appreciates receiving comments. CMS has shared comments with NCQA.

Call Letter Section	Summary of Comments	CMS Final Course of Action
Alcohol Screening and Follow-Up (Part C)	Commenters express support for this measure. Some commenters suggest a need for further measure specification. Commenters also express the opinion that implementing this measure would require having measure data collected comprehensively and electronically across all AOD providers.	CMS will continue to follow the development of this measure and appreciates receiving comments. CMS has shared the comments with NCQA.
Appropriate Pain Management (Part C)	There is general support for the measure but many respondents think it should be collected at the provider level since they are in the front line of pain management.	CMS will continue to follow the development of this measure and appreciates receiving comments. CMS has shared the comments with NCQA.
Plan Makes Timely Decisions about Appeals (Part C)	The majority of respondents do not agree with adding withdrawn and dismissed appeals to the Part C appeals measures. The few that support the additions point out that sponsor reporting requirements would have to change and that those changes would take time to implement.	CMS thanks the respondents for their comments. We will continue to review possible updates to the Part C appeals measures for 2019 Star Ratings.
New PQA-endorsed measures in development for future testing/consideration (Part D)	• Concurrent Use of Opioids and Benzodiazepines. Almost all commenters support testing this new PQA measure. A few concerns were raised that a number of new opioid-related measures are being implemented or tested in a short period of time, about how the measure aligns with policy, or that the measure is based solely on using claims data. • Adherence to Non-infused Disease Modifying Agents Used to Treat Multiple Sclerosis. Most commenters support testing this new measure. Commenters that oppose the measure mention that the measure includes a very small patient population, high prevalence of side effects, that many patients voluntarily discontinue use of the medications due to side effects, or lack of evidence to support that the 80% adherence threshold is associated with disease progression or delay.	Proceed as planned to test the new measures.
Breast Cancer Screening	CMS received a few responses regarding suggestions for changes in age ranges and current numerator exclusions for the Breast Cancer Screening measure.	CMS has shared those comments with NCQA.

Call Letter Section	Summary of Comments	CMS Final Course of Action
ODAG and CDAG	CMS received mixed feedback on the request for feedback. A few commenters support the idea of developing new or enhanced measure. One commenter suggest adding the % of denials or medical necessity when a network doctor does not provide additional information to the plan. A few commenters also oppose this suggestion. Commenters note variation among plans, negative impact of the development of measures related to provider outreach, and the welcoming of change to the current measures if the criteria were clear in the technical specifications. Several commenters have mixed reviews as well. Commenters request more guidance, suggest that the measures be based on the information that the plan had at the time of the decision, have concerns about resource intensive measures and their value add, and state that adverse reductions should be limited to objective findings that are not subject to interpretation. One commenter provides a suggestion to adopt a data governance program for these submissions.	CMS will continue to be interested in developing new or enhanced measures of beneficiary access. Additionally, we remain interested in potentially evaluating sponsors' compliance with effectuating appeals and provider outreach requirements, as well as appropriate clinical-decision making and notification to beneficiaries and their caregivers.

Appendix 3 – Guidance for Prescription Drug Plan (PDP) Renewals and Non-Renewals

The PDP renewal/non-renewal guidance has been removed from the Call Letter and is now posted at the following link: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html.