April 2, 2018

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

Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter

CMS received many submissions in response to our request for comments on Part I of the Advance Notice, published on December 27, 2017 and Part II of the Advance Notice/Draft Call Letter, published on February 1, 2018. Comments were received from professional organizations, Medicare Advantage (MA) and Part D sponsors, advocacy groups, state Medicaid agencies, pharmaceutical manufacturers, 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's 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.

In accordance with section 1853(b)(1) of the Social Security Act, we are notifying you of the annual capitation rate for each MA payment area for CY 2019 and the risk and other factors to be used in adjusting such rates. The capitation rate tables for 2019 and supporting data are posted on the CMS website at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Ratebooks-and-Supporting-Data.html. The statutory component of the regional benchmarks, qualifying counties, and each county's applicable percentage are also posted on this section of the CMS website.

Attachment I shows the final estimates of the National Per Capita MA Growth Percentage for 2019 and the National Medicare Fee-for-Service (FFS) Growth Percentage for 2019. These growth rates were used to calculate the 2019 capitation rates. As discussed in Attachment I, the final estimate of the National Per Capita MA Growth Percentage for combined aged and disabled beneficiaries is 5.93 percent, and the final estimate of the FFS Growth Percentage is 5.11 percent. Attachment II provides a set of tables that summarizes many of the key Medicare assumptions used in the calculation of the growth percentages.

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 2016 were posted on the above website with Part II of the Advance Notice.

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

Attachment III presents responses to Part C payment related comments on both Parts I and II of the Advance Notice of Methodological Changes for CY 2019 MA Capitation Rates and Part C and Part D Payment Policies (Advance Notice).

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

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

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

Attachment VII presents the final Call Letter.

Key Changes from the Advance Notice:

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

Calculation of FFS Cost: The Secretary has directed the CMS 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: This year, CMS will finalize the 100% phase in with adjustments based on the proportion of EGWP enrollment in PPOs vs. HMOs, but CMS intends to seek comment on modifications for 2020 that include additional or different adjustments for regional PPOs and rural local PPOs. Therefore, for 2019, CMS will fully transition to using only individual market plan bids to calculate the bid-to-benchmark ratios to set EGWP payments, as proposed in the 2019 Advance Notice, but with the adjustment proposed as an alternative. For 2019, the individual market ratios will be adjusted to account for the difference in the proportion of beneficiaries enrolled in HMOs and PPOs between EGWPs and individual market plans.

CMS-HCC Model: For 2019 CMS will use the updated CMS-HCC model without count variables for the blended risk score calculation. Therefore, for 2019 we will calculate risk scores as proposed, but with the updated CMS-HCC model without count variables. Specifically, we will blend 75% of the risk score calculated with the 2017 CMS-HCC model, using diagnoses from RAPS and FFS, summed with 25% of the risk score calculated with the updated CMS-HCC model without count variables, using diagnoses from encounter data, RAPS inpatient records, and FFS as discussed in more detail in Attachment III, Sections H and L.

RxHCC Risk Adjustment Model: CMS will not implement the updated model in 2019. We will continue to use the RxHCC model used in 2018, as published in the 2018 Rate Announcement.

Revised Normalization Factors:

RxHCC model: 1.019

Frailty Adjustment for PACE organizations and FIDE-SNPs: CMS will implement FIDE-SNP frailty factors consistent with the version of the CMS-HCC model being finalized for 2019. Consistent with CMS's proposal to blend risk scores, for FIDE SNPs a blended frailty score will be compared with PACE frailty in the same manner as for 2018 to determine whether that FIDE SNP has a similar average level of frailty as PACE.

Beneficiary Coinsurance and Dispensing and Vaccine Administration Fees in the Coverage Gap: The Bipartisan Budget Act of 2018 enacted changes to the Part D benefit design for 2019 related to the coverage gap discount program. Attachment IV details those changes as they relate to beneficiary costs in the coverage gap.

Part D Benefit Parameters: Attachment V provides the final 2019 Part D benefit parameters for the defined standard benefit, low-income subsidy, and retiree drug subsidy. The estimate for total covered Part D spending at the out-of-pocket threshold for applicable beneficiaries has been updated to reflect the coverage gap discount program-related changes to the 2019 Part D benefit design enacted in the Bipartisan Budget Act of 2018.

Enhanced Medication Therapy Management (MTM) Model: Given timing and operational considerations, we have determined that it will not be possible for the model's premium reductions to be considered when determining the 2019 low-income premium benchmarks.

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.

MA Benchmark, Quality Bonus Payments and Rebate: We will continue to implement the methodology used to derive the benchmark county rates, how the qualifying bonus counties will be identified, and the applicability of the star rating system.

IME Phase Out: We will continue phasing out indirect medical education amounts from the MA capitation rates.

End Stage Renal Disease (ESRD) State Rates: We will determine the 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 Private Fee-for-Service (PFFS) Plans in Plan Year 2020: The list of network areas for plan year 2020 is available on the CMS website at https://www.cms.gov/Medicare/Health-Plans/PrivateFeeforServicePlans/NetworkRequirements.html.

Adjustment for MA Coding Pattern Differences: We will implement an MA coding pattern difference adjustment of 5.90 percent for 2019.

ESRD Risk Adjustment Models: We will implement the updated ESRD dialysis and ESRD functioning graft models as proposed in the Advance Notice.

Final 2019 Normalization Factors:

CMS-HCC model without count variable being implemented in 2019, for blended risk score calculations: 1.038[1]

CMS-HCC model implemented in 2017, for blended risk score calculations: 1.041

CMS-HCC model used for PACE organizations: 1.159

CMS-HCC ESRD Dialysis model: 1.033

CMS-HCC ESRD Functioning Graft model: 1.048

Medical Loss Ratio Credibility Adjustment: We are finalizing the credibility adjustment factors as published in the Medical Loss Ratio final rule (CMS-4173-F), 78 FR 31284 (May 23, 2013).

Encounter Data as a Diagnosis Source for 2019 (non-PACE): CMS will calculate 2019 risk scores by adding 25% of the risk score calculated using encounter data (supplemented with RAPS inpatient data) and FFS diagnoses with 75% of the risk score calculated using RAPS and FFS diagnoses.

Encounter Data as a Diagnosis Source for 2019 (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 2019 threshold risk percentages and payment adjustments for Part D risk sharing will be finalized as stated in the Advance Notice.

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

/ s /
Demetrios Kouzoukas
Principal Deputy Administrator
and Director, Center for Medicare

I, Jennifer Wuggazer Lazio, am a Member of the American Academy of Actuaries. I meet the Qualification Standards of the American Academy of Actuaries to render the actuarial opinion contained in this Rate Announcement. My opinion is limited to the following sections of this

[1] Note that the CMS-HCC normalization factor has been updated to reflect the model finalized for 2019. Since the factor we are finalizing is the same as the proposed factor for the Payment Count model, we are categorizing this with other policies that are being finalized as proposed.

Rate Announcement: The growth percentages and United States per capita cost estimates provided and discussed in Attachments I, II and III; the qualifying county determination and calculations of Fee for Service cost, IME phase out, MA benchmarks, EGWP rates, and ESRD rates discussed in Attachment III; and Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2019 described in Attachment IV and in Attachment V.

/ s /
Jennifer Wuggazer Lazio, F.S.A., M.A.A.A.
Director
Parts C & D Actuarial Group
Office of the Actuary

Attachments

2019 ANNOUNCEMENT
TABLE OF CONTENTS

Attachment I. Final Estimates of the National Per Capita Growth Percentage and the National Medicare Fee-for-Service Growth Percentage for Calendar Year 2019

The Table I-1 below shows the National Per Capita MA Growth Percentage (NPCMAGP) for 2019. An adjustment of 1.786 percent for the combined aged and disabled is included in the NPCMAGP to account for corrections to prior years' estimates as required by section 1853(c)(6)(C). The combined aged and disabled change is used in the development of the ratebook.

Table I-1. Increase in the National Per Capita MA Growth Percentages for 2019

	Prior increases	Current increases			NPCMAGP for 2019 with §1853(c)(6)(C) adjustment[1]
	2003 to 2018	2003 to 2018	2018 to 2019	2003 to 2019	
Aged + Disabled	58.758%	61.593%	4.075%	68.178%	5.93%

[1]Current increases for 2003-2019 divided by the prior increases for 2003-2018.

Table I-2 below provides the change in the FFS United States Per Capita Cost (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 2019 divided by projected FFS USPCC for 2018 as estimated in the 2018 Rate Announcement released on April 3, 2017.

Table I-2 – FFS USPCC Growth Percentage for CY 2019

	Aged + Disabled	Dialysis–only ESRD
Current projected 2019 FFS USPCC	$891.07	$7,833.28
Prior projected 2018 FFS USPCC	847.73	7,133.42
Percent change	5.11%	9.81%

Table I-3 below shows the monthly actuarial value of the Medicare deductible and coinsurance for 2018 and 2019. In addition, for 2019, the actuarial value of deductibles and coinsurance is being shown for non-ESRD only, since the plan bids will not include ESRD benefits in 2019. These data were furnished by the Office of the Actuary.

Table I-3 - Monthly Actuarial Value of Medicare Deductible and Coinsurance for 2018 and 2019

	2018	2019	Change	2019 non-ESRD
Part A Benefits	$37.16	$36.59	−1.5%	$34.71
Part B Benefits[1]	126.88	133.57	5.3	122.91
Total Medicare	164.04	170.16	3.7	157.62

[1]Includes the amounts for outpatient psychiatric charges.

Medical Savings Account (MSA) Plans. The maximum deductible for current law MSA plans for 2019 is $12,650.

Attachment II. Key Assumptions and Financial Information

The United States Per Capita Costs (USPCCs) are the basis for the National Per Capita MA Growth Percentage. Attached is a table that compares last year's estimates of USPCCs with current estimates for 2003 to 2020. In addition, this table shows the current projections of the USPCCs through 2021. 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 2021.

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	383.91	367.93	367.93	751.84	751.84	1.000
2010	383.95	383.94	376.81	376.82	760.76	760.76	1.000
2011	388.18	386.94	386.45	386.24	774.63	773.18	1.002
2012	377.72	378.95	392.97	392.77	770.69	771.72	0.999
2013	381.73	381.19	399.67	399.56	781.40	780.75	1.001
2014	372.77	371.71	418.59	418.73	791.36	790.44	1.001
2015	376.31	374.40	435.76	436.25	812.07	810.65	1.002
2016	380.07	374.68	446.33	447.60	826.40	822.28	1.005
2017	384.70	378.11	464.36	462.05	849.06	840.16	1.011
2018	390.02	382.86	488.79	480.53	878.81	863.39	1.018
2019	400.52	396.50	514.10	511.10	914.62	907.60	1.008
2020	412.19	412.63	537.91	538.17	950.10	950.80	0.999
2021	427.98		568.79		996.77		

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	$371.20	$371.17	$374.92	$374.91	$746.12	$746.08	1.000
2011	371.70	370.01	384.70	384.39	756.40	754.40	1.003
2012	357.52	359.17	392.25	391.94	749.77	751.11	0.998
2013	366.28	365.50	396.04	395.85	762.32	761.35	1.001
2014	367.40	365.80	409.08	409.16	776.48	774.96	1.002
2015	372.76	370.14	429.23	430.15	801.99	800.29	1.002
2016	374.86	367.52	436.55	439.16	811.41	806.68	1.006
2017	376.30	369.28	456.25	455.72	832.55	825.00	1.009
2018	381.58	377.28	474.83	470.45	856.41	847.73	1.010
2019	391.63	390.42	499.44	498.55	891.07	888.97	1.002
2020	403.45	405.85	523.29	524.10	926.74	929.95	0.997
2021	417.97		552.01		969.98		

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	6,882.85	1.000
2014	6,900.22	6,900.22	1.000
2015	6,836.71	6,836.71	1.000
2016	6,977.18	6,796.37	1.027
2017	7,067.89	6,933.11	1.019
2018	7,586.28	7,133.42	1.063
2019	7,833.28	7,434.24	1.054
2020	8,099.11	7,745.31	1.046
2021	8,439.59		

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
2017	1.0158	0.9973	1.0130
2018	1.0929	0.9949	1.0873
2019	1.1313	0.9924	1.1227
2020	1.1726	0.9900	1.1608
2021	1.2248	0.9876	1.2096

Summary of Key Projections

Part A[1]

Year	Calendar year CPI percent change	FY inpatient 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	4.5
2012	2.1	−0.1	0.4
2013	1.4	2.8	5.0
2014	1.5	0.9	0.7
2015	−0.4	1.4	3.3
2016	1.0	0.9	4.2
2017	2.1	0.15	3.8
2018	2.2	1.81	3.3
2019	2.5	2.55	5.6
2020	2.6	3.6	6.0
2021	2.6	3.6	6.6

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	7.2	0.8
2014	0.5	0.6	12.4	3.4
2015	−0.5	0.7	7.3	2.7
2016	−0.4	−0.9	5.3	1.9
2017	0.3	0.6	7.8	3.1
2018	0.7	1.3	7.9	4.8
2019	0.4	3.2	7.7	4.8
2020	−0.5	3.3	9.0	4.6
2021	0.1	3.0	8.8	5.6

[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 preventive 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	39.950	8.171	37.247	7.254
2012	41.687	8.411	38.546	7.502
2013	43.087	8.629	39.779	7.732
2014	44.522	8.776	41.064	7.894
2015	45.911	8.852	42.310	7.974
2016	47.432	8.812	43.614	7.964
2017	48.908	8.618	45.092	7.811
2018	50.468	8.506	46.524	7.676
2019	52.083	8.501	47.996	7.661
2020	53.761	8.583	49.543	7.721
2021	55.472	8.625	51.116	7.759

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	29.210	6.659	26.440	5.736
2012	29.960	6.693	26.744	5.779
2013	30.330	6.691	26.948	5.790
2014	30.593	6.618	27.060	5.732
2015	30.948	6.489	27.273	5.607
2016	31.692	6.329	27.805	5.477
2017	31.929	5.985	28.027	5.172
2018	32.175	5.708	28.141	4.872
2019	32.921	5.570	28.740	4.724
2020	33.848	5.544	29.532	4.676
2021	34.787	5.487	30.328	4.614

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	0.429	0.416	0.371	0.358
2012	0.441	0.429	0.379	0.366
2013	0.453	0.441	0.384	0.371
2014	0.468	0.455	0.390	0.377
2015	0.482	0.468	0.393	0.379
2016	0.496	0.481	0.400	0.385
2017	0.508	0.492	0.400	0.384
2018	0.521	0.504	0.402	0.384
2019	0.535	0.517	0.410	0.392
2020	0.549	0.531	0.424	0.405
2021	0.562	0.543	0.433	0.413

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	2,627.03	571.74	155.18	1,249.92	13,126
2011	2,585.95	623.31	143.31	1,299.73	13,986
2012	2,489.44	541.69	135.64	1,359.40	15,163
2013	2,499.47	542.91	133.59	1,398.38	15,406
2014	2,443.81	536.28	128.80	1,358.05	15,513
2015	2,428.99	533.88	131.02	1,416.17	16,248
2016	2,446.56	507.66	126.23	1,476.49	17,285
2017	2,400.56	491.51	124.27	1,596.20	18,478
2018	2,370.87	487.64	124.76	1,693.07	19,672
2019	2,404.48	495.45	129.62	1,772.69	21,205
2020	2,458.39	512.83	133.69	1,837.30	22,955
2021	2,499.71	535.42	140.05	1,932.19	24,844

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

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	628.55	183.76
2011	1,442.78	668.57	175.83
2012	1,398.89	703.65	173.70
2013	1,356.04	741.35	152.53
2014	1,336.44	821.10	128.47
2015	1,341.91	874.75	133.06
2016	1,312.62	913.92	121.51
2017	1,304.29	965.00	113.54
2018	1,314.06	1,009.39	112.22
2019	1,346.78	1,070.39	120.46
2020	1,372.31	1,153.04	128.26
2021	1,402.70	1,243.05	132.23

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	102.19	407.29	83.31
2012	109.72	410.33	84.64
2013	109.31	409.67	81.74
2014	114.48	411.32	55.40
2015	114.76	424.26	55.33
2016	107.13	448.69	56.39
2017	108.21	471.17	55.95
2018	99.63	467.56	50.62
2019	94.35	484.31	47.10
2020	91.42	506.99	44.84
2021	102.20	528.70	49.23

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

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	1,221.49
2011	198.15	262.22	1,276.72
2012	205.08	246.70	1,367.46
2013	194.43	241.19	1,496.15
2014	200.27	234.52	1,706.67
2015	210.30	231.93	1,828.61
2016	215.60	226.52	1,940.99
2017	223.89	222.23	2,100.21
2018	228.63	223.16	2,355.93
2019	236.95	231.75	2,524.12
2020	246.11	238.88	2,659.53
2021	256.02	250.10	2,846.86

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

2019 Projections by Service Category for non-ESRD (Aged+Disabled)*

Service type	Current estimate	Last year's estimate	Ratio
Part A			
Inpatient hospital	$2,404.48	$2,398.56	1.002
SNF	495.45	552.29	0.897
Home health agency	129.62	137.44	0.943
Managed care	1,772.69	1,665.72	1.064
Part B			
Physician fee schedule	1,346.78	1,403.92	0.959
Outpatient hospital	1,070.39	1,087.13	0.985
Durable medical equipment	120.46	128.80	0.935
Carrier lab	94.35	113.95	0.828
Other carrier	484.31	481.11	1.007
Intermediary lab	47.10	54.60	0.863
Other intermediary	236.95	201.54	1.176
Home health agency	231.75	243.93	0.950
Managed care	2,524.12	2,403.89	1.050

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	0.000833	0.002111
2018	0.000833	0.002111
2019	0.000833	0.002111
2020	0.000833	0.002111
2021	0.000833	0.002111

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 2019 (before adjustment for prior years' over/under estimates) is calculated by adding the USPCCs for Part A and Part B for 2019 and then dividing by the sum of the current estimates of the USPCCs for Part A and Part B for 2018.

The FFS USPCC:

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

Attachment III. Responses to Public Comments

Section A. Final Estimate of the National Per Capita Growth Percentage and the Fee-for-Service (FFS) Growth Percentage for Calendar Year 2019

Comment: Two commenters expressed appreciation for the timely and detailed information released regarding the growth percentages, and encouraged us to continue to share more granular information regarding the underlying methodology and analyses related to the growth percentages and the development of the county benchmarks. Another commenter requested that we make the process more transparent so that interested parties can better understand how we arrive at these estimates and provide more meaningful comment on them, such as detailed information regarding the data and process used to determine the growth rates in each publication (early preview, Advance Notice, and Rate Announcement).

Response: We appreciate the support. With the final Rate Announcement we annually publish detailed information regarding the growth percentages. We believe that this provides useful information and support pertaining to USPCC levels and trends. Key economic assumptions underlying the USPCCs are included in Attachment II of this Rate Announcement. Also, consistent with prior years, we will publish additional information regarding trends for the prior five years at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/FFS-Trends.html. We will consider publishing additional information in future years that can help interested parties understand the potential impacts of changes.

Comment: One commenter noted that the increase in the Total USPCC is greater than the increase in the fee-for-service (FFS) USPCC, suggesting that payments to MA plans are expected to increase at a higher rate than payments to FFS Medicare providers. The commenter requested an explanation of the specific factors and their magnitude that contribute to differences between the Total USPCC and FFS USPCC.

Response: The higher trend for the total USPCC is due to larger relative growth in MA versus Medicare FFS. The primary reasons for the higher MA trend are as follows. In aggregate, the actual MA risk scores used for payment for contract years 2016 and 2017 are higher than those reflected in the submitted bids. Positive prior period adjustments for MA stem from the reflection of the actual 2016 and 2017 risk scores, and projected risk scores from the 2018 bids, in our spending baseline. These adjustments are also reflected in the total USPCC growth rate calculation.

Comment: One commenter noted that, for payment year 2012, we began excluding all claims for beneficiaries in Hospice status. While the commenter assumed that this aspect of the USPCC methodology has not changed since that time, there is no mention of how the Hospice member months and associated risk scores are handled. The commenter requested that we describe what

exclusions, if any, are made in the AGA (average geographic adjustment) factor and USPCC calculation for these beneficiaries in terms of their member months and associated risk scores.

Response: Beginning with the 2009 FFS experience, used in the development of the 2012 ratebook, claims for hospice services have been excluded from the calculation of the ratebook FFS rate. Non-hospice claims and enrollment for the FFS beneficiaries in hospice status are included in the calculation of the FFS rate, but the corresponding risk scores are excluded from the rate development.

The 2012 Advance Notice stated that "CMS proposes to tabulate the 2009 FFS costs for members that are not in Hospice status for the 2012 rate calculation." This proposal was modified in the 2012 Rate Announcement through the statement "We will improve the calculation of the USPCC and the AGA methodology by excluding hospice claims", and this methodology has not changed since that announcement.

Comment: One commenter questioned the relationship between the Effective Growth Rate included in the Fact Sheet and the FFS growth percentage included in the Advance Notice.

Response: The Effective Growth rate in the Fact Sheet reflects the impact, weighted by MA enrollment, of the FFS growth percentage, as well as the MA growth percentage that is applied to the pre-ACA benchmark cap.

Comment: One commenter expressed concern with regards to including beneficiaries enrolled in Part A only in the calculation of the USPCCs that determine the MA growth percentage, the FFS growth percentage, and the ESRD payment rates. The commenter recommended that CMS calculate FFS spending based only on beneficiaries enrolled in both Parts A and B. The commenter noted that the risk adjustment models are calibrated with FFS beneficiaries enrolled in Part A and Part B, and recommended that risk adjustment and payment rates be based on the same population.

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.

Comment: Two commenters expressed support of the dialysis-only ESRD USPCC growth percentage projected in the Advance Notice.

Response: We appreciate the support.

Comment: One commenter questioned whether the projected dialysis-only ESRD growth percentage includes expenditures for the drug Sensipar, which recently became covered under Part B (no longer covered under Part D).

Response: The projected dialysis-only ESRD growth rate reflects our best estimate of program spending for the ESRD population for CY2019, including the Part B coverage of Sensipar effective January 1, 2018.

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. Commenters believe that the inclusion of the quality bonus in the rate cap calculation undermines the quality bonus program. Commenters also indicated 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.

Commenters suggested that we review our options for exercising discretionary, regulatory, and/or demonstration authority to eliminate the cap or to remove quality bonuses from the cap calculation, or to find other ways to reward high quality plans. Commenters also offered legal analyses regarding this issue for consideration.

Response: As discussed in past Rate Announcements, we share 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: Two commenters expressed support for the proposed payment methodologies outlined in the Advance Notice, as being consistent with applicable law and also to bring MA plan payments in line with costs under FFS Medicare. The commenters believed the proposed policies to be critical to stabilizing the fiscal health of the Medicare program, ensuring efficient spending of taxpayer dollars, and continuing ample choice and stability in the MA program.

Response: We appreciate the support.

Comment: In the Advance Notice, we referred to a recently released notice of proposed rulemaking (NPRM) regarding contract consolidations and quality bonus star ratings. Subsequent to the Advance Notice release, Section 1853(o)(4) of the Social Security Act was amended by the Bipartisan Budget Act of 2018 to add subsection (D) regarding the determination of star ratings for consolidating MA plans. One commenter disagreed with the proposed policy regarding the star ratings of consolidated contracts. Several commenters expressed support regarding the proposed policy in the NPRM, and provided additional suggestions for further refinement of the star rating calculation.

Response: As indicated in the Advance Notice, the application of this policy will be addressed in the cited rulemaking. Please see the Final Call Letter for further information regarding star ratings.

Comment: A large number of commenters expressed support and appreciation for the counties in Puerto Rico that were determined to be eligible for the Qualifying County Bonus Payment. Commenters further requested that all 78 counties in Puerto Rico be classified as qualifying counties, at least as a temporary measure, given the unique definition of a county in Puerto Rico which results in a relatively high number of counties within the territory.

Response: As indicated in the Advance Notice, Section 1853(o)(3)(B) of the Act provides the criteria for determining a qualifying county. We do not have discretion to classify counties that do not meet the statutory criteria as qualifying counties for the double bonus payment.

Section C. Calculation of Fee for Service Cost

Comment: A large number of commenters requested that we 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) on the basis that it would be a more accurate, reasonable, appropriate, and/or equitable methodology. 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 stated that the FFS cost estimates should be calculated consistently with the coverage offered in order to ensure that it is representative of the expected spending. Commenters noted that, over time, as a higher percentage of beneficiaries join MA plans, a higher percentage of beneficiaries remaining in FFS do not enroll in Part B. Commenters expressed concern that high MA penetration leaves fewer, and a less representative population of, beneficiaries on which to calculate FFS spending. 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 MedPAC's recommendation that benchmarks be calculated based on FFS data for beneficiaries with both Part A and Part B, and also cited a recent Health Affairs Blog article on this topic. Commenters offered legal analyses regarding this issue for consideration. The legal analysis noted the statutory language under section 1876(a)(4) regarding the average per capita amount "would be payable in any contract year for services covered under parts A and B, or part B only, and types of expenses otherwise reimbursable under parts A and B, or part B only", noting that this language does not include a reference to "Part A only". The analysis concluded that under a reading of the plain language, Congress intended to exclude "Part A only" cost data from the calculation of MA rates, and noted that beneficiaries entitled to benefits under Part A only, but not enrolled under Part B, were not eligible for coverage under section 1876 plans. The analysis also offered that Congress could have directed the Secretary to combine the amounts calculated for Part A only under section 1818(d) and for Part B only under section 1839(a), but instead Congress tied the benchmark to the existing statutory language in

section 1876(a)(4) which encompasses amounts attributable to those beneficiaries enrolled in both Parts A and B or Part B only. The analysis offered additional statutory examples defining the scope of the MA program encompassing both Parts A and B, whereby the commenter interpreted that we would be permitted to exclude the costs attributable to beneficiaries enrolled only in Part A when calculating MA benchmarks.

Commenters requested that we apply a uniform approach in all counties to calculate benchmarks using FFS per capita projections based only on original [FFS] Medicare costs for 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, and suggested that we could introduce an interim adjustment targeting the most affected counties before implementing this policy change nationwide. Several commenters expressed support that the benchmarks in Puerto Rico be based on the Medicare costs for beneficiaries with both Part A and Part B coverage.

Response: We appreciate the feedback submitted by commenters regarding this issue. 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 only on the Medicare costs for beneficiaries who are enrolled in both Part A and Part B. With regard to the legal argument that CMS must develop the estimates of the USPCC using only data from beneficiaries who are enrolled in both Parts A and B of Medicare, we disagree with the commenter's interpretation of the statute and of the limits of our authority and discretion under the statute. We will continue to analyze this issue and consider whether any adjustments to the methodology on this point may be warranted in future years for areas outside of Puerto Rico.

Comment: One commenter proposed that we should promote stability of payments and benefits and not rebase every year, and furthermore proposed that we then could use a 6-year rolling average (instead of 5-year) after the year in which we do not rebase. Another 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: As discussed in past Rate Announcements, 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 have stated in previous Rate Announcements that we anticipate rebasing each year, and that the method for calculating the county level rates includes a five-year rolling average of historical claims experience which provides some measure of stability in the rates. In addition, we note that section 1853(n)(2)(E) specifies the calculation of the base amount to use in place of the FFS per capita estimate if it is not a rebasing year.

Comment: One commenter noted the Advance Notice stated that "the average of the five year geographic indices, based on the adjusted claims data, will be divided by the county's average five-year risk score from the 2019 risk model in order to develop the AGA for that county". The commenter pointed out that this language appeared to indicate that benchmarks would be standardized using only the new 2019 risk model proposed in the Advance Notice, and would be inconsistent with the Advance Notice proposal to phase in this new 2019 risk model.

Response: We clarify that the benchmarks will be standardized with the risk model being used for 2019 payment, including any blending/phase-in of the risk adjustment models.

Comment: We received several comments requesting more transparency regarding the calculation of the FFS rates, in order for stakeholders to provide comment on proposed changes. Two commenters expressed appreciation for the publication of 2016 FFS costs with the Advance Notice, and furthermore requested 2016 risk score information on the same basis. One commenter requested that we publish estimated AGAs and other adjustment factors in December, while another commenter requested that we publish an initial estimate of the county rates with the Advance Notice. One commenter requested information pertaining to the magnitude of adjustments for ACO shared savings and losses.

Response: With the Advance Notice, we published the most recent year's (2016) FFS cost data by county, as well as the proposed VA/DoD adjustment factors by county. With the final Rate Announcement, we are publishing files that contain the wage indices in each claim year (i.e., 2012-2016), the wage indices for 2018 by county, and the county-level adjustments that are applied to the FFS costs. We will consider publishing additional information in future years that can help interested parties understand the potential impacts of proposed changes in the Advance Notice.

Comment: One commenter requested information regarding how provider bonus payments under Alternative Payment Models (APM) and payments from the Merit-based Incentive Payment System (MIPS) would impact benchmarks.

Response: Any APM bonus payments and MIPS payments made to providers will be reflected in CMS's FFS claims experience. Thus, the payments will be represented in the FFS claims tabulations supporting the development of the ratebook average geographic adjustment (AGA) index and the corresponding FFS rate. Further, the aggregate impact of APM and MIPS payments are reflected in the FFS and total USPCCs.

Comment: One commenter expressed support for the proposed AGA methodology, including the rebasing, repricing, and VA/DoD adjustments.

Response: We appreciate the support.

Comment: In the Advance Notice, we sought public comment on the possibility of adjusting FFS experience in Puerto Rico to reflect the propensity of zero dollar beneficiaries nationwide. A large number of commenters requested that we make an adjustment to the Puerto Rico MA rates to reflect the prevalence of zero dollar beneficiaries nationwide.

Response: The Secretary has directed the Office of the Actuary to adjust the FFS 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 2012 through 2016 and only considered FFS beneficiaries enrolled mid-year. On average, 14.5 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 4.5 percent for 2012 through 2016. Accordingly, a 4.5 percent adjustment was applied to the pre-standardized Puerto Rico FFS rates supporting the CY 2019 ratebook development.

Comment: A large number of commenters expressed concern regarding socio-economic conditions in Puerto Rico, including beneficiary migration to the mainland and hurricane recovery efforts. Commenters noted the low FFS expenditure data in Puerto Rico despite a high cost of living, and expressed concern regarding payment disparity between Puerto Rico and the mainland. Commenters requested that we adjust the MA rates in Puerto Rico for any data anomalies, deficiencies, and/or fluctuations, particularly in light of the recent natural disaster.

Commenters provided suggestions for additional rate adjustments that we should consider for Puerto Rico such as establishing an AGA floor, using a proxy benchmark, and/or applying a hold harmless minimum benchmark. Commenters expressed concern that the FFS data we use to set the MA rates for Puerto Rico are not representative of the population to which rates are applied, given the level of MA penetration and the proportions of dual-eligible beneficiaries. A couple of commenters suggested that the Part B premium buy-down should be a basic benefit (like the Part A and Part B services and items) for full benefit duals in Puerto Rico.

A few commenters expressed concern regarding the migration of providers out of Puerto Rico resulting in provider shortages. One commenter indicated that the provider community in Puerto Rico has shouldered the significant funding reductions as a result of largely unilateral fee determinations imposed by local MA plans. Another commenter urged us to ensure that any rate

increases are passed on to providers in Puerto Rico, and not retained by MA plans for margins and/or Part B premium buy-downs.

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

Section D. IME Phase Out

Comment: In the Advance Notice, we indicated that we will continue to phase out IME amounts from MA capitation rates, and noted that PACE plans are excluded from the phase-out. One commenter advocated for common statutory and regulatory framework, including financing, for all integrated plans (SNP, MMP, PACE, etc.), instead of maintaining exclusions and separate structures that may unfairly advantage some integrated plans over others and reduce competition.

Response: As indicated in the Advance Notice, PACE programs are excluded from the IME phase-out pursuant to section 1894(d)(3) of the Act.

Section E. ESRD Rates

Comment: A couple of commenters expressed support for the proposed use of five years of historical claims data with repricing adjustments for setting ESRD rates. Several commenters expressed concern that the ESRD benchmarks are not representative of the costs for ESRD beneficiaries in MA, resulting in underpayment. Commenters requested that we begin studying methodologies to improve the accuracy of the ESRD benchmarks, given the expectation for increased ESRD enrollment in MA beginning in contract year 2021 as a result of the 21st Century Cures Act. Commenters also suggested that we publish information regarding the ESRD rates, such as a comparison with dialysis provider payments in the commercial and MA markets.

Commenters provided suggestions for additional refinement of the ESRD benchmarks, such as application of quality bonuses and calculation of county-level ESRD rates. One commenter expressed concern regarding the large differential between the ESRD dialysis rate and the post-transplant rate, such that MA plans may be incentivized to maintain ESRD enrollees on dialysis (rather than arranging for transplantation). The commenter suggested that the ESRD dialysis rate could be subdivided between ESRD-eligible and Aged/Disabled-eligible beneficiaries, or by age decile, or by the Estimated Post Transplant Survival (EPTS) scores, such that MA plans would not be incentivized to "cherry pick" younger and healthier ESRD-eligible beneficiaries and retain them on dialysis.

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. Note that the risk adjustment model is used to adjust the applicable state rate in payment, and takes into account each beneficiary's age and clinical profile.

Comment: One commenter noted that, under the 21st Century Cures Act, organ acquisition costs are to be excluded from the MA rate methodology and paid under FFS Medicare in 2021. The commenter requested that organ acquisition costs be treated as a pass through cost in 2019 and 2020, years preceding implementation of the 21st Century Cures Act organ acquisition cost pass-through methodology.

Response: Section 17006(b) of the 21st Century Cures Act 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 2019, we will continue to include kidney acquisition costs in MA capitation rates and benchmarks.

Comment: In the Advance Notice, we proposed to reprice ESRD historical claims, similar to the non-ESRD rate methodology. Regarding the repricing of the ESRD Prospective Payment System (PPS) dialysis claims for the years 2014 – 2016, commenters noted that certain drugs will be included in the ESRD PPS bundled payment and no longer payable under Part D when used for renal dialysis services. Commenters noted that calcimimetics are an important tool in the management of ESRD, and are often the largest single drug expense for patients on dialysis. Commenters noted that, with the shift in coverage from Part D to Part B, MA plans will be financially responsible for paying dialysis facilities for calcimimetic drugs under Part C. Several commenters requested that we consider the recent changes to specific classes of drugs from Part D to Part B in development of the payment rates, and requested confirmation that these drug costs have been factored appropriately into the AGAs and rates.

Response: The CY 2019 dialysis-only ESRD USPCC reflects our best estimate of the national per-capita cost, including changes to the ESRD bundled payments. The repricing adjustments to FFS costs, which support the AGAs, reflect changes in the wage index or GPCIs from the experience year to CY 2018 or FY 2018. The county-level repricing adjustments do not reflect updates to the composition of the bundle, such as changes in the covered drugs. The actual cost of the bundle changes will be reflected in the FFS experience and the estimates of the FFS per capita cost.

Comment: Commenters cited recent decreases in the ESRD rates in Puerto Rico, which they indicated results in funding inadequacies and provider access issues for ESRD beneficiaries in Puerto Rico. Commenters indicated that the information used in developing the ESRD benchmark in Puerto Rico may be missing data due to a longer Medicaid coordination period, such that certain claims are being paid by Medicaid rather than FFS Medicare. A couple of commenters expressed concern that the proposed repricing will not be sufficient to address the payment disparity in Puerto Rico. Commenters provided suggestions for additional ESRD rate adjustments that we should consider for Puerto Rico, such as establishing an AGA floor, using a proxy benchmark, and applying a minimum benchmark.

A couple of commenters noted that vulnerable ESRD patients are leaving Puerto Rico to receive life-sustaining care in the states, at a higher cost to the federal government. Commenters expressed concern regarding the migration of providers out of Puerto Rico resulting in provider shortages. A couple of commenters stated that ESRD beneficiaries in Puerto Rico have a more complicated clinical profile than ESRD beneficiaries on the mainland, based on the high incidence of diabetes and other comorbidities.

Response: We appreciate the concerns commenters have raised regarding ESRD rates in Puerto Rico. We will continue to analyze these issues and consider whether any refinements to the methodology may be warranted in future years. We note that the ESRD model – with both its dialysis and post-graft components – take into account these comorbidities.

Section F. MA Employer Group Waiver Plans

As mentioned above, for 2019, CMS will finalize the 100% phase in with adjustments based on the proportion of EGWP enrollment in PPOs vs. HMOs, but CMS intends to seek comment on modifications for 2020 that include additional or different adjustments for regional PPOs and rural local PPOs.

We will therefore, fully transition in 2019 to using only individual market plan bids to calculate the bid-to-benchmark (B2B) ratios, as proposed in the 2019 Advance Notice, used to calculate the 2019 EGWP county payment rates with one modification. The individual market ratios will be adjusted to account for the difference in the proportion of beneficiaries enrolled in HMOs and PPOs between EGWPs and individual market MA plans.

As a result, for 2019, the 2018 individual market B2B ratios have been adjusted to account for the difference in the proportion of beneficiaries enrolled in HMO vs. PPO between EGWPs and individual market MA plans. This adjustment was described in Part II of the Advance Notice as an additional step we were considering for EGWP payments in 2019. Specifically, to determine the weighted individual market B2B ratios, the individual market ratios have been calculated separately by plan type. HMO and HMOPOS plans have been combined into an "HMO plan type" and LPPO and RPPO plans have been combined into a "PPO plan type."[2] Then the plan type individual market B2B ratios by quartile have each been weighted by the total proportion of February 2018 EGWP enrollment in the plan type across all quartiles. The calculations for the B2B ratios are therefore as follows:

[2] "HMO" Health Maintenance Organization, "HMOPOS" Health Maintenance Organization Point of Service, "PPO" Preferred Provider Organization, "LPPO" Local Preferred Provider Organization "RPPO" Regional Preferred Provider Organization. "PFFS" Private Fee-for-Service individual market plans are excluded from these calculations.

First: [(weighted average of the intra-service area rate adjustment (ISAR) adjusted county bid amounts for 2018 individual market plan bids by February 2018 actual enrollment)/(weighted average of the county standardized benchmarks for 2018 individual market plans by February 2018 actual enrollment)] = 2018 individual market B2B ratios by quartile.[3]

Second: The 2018 individual market B2B ratios have been calculated separately for HMO plan types and PPO plan types by quartile. The PPO B2Bs by quartile have been weighted by the total proportion of EGWP PPO plan type enrollment, and the HMO B2Bs by quartile have been weighted by the total proportion of EGWP HMO plan type enrollment to result in the final B2B ratios for 2019 by quartile.

The bid-to-benchmark ratios applied in calculating 2019 MA EGWP Payment Rates are:

Applicable Percentage	Bid to Benchmark Ratio
0.95	86.1%
1	88.7%
1.075	88.5%
1.15	88.5%

The remaining steps in the payment methodology for 2019, as well as the applicable rules, are unchanged from what was described in the 2019 Advance Notice, and are being finalized as proposed.

Comment: Several commenters expressed support for CMS continuing to waive Part C bidding requirements for all organizations that offer 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 few commenters expressed support for CMS continuing to waive the requirement for EGWPs to allocate rebate dollars to any specific purpose for 2019.

Response: We appreciate the support.

[3] Territories have not been included in the weighted average B2B ratio, but were assigned the weighted average of the quartile within which their counties fall. To determine the CY 2019 applicable percentages, CMS ranked counties from highest to lowest based upon their 2018 average per capita FFS costs and placed the rates into four quartiles. When calculating the 2018 B2B ratios, CMS grouped counties by the 2018 unblended quartiles and these B2B ratios were then applied to the 2019 unblended quartiles.

Comment: A significantly large portion of commenters recommended that we implement an HMO/PPO adjustment to the bid-to-benchmark ratios to account for the differential in enrollment between plan types in the EGWP and Individual market plans. Several of these commenters suggested that no matter what is otherwise finalized in the development of this policy (i.e., continuing to blend the 2016 EGWP/individual market bids either 50/50, or 25/75, or moving forward with using 100% individual market bids), an adjustment to account for this plan type differential is necessary. Commenters suggested that incorporating this refinement 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 few commenters also suggested that paying EGWPs without making such an adjustment would result in payments that are not aligned with the very different cost structures of the two plan types and would result in over payments to HMO EGWPs and underpayments to PPO EGWPs, thereby creating inequities among plans, which would have a particularly noticeable negative impact on rural markets, which are primarily served by EGWP PPOs. A few additional commenters noted that their review of public data files suggests that the concerns we articulated in previous years regarding year-over-year instability in MA EGWP payment rates based on plan type weighting would appear to be unwarranted.

Response: We support an MA program that includes robust participation of Part C EGWPs that are accurately reimbursed for their services. We agree that PPOs are currently more prevalent in the EGWP market than in the individual market, as well as the fact that in the individual market PPO bids tend to be higher, in general, than individual market HMO bids due, in part, to the differing costs associated with these different benefit offerings. To address the concerns raised by commenters on the proposal detailed in the Advance Notice, for 2019, we have been persuaded to modify the methodology used to calculate the bid-to-benchmark ratios from the methodology proposed. For 2019, we will incorporate weighting by plan type to take into account the differential in plan types that exist in the differing markets. This adjustment was described in Part II of the Advance Notice as an additional step we were considering for EGWP payments in 2019. We recognize that in the 2017 and 2018 Rate Announcements, we expressed some concern about basing MA EGWP payment rates on the small number of PPO plans in the individual MA market. However, we have reconsidered this position for 2019 and believe that the methodology we are finalizing to account for the plan type differential (i.e., taking plan type weighing into account, while continuing to have a single combined bid-to-benchmark ratio within the formula) is an appropriate adjustment for 2019. We are concerned that if we were to not incorporate an adjustment to account for this differential between the markets it could lead to the unintended consequence of underpaying EGWP PPOs for their actual costs, which could result in fewer of these offerings in future years. We believe that incorporating this refinement to the payment methodology will facilitate the offering of Medicare benefits by employers and unions through MA EGWPs for 2019. We appreciate the detailed nature of the comments received on these issues and will continue to analyze data to refine the payment methodology for future years as needed.

Comment: A few commenters opposed continuing to waive Part C bidding requirements for sponsors of Part C EGWPs, asserting that we should reinstate the annual bidding process that existed prior to 2017. A couple of commenters asserted that bidding best reflects the experience of the employer group population, such as geographic service patterns and historical claims experience, and returning to the pre-2017 policy would stabilize the employer group market over time. Another commenter recommended that we could subject EGWP bids to additional scrutiny and could review historical data and medical loss ratio (MLR) submissions to increase transparency and plan accountability in the bidding process for these offerings and could implement penalties for plans found to be misrepresenting information in their bid submissions.

Response: While we appreciate the concerns raised, we continue 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 detailed previously, the alternative to the composite bids submitted prior to 2017 would require significantly more information to be collected, submitted, and reviewed by CMS. Moreover it would require reverting 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. In the course of our considerations, 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. If we were to implement this policy instead, MAOs 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. Moreover, MLR data is presently collected at the contract level which is often a composite of individual market plans and EGWP plans. If we were to incorporate the commenter's suggestion of using MLR data to review EGWP bid submissions, the MLR submissions from these entities would also need to be collected at the plan level, and we would need to develop a new process to "penalize" plans that misrepresent their bid submissions, each of which would result in increased burden for MLR reporting on the Government, employers, and MAOs.

We continue to believe that the policy being finalized for 2019 has the correct balance of facilitating the offering of these valuable products by reducing significant burden and increasing payment accuracy for these offerings, particularly in light of the incorporation of the new methodology for 2019 to take into account the differences in plan type in the EGWP and individual MA markets.

Comment: Several comments from beneficiaries enrolled in EGWP plans offered by their previous employers expressed concern about the stability and viability of EGWPs. These commenters also expressed significant support for and satisfaction with the coverage and benefits they presently experience in their Medicare Advantage plans such as prescription drug,

vision, hearing, dental coverage, wellness, fitness and chronic disease management programs, none of which are included in Medicare Parts A and B. These commenters asked us to consider the beneficiaries enrolled in these plans when setting payment policy so that their coverage will not experience disruptions, such as fewer benefits, increased cost sharing, co-pays and/or premiums, or losing access to doctors.

Response: We appreciate these commenters' concerns. We believe that incorporating the refinements to the payment methodology as described in this Rate Announcement will allay some of the concerns raised. While each plan and beneficiary experience will be distinct, we believe we have implemented the waiver and payment methodology in a manner that protects the Medicare Trust Funds, while also facilitating the offering of these valuable products by providing adequate funding to maintain benefits.

Comment: A significant number of commenters recommended that we maintain the bid-to-benchmark ratios used in payment year 2017 and 2018 that are weighted 50% MA EGWP bids from 2016 and 50% Individual market bids from 2016, and were opposed to our using only individual market plan bids from 2018 to calculate the bid-to-benchmark ratios in calculating the 2019 MA EGWP payment rates. Several commenters cited that maintaining the ratios used in payment year 2017 and 2018 as calculated would create a greater level of stability and certainty for these plans and would strengthen the industry by reducing the frequency and degree of policy and rate changes. A few commenters expressed concern that full implementation would force employers to materially reduce benefits or increase retiree premiums for 2019 and future years, with others cautioned that industry experience has shown reductions in payment being passed along to beneficiaries already in the form of rising premiums, lowering coverage, interfering with patient-provider relationships, and moving beneficiaries to Medicare Supplement coverage or dropping coverage altogether. Another commenter suggested that the blended benchmarks implemented for 2017 and 2018 achieved the goals identified by CMS by eliminating bidding and increasing payment parity between the EGWP and individual markets, and that moving to using only individual market bids does not materially advance any of CMS's original goals in altering the payment system.

Response: We appreciate the concerns raised by these commenters but believe that continuing to pay MA EGWPs based on 2016 bids for 2019 benefit offerings is not in keeping with the goal of increased payment accuracy. Moreover, we continue to believe that employers are in a better position to negotiate under this payment methodology due to the standardized and transparent payment amounts across competing plans. We do, however, recognize that, to the extent that payments are reduced, the result could be higher premiums for current levels of supplemental coverage or that employers could choose to reduce the supplemental coverage provided to employees under these plans. We also believe, however, that instead of reducing benefits for beneficiaries under this policy, MAOs could become more efficient and competitive in this market by competing on access, quality, customer service and the price of employer wrap-around benefits. Bearing this in mind, we continue to believe we have implemented the waiver and

payment methodology in a manner that will achieve the goal of protecting the Medicare Trust Funds, while alleviating administrative burden that facilitates the offering of these products, and maintaining benefit structures.

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 in previous years, 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. There is currently no mechanism available 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, we do not presently have a feasible solution to address this concern. As we have noted in the past, however, 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 we have continued to waive 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. Notwithstanding the foregoing, we are continuing to explore administrative operational mechanisms that could be developed in order to address this issue and are hopeful that a solution will be able to be implemented in the future.

Comment: A few commenters recommended that we consider releasing preliminary bid to benchmark ratios in an early preview or the Advance Notice rather than waiting until the April release of the Final Rate Announcement. 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 us to share more data with plans to allow the development of appropriate strategies that will minimize potential member disruption.

Response: As described in the Advance Notice, in order to have the most accurate data incorporated into the payment methodology the bid-to-benchmark ratios used for 2019 payment have been calculated using February 2018 enrollment, which was not available at the time the

Advance Notice was published. However, we appreciate these commenters concerns and will consider whether publishing additional preliminary information in future years would be helpful to have a more robust understanding of any proposed changes to this policy. In addition, for comparison purposes, below are the bid-to-benchmark ratios that would have been applied in 2019 had we finalized a policy to calculate the bid to benchmark ratios using 100% individual market plan bids from 2018 without making an adjustment for the differential in plan type offerings of HMO vs. PPO products in these markets:

Applicable Percentage	Bid to Benchmark Ratio
0.95	81.5%
1	85.1%
1.075	86.2%
1.15	87.3%

Comment: A few commenters recommended that we slow the transition of the proposed policy of using only 100% individual market bids to calculate the bid-to-benchmark ratios for 2019 by using 25% of the 2016 EGWP bids and 75% of the 2016 individual market bids to calculate the bid-to-benchmark ratios instead of either freezing the ratios at the 2017 and 2018 50/50 levels or finalizing the proposal. These commenters stated their belief that a more gradual phase-in would be consistent with CMS precedent in other programs, where it has incrementally made material changes over time to maintain stability. One commenter suggested a slower transition would continue to promote fiscally responsible MA payment policy while mitigating some of the potential for abrupt changes in retiree supplemental benefits and/or increased out of pocket costs. Another commenter suggested that implementing a longer transition period will permit EGWP plans to meet current contract requirements.

Response: As noted above, we continue to believe that we are implementing the waiver and revised payment methodology in a fair manner in order to achieve the goal of protecting the Medicare Trust Funds, alleviating administrative burden, and maintaining benefit structures. We are also refining the methodology for 2019 as described herein to account for the different proportion of HMO vs. PPO plan types in the differing markets. Moreover, the policy of using only individual market bids to pay EGWPs is being finalized two years after it was initially proposed for implementation, which has provided stakeholders a three year transition. We believe that this is consistent with other transitions we have implemented in the MA program.

Comment: A few commenters recommended modifications to the formulas used to calculate the bid-to-benchmark ratios. Some recommended that an HMO/PPO adjustment be made, but suggested that there should be separate ratios used for each plan type instead of weighting them to result in a single ratio per quartile, resulting in separate payment rates for HMO EGWPS and PPO EGWPs. One commenter recommended that D-SNPs be excluded from the calculation. One commenter recommended that before we implement any new methodology for 2019, we should study geographic differences, mortality rates, out of network utilization, allowed cost

differences and actual costs and risk score differentials between EGWP and Individual market plan members to determine if that is driving cost differentials in these markets, and take these findings into account in the payment methodology for a future year. One 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, and also suggested that retrospective annual reporting by organizations of EGWP experience may be beneficial to future policy development.

Response: We appreciate these commenters' detailed suggestions about other adjustments that could be analyzed to incorporate as refinements to the methodology being finalized for 2019 to the calculation of the bid-to-benchmark ratios. We are refining the methodology for 2019 as described above, to account for the different proportion of HMO vs. PPO plan types in the differing markets. We thank these commenters for their considered thoughts on this issue, and will continue to analyze and explore these commenters' suggestions, as well as other options for incorporating refinements to this payment methodology in the future.

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 2018 and urged us to not delay its implementation. These commenters cited to the government savings and greater payment equity between MA EGWP and MA non-EGWP plans from this policy, and reiterated concerns regarding MedPAC's finding that MA payments to EGWPs were previously substantially higher than fee-for-service costs, despite the provisions that have aligned overall Medicare Advantage payments with fee-for-service costs. These commenters also cited MedPAC and CMS assertions that while non-employer plans are under pressure to submit bids low enough to attract enrollment, EGWP bids are not submitted to attract enrollment, instead EGWP enrollment is negotiated with employers, and the benefit packages and premiums that the plans offer to the employers are not necessarily reflected in the bids. Another commenter stated that EGWPs tend to have healthier, lower-cost enrollees than other MA plans and face lower administrative costs related to enrollment and marketing. One commenter cited that lower Medicare payments do not seem to have harmed EGWPs' ability to attract enrollment given that enrollment in EGWPs has continued to grow.

Response: We appreciate the support for fully implementing the policy of using individual market plan bids from 2018, but believe that it is appropriate to finalize a methodology for 2019 as described above increases the accuracy of the payments to EGWPs, as PPOs have higher costs. We believe that this methodology will provide sufficient payment rates for EGWPs in 2019, which will further facilitate continued offering of these plans. We will monitor the effects of this policy and reevaluate it on an annual basis to refine the payment methodology for future years.

Section G. Medicare Advantage Coding Pattern Adjustment

Comment: The majority of commenters were pleased that we proposed not going above the statutory minimum and supported our application of the proposed 5.90% for the 2019 coding intensity adjustment.

Response: We appreciate the support of the commenters. We are finalizing the proposed adjustment of 5.90% for 2019.

Comment: We received a large number of comments expressing concerns regarding the alternative methodologies that we identified as informing our final decision-making process on whether to adopt a different coding pattern adjustment for 2019. Many commenters indicated that stakeholders need additional details and time to fully analyze the methods. Some commenters indicated that in regards to each of the three alternative methodologies, they do not believe we have met the standards for the Advance Notice as set forth in the Social Security Act to propose "changes to be made in the methodology from the methodology and assumptions used in the previous announcement," and should provide "an explanation of the assumptions and changes in methodology used in such announcement."

Some commenters indicated that the underlying data for the identified alternative methodologies may be outdated. Another commenter suggested that we consider how enrollment in MA plans, SNPs, MMPs, state initiatives for integrated care, and our passive enrollment policies may impact such adjustments, and whether $0 premiums for dual eligible beneficiaries may affect MA and FFS member comparisons. One commenter urged us not to calculate a new coding intensity adjuster until there are more years of data, and the FFS risk score trend and the FFS/MA coding differences, along with the impact of encounter data on risk scores, are better understood.

A few commenters felt that the alternative approach discussed in the 2016 Advance Notice would cap MA plan payments based on demographic factors (age, sex, Medicaid, and institutional status), which could result in underpayments to MA plans; the effect of only using demographic factors would be inconsistent with the requirements under the Social Security Act that risk adjustment account for enrollees' health status. One commenter recommended that we study the evidential root causes leading to improved health outcomes among MA enrollees before implementing a new coding adjustment factor that increases reliance on demographic indicators, while other commenters believed that the findings that "the health status of MA enrollees is no worse, and more likely is better, than the health status of FFS beneficiaries of similar age, sex, Medicaid, and institutional status," as evidenced in part by MA enrollees' lower mortality rates and lower utilization of high cost drugs than their FFS counterparts, is potentially flawed.

A few commenters indicated that it is unclear whether our reference to the 2017 MedPAC methodology was intended to incorporate all components of MedPAC's methodology.

MedPAC's recommendation from the March 2017 report to address coding pattern differences between MA and FFS had three parts: (1) develop a risk adjustment model that uses two years of FFS and MA diagnostic data, (2) exclude diagnoses that are only documented on health risk assessments from either FFS or MA, and then (3) apply a coding adjustment that fully and equitably accounts for the remaining differences in coding between FFS Medicare and MA plans.

While some commenters supported the implementation of a risk adjustment model that uses two years of data to predict costs, others noted that we had not proposed to implement a model using two years of data. One commenter indicated that a two-year model has the potential to be less predictable because the diagnosis data collection period is further from the payment period.

A few commenters urged that we continue to carefully monitor plans' use of in-home health risk assessments to ensure that these assessments show services for MA enrollees that are meaningful and effective for beneficiaries' clinical condition(s). One commenter disagreed with MedPAC's proposal to exclude diagnoses from HRAs, noting that MedPAC does not define HRAs, and for this reason, it is impossible to know how such a program would be implemented, while another commenter noted that we should ensure that none of the procedure codes on the claim indicate a medically necessary service equivalent to an evaluation and management office visit. One commenter indicated that requiring a subsequent encounter to confirm a diagnosis presupposes that such a diagnosis would otherwise be equated to payment error, which they stated requires a comparison to unsupported diagnoses in the FFS data that underlies the risk adjustment model.

One commenter noted that MedPAC's recommendation for adjusting for coding differences between MA and FFS is unclear.

Response: We thank commenters for their insights, and will take these comments into consideration as we consider options for the MA coding pattern adjustment in the future.

Comment: Several commenters stated that before changing the methodology for determining the MA coding adjustment factor, we should develop and implement a robust, transparent process – including meaningful stakeholder engagement – to evaluate both the methodology for making this calculation, as well as interpreting the appropriateness and implications of any results using the most current, relevant information should any future changes be considered.

Response: We thank the commenters for their suggestions.

Comment: A few commenters recommended that we implement a higher coding adjustment, indicating that the statutory minimum coding adjustment is insufficient to fully offset current coding intensity trends. A couple of commenters expressed concern about the methodology set forth in the 2010 Advance Notice and Rate Announcement, including the need to update the underlying data and assess more recent trends in the data. One commenter believes that the statutory minimum is too high, and noted that the American Taxpayers Relief Act of 2012 (P.L.

112–240, § 639 (2)) increased the minimum statutory coding pattern adjustment factor from 5.7 percent (as established in the Affordable Care Act (ACA)) to 5.9 percent. This commenter believes that the ACA-established minimum amount of 5.7 percent was more accurate because it relied on more current data. The commenter acknowledges that lowering the minimum coding pattern adjustment below the statutory minimum would require Congressional action, and believes that we should keep the adjustment level as low as possible for 2019, especially because a lower amount is more consistent with newer data.

Some commenters do not support an across the board adjustor, finding that coding patterns vary significantly across MA contracts, so that some contracts are unduly penalized by the statutory across-the-board adjustment, while others retain a significant amount of coding-related payment even after the adjustment; some commenters indicated that the across-the-board adjustment disproportionately penalizes physician organizations and plans that are properly coding to better manage population health.

Response: We continually develop our understanding of coding trends and make an assessment for each payment year regarding the appropriate adjustment based on specific considerations of both coding trends and other market changes. We believe that an industry-wide adjustment provides an even playing field when plans compete: newer contracts may be able to code just as intensely as older plans, but would not have been in existence long enough for us to calculate an adjustment factor for them. Per statute, the adjustment factor for 2019 and each subsequent year, should not be less than 5.9 percent. We believe that the optimal way to apply the adjustment is to do so uniformly and industry wide using the statutory minimum adjustment level for 2019.

Comment: One commenter disagreed with assertions of "upcoding" in MA. The commenter noted that because Risk Adjustment Data Validation audits prevent widespread fraudulent coding practices and CMS encourages plans to send in deletions retrospectively, coding intensity has likely declined over the last few years for many plans. The commenter thus asserted that risk adjustment payment to MA plans has been inaccurately reduced through the coding intensity factor.

Response: We are required by statute to apply an MA coding adjustment factor to the risk scores using a factor of at least 5.9 percent for 2019 to address the impact on risk scores of differences in MA and FFS coding patterns. As we have noted in previous Advance Notices and Rate Announcements, the statutorily-required MA coding pattern adjustment factor does not assume that MA coding is inaccurate in calculating the MA coding pattern adjustment factor. We understand that MA plans have made efforts to identify enrollees' conditions and may be coding more completely than FFS. These efforts may even be unrelated in many respects to increasing risk adjustment payments as MA plans have responsibilities to coordinate and manage care; plans may be identifying enrollees for the appropriate interventions related to care coordination and management. However, because MA coding patterns differ from FFS coding patterns, on which the risk adjustment model is based, the normalization factor (which is calculated based on

FFS coding) does not adjust for these different coding patterns. RADV audits, on the other hand, have the purpose of validating whether diagnosis codes submitted for risk adjustment are documented in the medical record and, therefore, are correctly reported for the beneficiary in question. In other words, these audits only address coding accuracy and do not address coding pattern differences between MA and FFS.

Section H. CMS-HCC Risk Adjustment Model for CY 2019

Comment: A large number of commenters strongly supported including the proposed additional conditions for Chronic Kidney Disease, mental health, and substance use disorder in the CMS-HCC model. Commenters agreed with our conclusion that the additional HCCs included in the model are clinically meaningful and will predict significant cost. Several commenters stated that including additional Chronic Kidney Disease, mental health, and substance use disorder HCCs will improve prediction for beneficiaries with those conditions and allow plans to better serve their members. Two commenters each recommended that one of the HCCs not be added.

Response: We appreciate the support for including the proposed Chronic Kidney Disease, mental health, and substance use disorder conditions.

Comment: A large number of commenters supported implementation of the "Payment Condition Count" model. However, many commenters also requested that CMS delay the implementation of the 21st Century Cures Act requirement to "take into account the total number of diseases or conditions of an individual enrolled in an MA plan." These commenters requested additional time to evaluate the impact of the proposed changes, to validate the results, and to provide additional feedback to us.

A few commenters stated that we are not required by the new statutory provision to add variables that count conditions to the model because the risk adjustment model already adds coefficients from individual conditions. One commenter recommended implementing the "All Condition Count" model. A number of commenters stated that the "All Condition Count" model would be disruptive due to the wide variability in the change in risk scores that it would produce. Many commenters agreed with our interpretation of the Act's requirement to "phase-in any changes to risk adjustment over a 3-year period, beginning with 2019, with such changes being fully implemented for 2022 and subsequent years" to mean that we could use the 2019 Advance Notice process to seek comment on risk adjustment changes that met the criteria established in the Act, and implement the required changes beginning in 2020. One commenter explicitly stated an interpretation that phasing in the new risk model by implementing the new proposed HCCs beginning in 2019 and phasing in a new condition count variable beginning in 2020, both with full implementation by 2022, is consistent with the statute.

Response: We understand that the proposed "Payment Condition Count" risk adjustment model has additional complexity, and that more time may be needed to fully assess the impact of the count variables. However, we note that many commenters strongly supported including the

proposed Chronic Kidney disease, mental health, and substance use disorder conditions. We only received two comments opposing the addition of some of the conditions (two commenters each opposed the inclusion of one of the proposed additional HCCs). Commenters noted that adding these HCCs to the risk adjustment model would improve the predictive accuracy of the model for beneficiaries with these conditions, and would strengthen plan sponsors' efforts to treat beneficiaries with Chronic Kidney Disease, mental health, and substance use disorders. Some of the same commenters that supported including the proposed Chronic Kidney Disease, mental health, and substance use disorder conditions also wanted more time to assess the proposed count variables. We agree with those commenters. As described in more detail in the Advance Notice Part I, the proposed mental health, substance use disorder, and Chronic Kidney disease conditions met the criteria we developed for including additional conditions in the risk adjustment model, and will improve the accuracy of payments under this new model.

Therefore, for payment year 2019, we will implement the updated CMS-HCC model without count variables that was provided in Part I of the Advance Notice for comparison. This model incorporates the proposed additional Chronic Kidney Disease, mental health, and substance use disorder conditions, updates the data years used to calibrate the model from 2013 diagnoses predicting 2014 cost to 2014 diagnoses predicting 2015 cost, and selects 2014 diagnoses for calibration with the CPT/HCPCS-based methodology that is used to select risk adjustment eligible diagnoses submitted to the encounter data system. While we do not think we are required to implement a new risk adjustment model in 2019, we believe that implementing the updated CMS-HCC model without count variables is beneficial for payment in 2019 for several reasons. First, implementing a model in 2019 with additional Chronic Kidney Disease, mental health, and substance use disorder HCCs will improve the accuracy of the CMS-HCC model for beneficiaries with these conditions. Second, updating the data years used to calibrate the model will better reflect the relative cost of conditions in the model in the payment year. Finally, since we are finalizing the encounter data blend as proposed, and will calculate the updated CMS-HCC model risk scores with diagnoses selected from encounter data records, using a model that is calibrated with diagnoses selected in the same manner will improve the accuracy of the encounter data risk scores.

Specifically, for payment year 2019, we will calculate risk scores as proposed, but with the updated CMS-HCC model without count variables. We are finalizing the model blend and underlying data used to calculate the risk scores as proposed: we will blend 75% of the risk score calculated with the 2017 CMS-HCC model and diagnoses submitted on RAPS records and FFS claims with 25% of the risk score calculated with the updated CMS-HCC model without count variables and diagnoses submitted on encounter data records, RAPS inpatient records, and FFS claims.

Given that most commenters supported the additional HCCs that we proposed to add to the model, and the other policies finalized for PY2019, we believe that most commenters would support implementing the updated CMS-HCC model without count variables in PY2019. These

changes to the risk adjustment model will improve the model, while introducing less complexity than implementing all of the proposed changes at once, and will provide additional time to review the model that incorporates the payment condition count variables.

We appreciate comments suggesting that we do not need to include a count of conditions in the model. However, we interpret the Act's requirement to take into account the total number of conditions as requiring a change to the current risk adjustment model's structure. We believe that Congress is aware of the additive nature of the current model and thus intended the direction to "make an additional adjustment [under section 1853(a)(1)(C)] as the number of diseases or conditions of an individual increases" to mean that they wanted us to add variables to the Part C CMS-HCC model that take into account the number of conditions a beneficiary may have. We believe the most efficient way to meet this requirement is through the inclusion of additional variables in the CMS-HCC model that count the number of conditions a beneficiary has. We plan to implement the proposed "Payment Condition Count" model in 2020.

We believe our final decision– to implement the updated CMS-HCC model without count variables for CY 2019 payment and to begin the phase-in of the proposed "Payment Condition Count" model in 2020 (with complete implementation for payments in CY2022) – is consistent with our authority under section 1853 as amended.

Comment: Many commenters requested further information related to how we determined the structure of count variables in both the "Payment Condition Count" model that we proposed, and the analytic models that were developed for our research. Several commenters expressed concern that the proposed "Payment Condition Count" model would decrease risk scores for full dual eligible beneficiaries with multiple chronic conditions. Some commenters requested that we further explain why we believe the count variables in the "Payment Condition Count" model is the model specification that best meets the 21st Century Cures Act's requirements.

Response: We appreciate the comments. We will consider ways that we can work with stakeholders to share additional information related to the "Payment Condition Count" model at a later date in light of our decision to delay implementation of the count variables in the updated CMS-HCC model until CY2020. We note that on average the predictive accuracy of the "Payment Condition Count" model is better than or similar to the updated CMS-HCC model without count variables for the full dual eligible population. It either keeps the predictive ratios about the same, or moves them closer to 1.0. Table III-1illustrates the differences in predictive ratios by deciles of risk for full dual eligible individuals. As we stated in Part I of the Advance Notice, the goal of the CMS-HCC model is to predict accurately across large subgroups of the population, and that historically we have interpreted an improvement in the risk adjustment model to mean an improvement in the predictive ratio by the decile of predicted risk. The "Payment Condition Count" model also improves prediction across all beneficiaries, – that is, on average beneficiaries' predicted cost is closer to their actual cost – when grouped by deciles of predicted risk relative to the updated CMS-HCC model without count variables.

Table III-1

	Full Dual Aged		Full Dual Disabled	
Decile	**Updated CMS-HCC model without count variables**	**Payment Condition Count Model**	**Updated CMS-HCC model without count variables**	**Payment Condition Count Model**
First (lowest)	0.945	0.958	0.973	1.083
Second	0.992	1.011	0.901	1.021
Third	0.984	0.994	0.863	0.892
Fourth	0.982	1.001	0.920	0.948
Fifth	1.000	0.999	0.967	0.982
Sixth	1.001	0.999	0.999	0.997
Seventh	1.007	1.005	1.031	1.018
Eighth	1.015	1.006	1.045	1.022
Ninth	1.011	1.000	1.043	1.010
Tenth (highest)	0.998	1.001	1.001	1.001
Top 5%	0.995	1.004	0.982	0.995
Top 1%	0.966	0.981	0.965	0.985

When considering alternative specifications to the models that counted payment conditions, we found that the predictive accuracy improved on average across risk deciles, and that the predictive accuracy was not significantly affected by how we counted the payment conditions. That is, there was little difference between a model with a variable for 5+ payment conditions and a model with variables for groups of payment condition counts, 1 – 3, 4 – 5, 6+ etc. Rather, in the analytic models that we reviewed, it was the set of HCCs included in the count that most improved the accuracy of the model by count of condition.

Comment: Several commenters also suggested that the model should have been calibrated with ICD-10 diagnoses to align predicted relative cost with more current data, or to use two years of diagnosis data in the calibration to improve the accuracy of the diagnostic information used in risk adjustment, and reduce the year-to-year variation in documenting chronic conditions.

Response: We recognize that using ICD-10 diagnoses or two years of diagnosis data to calibrate the model may result in differences in predicted risk. While we did not propose to implement a model based on ICD-10 diagnoses or two years of diagnosis data for payment year 2019, we will consider these changes to the model in future payment years.

Comment: A commenter questioned whether our proposal (to blend 75% of the risk score calculated with the 2017 CMS-HCC model and diagnoses submitted on RAPS records and FFS claims with 25% of the proposed Payment Condition Count model and diagnoses submitted on encounter data records, RAPS inpatient records, and FFS claims) was consistent with previous

CMS model blends. This commenter recommended that we blend a RAPS and encounter data score for each model, before blending the model scores.

Response: We agree that there are multiple differences between the risk scores that will be blended. These differences will include not only the different models, which have differences in predicted risk, but also the data sources from which MAO-reported diagnoses are selected to calculate risk scores. First, as we noted in the Advance Notice, we believe that this approach of blending two risk scores reduces burden on plans, which would otherwise be required to track four risk scores and need to process a variety of reports that would have to be expanded to accommodate the additional risk scores. Second, we believe that blending risk scores produced by the two models in this way meets the requirements of the 21st Century Cures Act to phase in the new model. Third, the updated CMS-HCC model without count variables is calibrated with diagnoses selected in the same manner as diagnoses selected from encounter data records. Because predicted risk is driven by the diagnoses in the calibration, aligning the data source used to estimate the model with a similar diagnosis code selection approach results in equivalent risk scores when blending between the old and new model, assuming complete submissions.

Comment: Many commenters suggested additional conditions or interactions that should be added to the CMS-HCC risk adjustment model, including HCC 51 Dementia with Complications, HCC 52 Dementia without Complications, HCC 61 Depression, HCC 62 Anxiety Disorders, and HIV/AIDS interacted with specific conditions. Several commenters requested that a new condition be created from ICD-10 Z codes to account for social determinants of health in the risk adjustment model.

Response: As noted in Part I of the Advance Notice, HCC 61 met some but not all of the model evaluation criteria, and HCC 62 did not meet the criteria to be included in the model. HCC 62 has low expected costs, and beneficiaries with this condition are currently predicted accurately. We will continue to evaluate whether additional conditions or social determinants of health meet the requirements to be included in the risk adjustment model for future payment years.

Comment: One commenter stated that they were concerned about the choice of the term "drug abuse" instead of "substance use disorder." They noted that, from a medical perspective, "substance use disorder" is the more appropriate term for this condition.

Response: We agree, and carefully used the term "substance use disorder" throughout the Advance Notice. We note that HCC 56 – Drug Abuse, Uncomplicated, Except Cannabis – does use the term "Drug Abuse". This is because the HCC's name reflects the naming convention of some of the underlying diagnoses that are mapped to this HCC. We will change the name of the HCCs for 2019 to be consistent with our presentation in the 2019 Advance Notice. The revised labels for the Substance Use Disorder HCCs and interaction term is included in Table III-2.

Table III-2

HCC/Interaction	Current Label	New Label
HCC 54	Drug/Alcohol Psychosis	Substance Use with Psychotic Complications
HCC 55	Drug/Alcohol Dependence, or Abuse/Use with Complications	Substance Use Disorder, Moderate/Severe, or Substance Use with Complications
HCC 56	Drug Abuse, Uncomplicated, Except Cannabis	Substance Use Disorder, Mild, Except Alcohol and Cannabis
HCC 202	Drug Use, Uncomplicated, Except Cannabis	Drug Use, Uncomplicated, Except Cannabis [same as current label]
HCC 203	Alcohol Abuse and Cannabis Use/Abuse, Uncomplicated, Non-Psychoactive Substance Abuse, and Nicotine Dependence	Alcohol/Cannabis Use or Use Disorder, Mild or Uncomplicated; Non-Psychoactive Substance Abuse; Nicotine Dependence
gSubstanceAbuse_ gPsychiatric_V23	Substance Abuse*Psychiatric	Substance Use Disorder*Psychiatric

Comment: Several commenters noted that the CMS-HCC Risk Adjustment model is applied in other payment models and demonstrations. They stressed the importance of accurate prediction for beneficiaries with specific conditions currently not in the model, and multiple chronic conditions for these payment systems.

Response: We appreciate the comments. The CMS-HCC Risk Adjustment model is developed for use in risk adjusting capitation payments that cover Part A and Part B services for MA organizations and PACE organizations. The primary goal of policies discussed and implemented in the Advance Notice and Rate Announcement is to provide accurate payments in that context and not others.

Comment: Several commenters expressed support for our decision not to implement a new model for PACE organizations in 2019, but requested that we consider updating the model for PACE organizations in 2020.

Response: We appreciate the support. We will evaluate the CMS-HCC model for PACE organizations in the coming year, and propose any needed updates in the 2020 Advance Notice.

Section I. ESRD Risk Adjustment Model for CY 2019

Comment: While many commenters appreciated that we proposed to update the ESRD model and acknowledged the need to recalibrate the model to update the underlying data, they expressed concern that the proposed model, in combination with other updates, such as the ESRD FFS normalization factor, will result in a substantial decrease in risk scores. Furthermore, a few commenters do not support updating the ESRD model at this time. Many commenters

recommended that if the recalibrated ESRD risk adjustment model is implemented, we should gradually phase-in this recalibrated model over three years. One commenter suggested that we consider using the new model only on the Encounter Data System portion of the risk score.

Response: We appreciate the support, and we acknowledge the commenters' concerns. However, continuing the use of the current ("2012") ESRD model in 2019, either on its own or as part of a risk score blend, would produce lower risk scores, on average, due to the normalization factors that would be applied in conjunction with the current model. This relationship holds true for both the dialysis and the post-graft components of the ESRD model. Using the recalibrated model allows us to use lower normalization factors because the denominators are more recent. Table III-3 provides the FFS risk score trend with the 2012 ESRD dialysis and ESRD post-graft models. The ESRD dialysis normalization factor would have been 1.092 and the ESRD post-graft normalization factor would have been 1.159 using the 5 year linear slope methodology finalized for PY2019.

Table III-3: FFS Risk Score Trend

Year	2012 ESRD Dialysis Model	2012 ESRD Post-graft Model
2013	1.027	1.042
2014	1.030	1.048
2015	1.034	1.052
2016	1.048	1.079
2017	1.062	1.101

Since keeping the 2012 ESRD model with the current normalization methodology would put more downward pressure on ESRD risk scores than the combination of the 2019 ESRD model with the current normalization methodology for 2019, we will fully implement the updated ESRD risk adjustment model as proposed in the 2019 Advance Notice. Also as proposed, for the ESRD dialysis and ESRD post-graft risk score calculations, we will blend risk scores by summing 75 percent of the risk score calculated with diagnoses submitted on RAPS records and FFS claims, with 25 percent of the risk score calculated with diagnoses submitted on encounter data records, RAPS inpatient records, and FFS claims.

Comment: Several commenters questioned why risk scores decreased when the average cost had increased since the last update and suggested that the new model's cost structure may result in underpayment relative to the current ESRD cost structure. A few commenters also incorrectly assumed that the proposed 2019 ESRD risk adjustment model should result in risk score neutrality relative to the 2012 model.

Response: When we update the underlying data years in a CMS-HCC model, there are a number of factors that can result in a decrease in risk score between models. These factors include changes in the demographic mix of the population, diagnostic coding patterns, and underlying FFS cost. A risk score is the expected cost of covering a beneficiary relative to the national

average per capita cost. A risk score of 1.0 indicates the beneficiary is predicted to have an annual cost equal to the national average per capita cost. We note that the dialysis and post-graft components of the ESRD model, as with other Part C risk adjustment models, are each set to a 1.0 average risk score in FFS. The average risk score for Medicare Advantage plans can change when models are recalibrated, and can be different from the FFS risk score due to differences in demographics and the clinical profiles of the populations.

Further, we note that while the post-graft model predicts relative costs for the population of beneficiaries who have functioning kidney transplants, this component of the ESRD model is denominated using a non-ESRD population. In other words, the 1.0 is set in the general aged/disabled population, not the post-graft population. Specifically, the denominator for the post-graft model is calculated using the underlying Part C model, calibrated on the non-ESRD population.

There are several outcomes of setting the post-graft risk score to 1.0 in this way. First, the average risk score among the post-graft population is much higher than 1.0, but because it is not anchored at any particular average risk score, this average can change when the post-graft model is recalibrated. Second, this approach of setting the 1.0 FFS risk score aligns the post-graft risk scores with the county ratebook that we use to pay for post-graft beneficiaries enrolled in plans, for which the 1.0 risk score is for the non-ESRD population. We note that, since the last ESRD model calibration, the ESRD post-graft model denominator increased 17 percent. While on average, the predicted cost of the post-graft population has increased, the average predicted cost of the non-ESRD population has increased faster. As a result of this increase in the denominator, the average post-graft risk score, relative to the risk score among the non-ESRD population, has decreased, although it remains much higher than 1.0.

Comment: Some commenters requested that we clarify the impact of the new calibration on plans, while others requested that we share additional information about the ESRD model and trends, including sharing the regression model, our rationale for inclusion of some conditions and not others, and whether or not we recalibrated each component of the ESRD risk adjustment model. The additional information was generally requested to assist MAOs in preparing for a likely increase in enrollment of ESRD beneficiaries in MA plans beginning in 2021.

A few commenters requested additional information with respect to the process and timeline for conducting an initial evaluation of the ESRD model by December 31, 2018, as required by the 21st Century Cures Act,[4] as well as opportunities for stakeholder engagement. A few commenters also requested that future updates to the ESRD risk adjustment model be communicated under a similar timeline as the CMS-HCC model (i.e., we should allow

[4] The 21st Century Cures Act (P.L. 114-255), section 17006(f)(2)(A)(ii), requires a report on the risk adjustment model and the ESRD risk adjustment model under the MA program by December 31, 2018, and every three years thereafter.

stakeholders at least 60 days to review and submit comments on all risk adjustment model proposals) in order to give plans enough time to properly analyze any contemplated updates.

Response: We released plan level risk scores in HPMS on February 16, 2018 under the ESRD model implemented in 2012 and under the proposed 2019 ESRD model so that plans could assess the impact of the update of the proposed model in developing their responses to the Advance Notice. Risk scores and accompanying technical notes can be found in the Risk Adjustment module of HPMS under the heading "Proposed PY2019 ESRD Model Risk Scores."

The recalibration of each component of the ESRD model includes only one change to the structure of the model: updating the Medicaid status to be concurrent, to operationally align the ESRD model with the Part C model. The inclusion of HCCs in the ESRD model, as with the other risk adjustment models, was determined based on how well each condition predicted Medicare costs and the degree to which an HCC was clinically meaningful category with minimal clinical discretion.

Per the 21st Century Cures Act, we are working on an initial evaluation of the proposed ESRD model, and will engage with stakeholders as we continue to develop the ESRD risk adjustment model.

Comment: A few commenters recommended a variety of specific modifications to the ESRD model. One commenter suggested that we develop a hybrid concurrent/prospective model rather than rely only on a simple prospective demographic model for new high-cost ESRD members. Another commenter recommended that we allow members who would be considered to be new enrollees under the current methodology to instead be considered as full risk eligible if an HCC is identified during the calendar year. One commenter would like us to make adjustments to the ESRD model similar to those proposed for the CMS-HCC model to take into account the number of conditions of an enrollee and to include the new HCCs for mental health and substance use disorder. Another commenter believes that the transplant model should account for certain risk factors, such as smoking, socio-economic factors, donor characteristics, and recipient characteristics. A few commenters who support the proposed ESRD model encouraged us to streamline the risk adjustment model so there is only one version that is utilized across all programs. One commenter encouraged us to tailor the risk adjustment model for specific demonstration populations.

Response: We appreciate the comments and recommendations for updates to the ESRD model.

In response to the comments regarding new enrollees, new enrollee risk scores are scores that we use when a beneficiary does not have adequate diagnoses in the data collection year to calculate a full risk score (operationalized as having fewer than 12 months of Part B in the data collection year). Because prior year data is insufficient to predict risk in the payment year for these beneficiaries, we use a combination of demographic factors (age, sex, Medicaid eligibility, and factors related to the original reason for Medicare entitlement) to determine the risk score of a

new enrollee. The new enrollee model is calibrated using concurrent status to individually predict for each combination of these demographic factors, and the beneficiaries in the model sample are limited to those with less than 12 months of Part B in the data collection year so that predicted costs are reflective of the new enrollee population. For the dialysis component of the ESRD model, the new enrollee scores are calibrated with the new enrollees in the dialysis population. For the post-graft population, we use the new enrollee factors calibrated with the non-ESRD population, supplemented with the post-graft add on factors that we calibrated with the full risk post-graft population. We believe that the new enrollee scores as currently calibrated work well for risk adjusting payments for ESRD beneficiaries who are newly entitled to Medicare. However, we will continue to evaluate these models and make improvements where needed.

With regard to comments requesting a streamlined version of risk adjustment, it was unclear whether stakeholders were asking for one risk model for all MA programs, or one ESRD model for all ESRD populations. However, please note that we use separate models in a number of different circumstances, including when costs and cost patterns differ between populations. For example, with the non-ESRD Part C model, we maintain separate segments for different subpopulations of the community population, and for the long term institutional population. The CMS-HCC ESRD dialysis model is structured similarly to the CMS-HCC model for the non-ESRD population, except that the coefficients are estimated using the dialysis population. This allows us to calculate risk scores that are more appropriate for the dialysis population.

Comment: We received requests for clarification on whether costs for specific items and subpopulations were factored into the proposed ESRD model. Some commenters believe that the risk adjustment model for kidney transplant is undervaluing the costs associated with transplants, and encouraged us to revisit the model for beneficiaries who receive kidney transplants. A few commenters requested clarity on whether we only used MS-DRG 652 (Single Kidney Transplant) to identify a kidney transplant event, or if we also used this single DRG to calculate kidney transplant costs, and noted that if we took the latter approach, the result would underestimate transplant reimbursement by excluding costs associated with multi-organ transplants that include kidneys.

One commenter requested clarity on how the costs of dialysis during the month of transplant are factored in when a patient is shifting from dialysis to the transplant, as well as how complications are factored in. Another commenter noted that a proportion of transplant patients continue on dialysis for some period after the transplant, and suggested that the transplant payment factor should be extended beyond three months, until the beneficiary no longer requires dialysis. A few commenters noted that Sensipar and other calcimimetics used for treatment of ESRD is covered under Part B and not under Part D as of January 1, 2018, and requested that we clarify if Sensipar expenditures were incorporated in the newly recalibrated ESRD model.

Response: To accommodate the high one-time cost of a kidney transplant, we make payments to the applicable MA plan over three months to cover the transplant and immediate subsequent services. ESRD transplant factors are used in payment for the month of a kidney transplant and the two following months, and are intended to cover the full range of expenditures that are incurred during a stay for a transplant. We estimate the monthly factors by aggregating the costs for different portions of the transplant costs. The Month 1 transplant payment aggregates the costs incurred during the hospital stay for the transplant and consists of payments made during the months covering the admission through discharge. Payments to hospitals and physicians and other providers in Month 1 are deemed transplant costs. The Months 2 and 3 transplant payments cover the two full months following discharge, and data for these months could be related to transplants performed in the prior year. As we indicated in Table V-8 of the 2019 Advance Notice, kidney transplant is identified by MS-DRG 652. Costs are determined by Part A and B claims for these beneficiaries.

As noted in the 2019 Advance Notice, we used 2014 diagnoses and 2015 expenditures to recalibrate the ESRD model. We estimated the coefficients for the condition categories by regressing the total expenditures for A/B benefits for each FFS ESRD beneficiary onto their demographic factors and condition categories, as indicated by their diagnoses. Drugs covered under Part B in 2015 would have been included in the total expenditures used to re-estimate the coefficients. Since we used 2014/2015 data for the recalibration, Sensipar would have been paid through Part D. We did not reclassify any drugs in relation to the ESRD risk adjustment models. This would have been an imperfect task, involving determining which prescription drug event would have been classified as Part B in a later year and repricing the involved drugs with Part B costs. Note that we will not have FFS Medicare costs for Sensipar covered under the ESRD Prospective Payment System (PPS) bundled payment until 2018 expenditures are available. Also, as noted above, the projected dialysis-only ESRD growth rate reflects our best estimate of program spending for the ESRD population for 2019, including the Part B coverage of Sensipar effective January 1, 2018.

Comment: A few commenters noted that organ acquisition costs substantially increase the cost of the transplant, and recommended that we reimburse MA plans separately for organ acquisition costs as it does under traditional Medicare.

Response: Section 17006(b) of the 21st Century Cures Act 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 2019, we will continue to include kidney acquisition costs in MA capitation rates and benchmarks. There will be no separate payment to MA plans for kidney acquisition costs.

Comment: One commenter expressed concern that health plans will not be properly reimbursed for members in the ESRD model, noting that dialysis companies command much higher rates for dialysis than the FFS Medicare payments which are the basis for risk adjustment, and that we are not taking these types of payment arrangements into consideration.

Response: We appreciate the commenter's concerns. We pay for ESRD beneficiaries using a risk adjustment model that is set to 1.0 in the FFS population to align with the ratebooks used in payment, which allows for geographic variation in payments (the State ratebook for the dialysis population and the county ratebook for the post-graft population). We will continue to analyze and consider whether any refinements to the methodology for the ESRD model may be warranted in future years.

Section J. Frailty Adjustment for PACE organizations and FIDE SNPs

As noted in Section H, we will implement a CMS-HCC model with additional clinical conditions without count variables for 2019 payments. We will implement the frailty factors that have been calculated based on this model (Table III-4). These frailty factors will be included in the calculation that determines frailty scores for Fully Integrated Dual Eligible Special Needs Plans (FIDE-SNPs). There will be no change to the frailty factors included in the frailty score calculation for PACE organizations in PY 2019.

Consistent with our proposal to blend risk scores, we also proposed to blend frailty scores calculated for FIDE-SNPs. We are finalizing that policy and will blend the frailty scores calculated for FIDE-SNPs for 2019; we will compare this blended frailty score with PACE frailty in the same manner as we do for 2018 payments to determine whether that FIDE-SNP has a similar average level of frailty as PACE. The frailty factors for the CMS-HCC model used in payment years 2017 and 2018 can be found in the Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter.

Table III-4. FIDE SNP Frailty Factors for CY 2019

ADL	Non-Medicaid	Medicaid
0	−0.077	−0.138
1-2	0.160	0.019
3-4	0.302	0.146
5-6	0.302	0.367

Comment: Some commenters supported the use of updated frailty factors to determine frailty scores for FIDE-SNPs.

Response: We appreciate the support.

Comment: Several commenters requested that the requirements for eligibility to receive frailty adjustments be expanded to include other plan types, such as I-SNPs and C-SNPs.

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

Comment: One commenter expressed concern with the frailty score calculation, specifically how FIDE-SNP frailty scores are compared to the average level of PACE frailty.

Response: The statute directs us to look at a FIDE-SNP's level of frailty (i.e., plan-level frailty) in comparison to the PACE level of frailty. We believe that our policy is consistent with the statute. As previously discussed in earlier Advance Notices and Rate Announcements, in order to compare FIDE-SNP frailty scores to PACE frailty scores, we first establish a PACE organization range of frailty based upon those PACE organizations with at least 100 respondents to the HOS survey. Once the PACE range is established, those FIDE-SNPs that have a frailty score above the minimum PACE score will receive a frailty add-on to their qualifying beneficiaries' risk scores. Low enrollment (30 or fewer respondents to the Health Outcome Survey (HOS)/Health Outcome Survey - Modified (HOS-M)) or new FIDE-SNPs (those who were not eligible to participate in the HOS because they were not eligible due to the length of time the plan was in operation) are not able to receive a frailty score.

Comment: One comment was received regarding the timing of frailty score release, specifically requesting that scores be provided before bidding.

Response: The frailty scores for the upcoming year are calculated using results from the most current HOS/HOS-M survey. To provide frailty scores at an earlier date, we would have to use older survey data for frailty score calculation. Using the survey results from the most current HOS/HOS-M enables us to calculate frailty scores for an upcoming payment year that are based on the most current reflection of the plan's frailty. Further, using older data would pose challenges to new plans, whose sponsors would need to wait another year before having a frailty score applied in payment. However, we will continue to consider ways to improve the timing of the frailty calculations in future years.

Comment: A few commenters expressed concerns about the HOS-M survey administration and response rates. One commenter suggested that we investigate the accuracy of factors for specific ADL levels.

Response: The Health Outcome Survey has had considerable validation of its ability to accurately capture functional limitation and other health related characteristics. For example, see Journal of Ambulatory Care Management. 2008 Apr-Jun; 31(2):161-77, "Patients' self-report of diseases in the Medicare Health Outcomes Survey based on comparisons with linked survey and medical data from the Veterans Health Administration," Miller DR, Rogers WH, Kazis LE, Spiro A 3rd, Ren XS, Haffer SC. The HOS-M comprises a subset of the questions included in the HOS. While we understand that surveys have their own operational challenges, we believe that the HOS and HOS-M continue to provide an accurate measurement of frailty at the plan level because they collect ADL-related data in the same manner that we collect it for model calibration, i.e., written surveys. In addition, they collect data consistently across respondents and survey results can be compared across plans.

Comment: One commenter suggested that we consider calculating frailty at alternate levels of aggregation (e.g., county level).

Response: We appreciate the suggestion and will take it into consideration. We believe that calculating frailty scores at a lower level of aggregation (the PBP level) provides our best estimate of a plan's frailty score.

Section K. Normalization Factors

Comment: Many commenters were concerned that the last two years in the trend (2016 and 2017) were outliers, and that they did not have enough information about the causes of this recent increase in FFS risk scores. A number of comments cited the transition from ICD-9 to ICD-10 as a driver in this recent increase in FFS risk scores, and suggested that these higher scores are not a real indication of higher risk scores in FFS. Further, a number of commenters suggested these recent increases may not continue and that, therefore, the projected risk score is overstated. Many commenters requested that we incorporate more years of data in the trend to smooth the impacts of changing trends in FFS risk scores, with most suggesting the use of seven years of data.

Response: We are finalizing the normalization methodology as proposed. While we appreciate the careful thinking and suggestions about how we calculate the normalization factors, we believe that the proposed methodology – using a linear approach with 5 years of data – will produce the best estimate of the 2019 average risk score under each model. This is the methodology we have used for many years, excepting the years from 2015 through 2017 when we used a quadratic function, with the objective of smoothing the impact of changes in trends over time. We believe including more than 5 years of data in the trend when forecasting the 2019 FFS risk score is problematic for two reasons. First, including more years of data in the

trend would result in an estimated risk score that is lower than the 2017 actual risk score. Given the recent increases in the FFS risk score, we do not believe a decrease in the FFS risk score is likely between 2017 and 2019. Second, to the extent that recent increases in the FFS risk score are driven by changing incentives in FFS Medicare, or the implementation of ICD-10, including years prior to these changes taking effect would place additional emphasis on factors not influencing the current trend.

While understanding the drivers of the FFS risk score trend can provide insights into the underlying changes in FFS Medicare, the goal of normalization is to set the FFS risk scores to 1.0 in a payment year, regardless of the drivers. If we were to under-normalize risk scores – i.e., if the average risk score were higher than 1.0 – an update to the denominator year as part of a future model recalibration would have a downward effect on risk scores by resetting the average FFS risk score to 1.0.

The historical data and, therefore, the trend for updated CMS-HCC model without count variables are identical to the "Payment Condition Count" model. For PY2019, the normalization factor for the updated CMS-HCC model without count variables will remain 1.038. Table III-5 provides the trend calculated with the updated CMS-HCC model without count variables.

Table III-5: FFS Risk Score Trend

Year	Updated CMS-HCC model without count variables
2011	0.987
2012	0.996
2013	0.994
2014	0.998
2015	1.000
2016	1.019
2017	1.030

Comment: A number of commenters requested that the PACE normalization factor be calculated with more years of data in the trend, many requesting that we use 9 years of data for the PACE normalization factor instead of five years to better account for the trend in FFS coding between the denominator year and the payment year. In addition to the concerns cited by other commenters, these commenters noted the age of the PACE model and the impact of the large normalization factor associated with the model.

Response: We appreciate the commenters' concerns. We are finalizing the normalization factor for the PACE model as proposed. However, we recognize the importance of using a more recent risk adjustment model to pay PACE organizations. We will evaluate the CMS-HCC model for PACE organizations in the coming year, and propose any needed updates in the 2020 Advance Notice. As with the Part C risk adjustment model used to pay Medicare Advantage plans, the goal of the normalization factor is to adjust for the trend in FFS risk score between the

denominator year and the payment year. One reason to continue to calculate normalization factors using the same approach is to minimize shifts in average risk scores when models are updated with more recent denominators.

Comment: One commenter asked why the FFS dialysis risk scores did not reflect the changes in MA risk scores.

Response: The FFS risk scores that we use to normalize risk scores for each Part C model are aligned with the ratebooks used in payment. In the case of the ESRD dialysis model, the risk scores are normalized to align with the ESRD dialysis state ratebook, which is used to pay plans for beneficiaries who are in dialysis and transplant status.

Comment: One commenter requested that we include the same data years in the RxHCC model trend, which is forecasted from 2012 – 2016 data, as the Part C models, which are forecasted from 2013 – 2017 data.

Response: The normalization trend for the RxHCC model includes Medicare Advantage beneficiaries. Final 2017 Medicare Advantage risk scores were not available prior to publishing the 2019 Advance Notice. Therefore the same data years cannot be used.

The 2019 normalization factor for the RxHCC model for is 1.019. Since we are not finalizing the proposed 2019 RxHCC model (see Section A in Attachment IV below), the RxHCC model normalization factor for PY2019 was calculated with the 2018 RxHCC model. The 2018 RxHCC model has a 2015 denominator. Between 2012 and 2016, the trend estimated from the population of beneficiaries enrolled in a PDP or an MA-PD is 0.005. The normalization factor for the RxHCC model is applied to all Part D risk scores for beneficiaries enrolled in an MA-PD or PDP plan. There are four years of trend between the denominator year and the payment year. The risk scores used to calculate the proposed 2019 normalization factor for the RxHCC model are included in Table III-6.

Table III-6: Part D Risk Score Trend

Year	2018 RxHCC Model
2012	0.997
2013	0.990
2014	0.995
2015	1.000
2016	1.015

Section L. Encounter Data as a Diagnosis Source for 2019

Comment: A few commenters concurred with our proposal to increase the encounter data risk score blend to 25%, while a majority of commenters recommended that we maintain the current blend of 15% encounter data for risk scores in 2019, and a small number of commenters

recommended that we cease using encounter data for risk scores altogether. Many commenters continue to detail concerns about challenges they believe to be problematic for calculating risk scores with encounter data and cited the GAO and other externally generated analytic reports that have made recommendations to improve the quality of encounter data. Some commenters acknowledged that we have made significant improvements to support the complete collection of encounter data, while some others suggested that the operational reporting back to MAOs about the diagnoses filtered from encounter data could still be improved. Most commenters supported the inclusion of RAPS inpatient data as part of easing the transition to using encounter data. Some commenters disagreed with this policy on the grounds that there is ample opportunity to submit complete inpatient data for 2018 dates of service, and one commenter noted that supplementing with inpatient RAPS data introduces operational complexity. A few commenters identified the proposal to supplement encounter data with inpatient RAPS data as an indication that there are still data accuracy issues. Some commenters expressed concern that an increased use of encounter data has a disproportionate effect on SNP risk scores. A few commenters requested that we release validation studies and an operational plan for remediating issues, and publicize a timeframe for using the data for payment.

Response: We appreciate the feedback related to the ongoing implementation of encounter data and are committed to continuing our work with stakeholders to improve encounter data submissions and address submission challenges. We have taken several actions in the last few years to assess and improve the encounter data submission process, and thereby improve encounter data integrity. We have conducted outreach to provide technical assistance and solicit feedback on submission issues through various channels, including 1-on-1 calls, site visits, user group calls, and listening forums. Following GAO's recommendations, we have conducted numerous statistical analyses to understand the completeness and validity of encounter data, shared results with stakeholders, and introduced our approach to monitoring and compliance via the 2018 and 2019 Call Letters. We have done extensive work over the last couple of years to improve reporting to plans, and will continue to work with plans to improve and facilitate the submission of encounter data and to assist with confirming the status of risk adjustment eligible diagnoses submitted to the Encounter Data System. In addition, we have extended payment deadlines to submit encounter data to allow plans more time to review the updated reports that show which diagnoses are eligible for risk adjustment and, if needed, to revise or resubmit encounter data records in accordance with our guidance. This will further assist in ensuring that payments are accurate.

Given the steps taken together by CMS and the plans to improve data accuracy and quality, we are finalizing the proposal to calculate 2019 risk scores by adding 25% of the risk score calculated using encounter data and FFS diagnoses (with inpatient RAPS data to supplement encounter data) and 75% of the risk score calculated using RAPS and FFS diagnoses. As discussed in the Advance Notice, CMS observes that Encounter Data inpatient submissions are low compared to corresponding RAPS inpatient submissions. Amending inpatient diagnoses

from Encounter Data with inpatient diagnoses from RAPS will improve the completeness of the data for payment in 2019. We envision the inclusion of inpatient RAPS data in the encounter data risk score to be temporary, and in addition to improving the completeness of the data, minimize any potential impact from incomplete data for the remaining plans that may face operational challenges submitting encounter data records.

Comment: A few commenters noted concern that estimates in the Advance Notice and in the President's Budget indicate encounter data as a cost saving.

Response: We expect that as the quality of encounter data submissions continues to improve and more accurately reflect the items and services rendered to MA beneficiaries, any differential between risk adjusted payments using encounter data vs. RAPS will continue to narrow.

Comment: One commenter supported the proposal that we continue to pool risk adjustment-eligible diagnoses from encounter data, RAPS and FFS to calculate risk scores for PACE organizations.

Response: For PACE organizations for PY 2019, we are finalizing the proposal to pool risk adjustment-eligible diagnoses from the following sources to calculate a single risk score (with no weighting): (1) encounter data, (2) RAPS, and (3) FFS claims. This approach will apply to Part C, ESRD, and Part D risk scores for PACE enrollees.

Comment: A few commenters requested that we apply a payment adjustment to address the risk score differential between RAPS and encounter data in 2019 and prior years.

Response: We are unable to make changes to payment methodologies for prior years. In addition, we do not believe an adjustment is necessary for 2019 given the notable improvements in reporting and data submission, in addition to supplementing encounter data with inpatient RAPS data.

Comment: One commenter noted concerns that a rapid increase in the inclusion of encounter data will encourage MA plans to impose additional reporting requirements on contracted providers, resulting in a substantial administrative burden. They are also concerned that if the quality of the encounter data is poor, it will result in inadequate payments to plans and subsequently to providers, which could compromise providers' ability to deliver quality care.

Response: We appreciate the concerns of the commenter. In providing submission guidance to plans, our goal is to minimize plan administrative burden, while ensuring that the data submitted are accurate and complete. We maintain a variety of data checks on key elements to ensure data element quality. We will continue to work with interested stakeholders on technical and operational issues to improve the acceptance, completeness, and quality of encounter data.

Section M. Quality Payment Program

Comment: One commenter requested that we permit until September 1, 2018 for Medicare Health Plans to submit the applications that we will use to determine whether their payment arrangements are Other Payer Advanced Alternative Payment Models (APMs). Another commenter requested that we allow a rolling determination process for payer-initiated applications instead of requiring that applications be submitted within a time-limited window.

Response: As explained in the CY2018 Quality Payment Program 2018 final rule with comment period (82 FR 53568, 53856), we believe that it is important for both payers and us, particularly in the first year of implementing the Payer-Initiated Process, to have a clear structure for the process that can be easily understood. We believe that the deadlines are important so that we can timely generate and publish the list of Other Payer Advanced APMs on the CMS web site. We may consider making changes to the time period in which Medicare Health Plans' may submit applications for Other Payer Advanced APM determinations after we have more experience in operating the Payer-Initiated Process. We encourage interested parties to review and comment on to the notices of proposed rulemaking on the Quality Payment Program that are issued by CMS.

Comment: One commenter encouraged us to release draft versions of the anticipated Quality Payment Program module and related instructions for review and comment before they are finalized, so that end-users have the opportunity to identify and bring to our attention any potential operational barriers, questions, or concerns prior to implementation.

Response: Medicare Health Plans will use the Quality Payment Program module on the Health Plan Management System (HPMS) to complete the Payer Initiated Submission Form. In the Quality Payment Program 2018 final rule with comment period (82 FR 53855), we indicated that the Payer Initiated Submission Form is subject to the Paperwork Reduction Act (PRA) approval process, which includes an opportunity for public comment. The PRA package (CMS-10621) is available on the CMS Web site at: https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/Downloads/CMS-10621.zip. The comment period is now closed. However, as noted in the CY 2018 Quality Payment Program final rule with comment period (82 FR 53855), if we determine after our first year of implementing of the Payer Initiated Process that it is necessary to update or amend the Payer Initiated Submission Form and related instructions, we intend to make those updates available as soon as possible.

Comment: One commenter requested that we provide clarification and guidance on the process PACE organizations should use to apply as Other Payer Advanced APMs since they do not submit Part C bids.

Response: All organizations that use HPMS, including PACE organizations, may submit payment arrangements for Other Payer Advanced APM determinations, even if they are not submitting an annual bid for an MA contract. As noted above, the Payer Initiated Submission

Form will be included in the new Quality Payment Program module on HPMS. The Payer Initiated Submission Form will be available to organizations that use HPMS when the Quality Payment Program module goes online in April 2018. Payer Initiated Submission Forms for the 2019 Quality Payment Program performance period must be submitted by the initial 2019 bid submission deadline in June 2018.

Comment: A couple of commenters requested that we implement the Eligible Clinician-Initiated Process for determining Other Payer Advanced APMs prior to the 2019 performance period. One of the commenters recommended that we begin collecting information for Other Payer Advanced APM determinations from both payers and clinicians in April 2018.

Response: The Payer-Initiated process is designed to reduce the reporting burden for APM Entities and eligible clinicians, while allowing us to collect the information needed to make Other Payer Advanced APM determinations. Payers that choose to use the Payer Initiated Submission Process can assist their networks of clinicians by submitting to CMS information regarding their payment arrangement. We believe that clinicians are less likely to produce duplicative submissions during the clinician-initiated submission period if CMS has already determined that their payment arrangements are Other Payer Advanced APMs based on information voluntarily submitted by payers. We may consider making changes to the submission period when we have more experience in operating the clinician-initiated process.

Comment: A couple of commenters requested that we provide more details on the criteria that will be used to determine whether a payment arrangement qualifies as an Other Payer Advanced APMs, so that MAOs are better able to support clinician participation.

Response: We encourage the commenters to review the Other Payer Advanced APM criteria set forth in the regulations at 42 CFR 414.1420 and discussed in the CY 2017 Quality Payment Program2017 final rule with comment period (81 FR 77008, 77463-68). Additional information about Other Payer Advanced APMs is available at https://qpp.cms.gov/.

Comment: One commenter requested that we consider any payment arrangement submissions from MA plans or clinicians to be protected as confidential information in the same manner as MA bid submissions.

Response: As we stated in the CY 2018 Quality Payment Program final rule with comment period (81 FR 53872-73), information submitted to us for Other Payer Advanced APM determinations will be kept confidential to the extent permitted by federal law.

Comment: One commenter requested that we provide additional information regarding the application of Quality Payment Program adjustments to MA non-contract provider payments.

Response: We are preparing to publish guidance in the near future that will specify whether and how the Merit-based Incentive Payment System (MIPS) payment adjustments and APM

incentive payments apply to MA non-contract provider payments. We will issue an announcement via HPMS when this guidance is available.

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

Section A. Update of the RxHCC Model

Comment: One commenter expressed support for the proposed RxHCC model and requested that future updates be provided with more review time (similar to the timeline for the CMS-HCC model) in the future.

Response: We appreciate the support and will take the request into consideration.

Comment: Two commenters noted that changes in the Bipartisan Budget Act of 2018 (BBA of 2018) reduces plan liability for brand drugs and requested that we recalibrate the model to reflect the updates, citing concerns about payment accuracy and the accuracy of bid standardization. One commenter requested that we provide information as soon as possible if the RxHCC model is recalibrated to provide sufficient time to review the model impact and evaluate model changes.

Response: It requires extensive time to prepare the data for, calibrate, review, and finalize an updated model. For example, for the RxHCC model, this work includes remapping all the PDEs to the new plan liability in the gap and re-estimating the RxHCC coefficients based on the updated plan liability. Neither the RxHCC model proposed in the 2019 Notice nor the existing RxHCC model being used for 2018 are completely consistent with the plan liability as established in the BBA of 2018. To provide sufficient time for us to recalibrate the model based on the final plan liability parameters and release information to support review and comment on the updated model, we will recalibrate the RxHCC model based on the updated benefit structure and propose any changes for 2020. For 2019, since the current ("2018") model more closely aligns with plan liability in the gap for brand drugs in the BBA of 2018, we will not implement the updated model. We will continue to use the RxHCC model used in 2018, as published in the 2018 Rate Announcement (see Attachment VII, Tables, 1-5 of the 2018 Rate Announcement).

Comment: Two commenters recommended that we add Chronic Kidney Disease (CKD) Level 3 to the RxHCC model consistent with the addition to the CMS-HCC model, citing that beneficiaries with CKD 3 have significant drug costs and that CKD 3 was included in the CMS-HCC and RxHCC models in previous years.

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. We will take the recommendation into consideration for a future RxHCC model update.

Comment: One commenter recommended that we ensure that specific conditions are properly accounted for in the model and suggested alternative variables (e.g., drug utilization) be included in the model calibration.

Response: We appreciate this recommendation.

Section B. Encounter Data as a Diagnosis Source for 2019

We did not receive any comments specifically related to the RxHCC model risk scores. Please refer to Section L in Attachment III, above, for comments and responses on the use of encounter data as a diagnosis source in 2019.

Section C. Part D Risk Sharing

Comment: Several commenters supported the decision not to change the Part D risk sharing parameters and agreed with our analytical approach for reaching that decision.

Response: We appreciate the support.

Section D. Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2019

Comment: One commenter expressed concern about the underlying drug price trends driving the annual Part D parameter updates and urged us to continue to monitor and identify strategies for addressing the escalating drug costs for Part D beneficiaries.

Response: We appreciate the commenter's concern and will continue monitoring Part D drug cost trends and their impact on beneficiaries.

Comment: Several commenters pointed out that certain Part D benefit parameters will need to be updated to reflect the Part D benefit design changes for 2019 as enacted in the BBA of 2018.

Response: We have updated the necessary parameters in Attachment V below.

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

Comment: Several commenters requested confirmation that we will implement the coverage gap discount program-related changes to the Part D benefit design enacted in the BBA of 2018, for CY 2019.

Response: We will immediately implement the coverage gap discount program-related changes for CY 2019 enacted in the BBA of 2018. However, we have significant concerns about the impact these changes will have on drug costs under Part D in 2019 and future years, particularly as plan liability in the gap significantly decreases for brand name drugs beginning in 2019. We remain committed to addressing the rising cost of prescription drugs for seniors, and will closely monitor the effects of the changes enacted in the BBA of 2018 on drug utilization and the pace of

progression of beneficiaries into the catastrophic phase of the benefit. This may include, but is not limited to, changes in generic drug uptake, formulary inclusion, tier composition, and substitutions. As we gain experience under this new benefit structure, we will consider additional changes necessary to protect beneficiary out-of-pocket costs and federal spending. We are interested in stakeholder recommendations on how, such as through changes to the Part D risk corridors, Part D sponsors might be incented to promote the use of high value drugs in the Part D program given the modified benefit structure. We are also interested in recommendations on additional measures we could monitor to ensure the integrity of the competitive marketplace which has been the cornerstone of the Part D program's success.

Comment: Several commenters requested updated guidance on the coverage gap discount program that takes into account changes to statute enacted in the BBA of 2018.

Response: Section 53113 of the BBA of 2018 amended the definition of "applicable drug" for purposes of the coverage gap discount program to include biological products licensed under section 351(k) of the Public Health Service Act (PHSA) – that is, biosimilar and interchangeable products – effective for CY 2019. This means that beginning in CY 2019 all biological products licensed under section 351 of the PHSA will be applicable drugs for purposes of the coverage gap discount program. Additionally, section 53116 of the BBA of 2018 lowered the "discounted price" specified at section 1860D-14A(g)(4) for purposes of the coverage gap discount program from 50 to 30 percent of the negotiated price of the applicable drug, thereby increasing the manufacturer gap discount from 50 percent to 70 percent. Finally, section 53116 of the BBA of 2018 also accelerated the reduction in coinsurance paid by applicable beneficiaries for applicable drugs in the coverage gap by one year, lowering it to 25 percent beginning in CY 2019 instead of CY 2020.

Therefore, the guidance on reduced coinsurance for applicable beneficiaries in the coverage gap for CY 2019 is updated to be the following:

The law requires phased reduction in applicable beneficiary cost-sharing for drugs in the coverage gap phase of the Medicare Part D benefit. This gradual reduction in cost-sharing began in CY 2011 and continues through CY 2019 for applicable drugs and CY 2020 for non-applicable drugs, ultimately resulting in 95 percent cost-sharing for applicable drugs, prior to the application of the 70 percent manufacturer discounts required by statute, and 25 percent cost-sharing for other, non-applicable Part D covered drugs. An applicable drug is defined in section 1860D-14A(g)(2) of the Act to generally include covered Part D brand drugs that are either approved under a new drug application (NDA) under section 505(c) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biological products, licensed under section 351 of the Public Health Service Act (PHSA). Note that applicable drugs also include any biosimilar or interchangeable products licensed under section 351(k) of the PHSA, per section 1860D-14A(g)(2)(A) of the Act, as amended by section 53113 of the BBA of 2018. Non-applicable drugs generally are covered Part D drugs that do not meet the definition of an applicable drug,

such as generic drugs. The reductions in cost-sharing, in conjunction with the Coverage Gap Discount Program, will effectively serve to close the Medicare Part D coverage gap for non-LIS beneficiaries by CY 2019 for applicable drugs and CY 2020 for non-applicable drugs.

In 2019, the coinsurance for applicable beneficiaries under basic prescription drug coverage is reduced to 37 percent for *non-applicable* covered Part D drugs purchased during the coverage gap phase of the Part D benefit. After applying the 70 percent manufacturer discount, the beneficiary coinsurance under basic prescription drug coverage is reduced to 25 percent for *applicable* covered Part D drugs purchased during the coverage gap phase of the Part D benefit in 2019.

Table IV-1. Cost-Sharing for Applicable Drugs in the Coverage Gap

	Beneficiary Coinsurance	Plan Liability	Manufacturer Discount
2010	100% minus $250 rebate[5]	0%	0%
2011	50%	0%	50%
2012	50%	0%	50%
2013	47.5%	2.5%	50%
2014	47.5%	2.5%	50%
2015	45%	5%	50%
2016	45%	5%	50%
2017	40%	10%	50%
2018	35%	15%	50%
2019 +	25%	5%	70%

[5] The law authorized a coverage gap rebate payment of $250 to any Part D beneficiary who reached the initial coverage phase in 2010. The rebate was not required to be spent on drugs.

Table IV-2. Cost-Sharing for Non-Applicable Drugs in the Coverage Gap

	Beneficiary Coinsurance	Plan Liability
2010	100%	0%
2011	93%	7%
2012	86%	14%
2013	79%	21%
2014	72%	28%
2015	65%	35%
2016	58%	42%
2017	51%	49%
2018	44%	56%
2019	37%	63%
2020 +	25%	75%

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

As beneficiary liability for covered Part D drug costs in the coverage gap decreases and the manufacturer gap discount for applicable drugs increases, plan liability changes in 2019 – for non-applicable drugs, plan liability increases, but for applicable drugs, plan liability decreases. In either case, plan liability amounts do not count toward TrOOP. Part D sponsors must account for the reductions in cost-sharing and changes in plan liability when developing their Part D bids for payment year 2019.

Comment: One commenter asked for clarification on whether the BBA of 2018 alters the treatment of biosimilars for purposes of the low-income cost-sharing subsidy (LICS) in the coverage gap, and whether the BBA of 2018 also closes the coverage gap for non-applicable drugs in 2019.

Response: The BBA of 2018 does not alter the treatment of biosimilar or interchangeable products for LICS purposes. Also, as stated above, the BBA of 2018 closes the coverage gap only for applicable drugs in 2019; the coinsurance for applicable beneficiaries for non-applicable Part D drugs purchased in the coverage gap remains 37 percent in 2019, and plan liability for non-applicable Part D drugs purchased in the coverage gap by applicable beneficiaries remains 63 percent.

Section F. Dispensing Fees and Vaccine Administration Fees for Applicable Drugs in the Coverage Gap

Comment: Several commenters asked for updated guidance on the coverage gap discount program that takes into account changes to statute enacted in the BBA of 2018.

Response: As noted above, section 53116 of the BBA of 2018 accelerated the reduction in coinsurance paid by applicable beneficiaries for applicable drugs in the coverage gap by one year, lowering it to 25 percent (after the 70 percent manufacturer discount) beginning in CY 2019 instead of CY 2020. This has the effect of reducing beneficiary liability for dispensing and vaccine administration fees for applicable drugs in the coverage gap in 2019 from 30 percent to 25 percent and increasing plan liability for such fees in 2019 from 70 percent to 75 percent. Therefore, the guidance on dispensing fees and vaccine administration fees for applicable drugs in the coverage gap for CY 2019 is updated to be the following:

As described in the previous section, the law phases in a reduction in beneficiary cost-sharing for drugs in the coverage gap phase of the Medicare Part D benefit. Consistent with our policy on liability for dispensing and vaccine administration fees, as described in the Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, applicable beneficiaries will pay a portion of the dispensing fee (and vaccine administration fee, if any) that is commensurate with their coinsurance in the coverage gap, after the application of the coverage gap discount program discount when applicable. The Part D sponsor will pay the remainder of the dispensing fee and vaccine administration fee, if any.

In 2019, applicable beneficiaries will pay 25 percent and plans will pay 75 percent of dispensing fees and vaccine administration fees for applicable drugs in the coverage gap.

Section G. Part D Calendar Year Employer Group Waiver Plans

Comment: One commenter expressed support for the proposal to continue to pay Calendar Year Part D EGWPs prospective reinsurance in 2019.

Response: We appreciate the support.

Section H. Enhanced Medication Therapy Management (MTM) Model

Comment: In the Advance Notice, we indicated that we were determining whether it would be possible for the Enhanced MTM model's premium reductions to be considered when determining the 2019 low-income premium benchmarks. One commenter noted that the determination (and its timing) regarding whether the model's premium reductions will be considered in the low income premium benchmarks will impact the preparation of 2019 bids, and requested that we provide the following information as soon as it is available: (1) confirmation regarding the inclusion (or exclusion) of MTM model performance based incentive payments in

the low income benchmark calculations, and (2) a list of the participating plans in the model that will be receiving a performance based incentive payment in 2019.

Response: Given timing and operational considerations, we have determined that it will not be possible for the model's premium reductions to be considered when determining the 2019 low-income premium benchmarks. We anticipate notifying plans of their eligibility for performance based incentive payments shortly after initial 2019 bids are due to us in June. We will release additional information in forthcoming guidance.

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

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

Annual Percentage Increases

	Annual percentage trend for 2018	Prior year revisions	Annual percentage increase for 2019
API: Applied to all parameters but (1) and (2)	3.96%	−1.95%	1.94%
July CPI (all items, U.S. city average): Applied to (1)	2.58%	−0.73%	1.83%
September CPI (all items, U.S. city average): Applied to (2)	1.95%	−0.17%	1.78%

Part D Benefit Parameters

	2018	2019
Standard Benefit		
Deductible	$405	$415
Initial Coverage Limit	$3,750	$3,820
Out-of-Pocket Threshold (1)	$5,000	$5,100
Total Covered Part D Spending at Out-of-Pocket Threshold for Non-Applicable Beneficiaries (3)	$7,508.75	$7,653.75
Estimated Total Covered Part D Spending for Applicable Beneficiaries (4)	$8,417.60	$8,139.54
Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit		
Generic/Preferred Multi-Source Drug	$3.35	$3.40
Other	$8.35	$8.50
Full Subsidy-Full Benefit Dual Eligible (FBDE) Individuals		
Deductible	$0.00	$0.00
Copayments for Institutionalized Beneficiaries [category code 3]	$0.00	$0.00
Copayments for Beneficiaries Receiving Home and Community-Based Services] [category code 3] (5)	$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		
Generic/Preferred Multi-Source Drug (6)	$1.25	$1.25
Other (6)	$3.70	$3.80
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	$3.35	$3.40
Other	$8.35	$8.50
Above Out-of-Pocket Threshold	$0.00	$0.00

	2018	2019
Full Subsidy-Non-FBDE Individuals		
Applied or eligible for QMB/SLMB/QI or SSI, income at or below 135% FPL and resources ≤ $9,060 (individuals, 2018) or ≤ $14,340 (couples, 2018) [category code 1] (7)		
Deductible	$0.00	$0.00
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$3.35	$3.40
Other	$8.35	$8.50
Maximum Copayments above Out-of-Pocket Threshold	$0.00	$0.00
Partial Subsidy		
Applied and income below 150% FPL and resources below $14,100 (individual, 2018) or $ 28,150 (couples, 2018) [category code 4] (7)		
Deductible (6)	$83.00	$85.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$3.35	$3.40
Other	$8.35	$8.50
Retiree Drug Subsidy Amounts		
Cost Threshold	$405	$415
Cost Limit	$8,350	$8,500

(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 eligible beneficiaries 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 partial LIS deductible is increased from the unrounded 2018 value of $83.46, and the maximum copayments for non-institutionalized FBDE individuals with incomes no greater than 100 percent of the FPL are increased from the unrounded 2018 values of $1.24 for generic/preferred multi-source drugs and $3.73 for all other drugs.
(7) These resource limit figures will be updated for contract year 2019. Additionally, these amounts include $1,500 per person for burial expenses. See the HPMS memorandum titled, "2018 Resource and Cost-Sharing Limits for Low-Income Subsidy (LIS)" for additional details.

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

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

Deductible: From $405 in 2018 and rounded to the nearest multiple of $5.

Initial Coverage Limit: From $3,750 in 2018 and rounded to the nearest multiple of $10.

Out-of-Pocket Threshold: From $5,000 in 2018 and rounded to the nearest multiple of $50.

Minimum Cost-Sharing in the Catastrophic Coverage Portion of the Benefit: From $3.35 per generic or preferred drug that is a multi-source drug and $8.35 for all other drugs in 2018, 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 $3.35 per generic or preferred drug that is a multi-source drug and $8.35 for all other drugs in 2018, rounded to the nearest multiple of $0.05.

Deductible for Low Income (Partial) Subsidy Eligible Enrollees: From $83[6] in 2018 and rounded to the nearest $1.

Maximum Copayments above the Out-of-Pocket Threshold for Low Income (Partial) Subsidy Eligible Enrollees: From $3.35 per generic or preferred drug that is a multi-source drug and $8.35 for all other drugs in 2018, 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 we use the annual percentage increase in the CPI, All Urban Consumers (all items, U.S. city average) as of September of the previous year to update the maximum copayment amounts up to the out-of-pocket threshold for full benefit dual eligible enrollees with incomes not exceeding 100 percent of the Federal Poverty Level. These copayments are increased from $ 1.25 per generic or preferred drug that is a multi-source drug

[6] Per section 1860D-14(a)(4)(B) of the Act, the update for the deductible for partial low income subsidy eligible enrollees is applied to the unrounded 2018 value of $83.46.

and from $3.70 for all other drugs in 2018 and rounded to the nearest multiple of $0.05 and $0.10 respectively.[7]

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 2019 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 2018 is lower than the change in CPI+2% during that period, and, therefore, the API will apply to the out-of-pocket threshold. The threshold is increased from $5,000 in 2018 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 2019 benefit parameters, Part D program data is used to calculate the annual percentage trend as follows:

$$\frac{August\ 2017 - July\ 2018}{August\ 2016 - July\ 2017} = \frac{\$3{,}730.80}{\$3{,}588.60} = 1.0396$$

In the formula, the average per capita cost for August 2016 – July 2017 ($3,588.60) is calculated from actual Part D PDE data, and the average per capita cost for August 2017 – July 2018 ($3,730.80) is calculated based on actual Part D PDE data incurred from August 2017 – December 2017 and projected through July 2018.

The 2019 benefit parameters reflect the 2018 annual percentage trend, as well as an update for revision to prior year estimates for API. Based on updated NHE prescription drug per capita costs and PDE data, the annual percentage increases are now estimated as summarized by Table V-2.

[7] Per section 1860D-14(a)(4)(A) of the Act, the copayments are increased from the unrounded 2018 values of $1.24 for multi-source generic or preferred drugs, and $3.73 for all other drugs.

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

Year	Prior Estimates of Annual Percentage Increases	Revised Annual Percentage Increases
2007	7.30%	7.30%
2008	5.92%	5.92%
2009	4.69%	4.69%
2010	3.14%	3.14%
2011	2.36%	2.36%
2012	2.16%	2.15%
2013	2.53%	2.53%
2014	−3.14%	−3.14%
2015	10.09%	10.12%
2016	9.90%	9.92%
2017	4.14%	4.00%
2018	3.94%	2.02%

Accordingly, the 2019 benefit parameters reflect a multiplicative update of -1.95 percent for prior year revisions. In summary, the 2018 parameters outlined in Section A are updated by 1.94 percent for 2019, as summarized by Table V-3.

Table V-3. Annual Percentage Increase

Annual percentage trend for July 2018	3.96%
Prior year revisions	−1.95%
Annual percentage increase for 2019	1.94%

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 cost-sharing requirements into the development of the benefit, any marketing materials, and necessary systems, CMS includes in its methodology to calculate the annual percentage increase in the CPI for the 12-month period ending in September 2018, an estimate of the September 2018 CPI based on projections from the President's FY2019 Budget.

The September 2017 value is from the Bureau of Labor Statistics. The annual percentage trend in the September CPI for contract year 2019 is calculated as follows:

$$\frac{\text{Projected September 2018 CPI}}{\text{Actual September 2017 CPI}} \; or \; \frac{251.6}{246.8} = 1.0195$$

(Source: President's FY2019 Budget and Bureau of Labor Statistics, Department of Labor)

The 2019 benefit parameters reflect the 2018 annual percentage trend in the September CPI of 1.95 percent, as well as a revision to the prior estimate for the 2017 CPI increase over the 12-month period ending in September 2017. Based on the actual reported CPI for September 2017, the September 2017 CPI increase is now estimated to be 2.23 percent. Accordingly, the 2019 update reflects a -0.17 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 Level are updated by 1.78 percent for 2019, as summarized by Table V-4.

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

Annual percentage trend for September 2018	1.95%
Prior year revisions	−0.17%
Annual percentage increase for 2019	1.78%

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 2018, the methodology to calculate the annual percentage increase in the CPI for the 12-month period ending in July 2018 includes an estimate of the July 2018 CPI based on projections from the President's FY2019 Budget.

The July 2017 value is from the Bureau of Labor Statistics. The annual percentage trend in CPI for contract year 2019 is calculated as follows:

$$\frac{\text{Projected July 2018 CPI}}{\text{Actual July 2017 CPI}} \; or \; \frac{251.1}{244.8} = 1.0258$$

(Source: President's FY2019 Budget and Bureau of Labor Statistics, Department of Labor)

The 2019 benefit parameters reflect the 2018 annual percentage trend in the July CPI of 2.58 percent as well as a revision to the prior estimate for the 2017 CPI increase. Based on the actual reported CPI for July 2017, the CPI increase over the 12-month period ending in July 2017 is estimated to be 1.73 percent. The prior year revision here reflects the difference between this actual 1.73 percent increase in CPI observed in July 2017 and the 2017 CPI increase estimate from the CY 2018 Rate Announcement.

In summary, the cumulative annual percentage increase in July CPI for 2019 is 1.83 percent, as summarized by Table V-5. This value plus two percentage points is greater than the 1.94 percent cumulative API for 2019 described above. Thus, the out-of-pocket threshold will be increased by 1.94 percent for 2019.

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

Annual percentage trend for July 2018	2.58%
Prior year revisions	−0.73%
Annual percentage increase for 2019	1.83%

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

Section D. Retiree Drug Subsidy Amounts

Per 42 CFR 423.886(b)(3), the cost threshold and cost limit for qualified retiree prescription drug plans are also updated using the API, as defined previously in this document. The updated cost threshold is rounded to 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 $400 and $8,250, respectively, for plans that end in 2017, and as $405 and $8,350 for plans that end in 2018. For 2019, the cost threshold is $415 and the cost limit is $8,500.

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

For 2019, the total covered Part D spending at out-of-pocket threshold for applicable beneficiaries is $8,139.54. 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.
- 37 percent beneficiary cost-sharing for non-applicable drugs purchased in the coverage gap phase of the benefit.
- 95 percent cost-sharing for the ingredient cost and sales tax for applicable drugs purchased in the coverage gap phase of the benefit—comprised of 25 percent beneficiary coinsurance and 70 percent Coverage Gap Discount Program discount.
- 25 percent cost-sharing for the dispensing and vaccine administration fees for applicable drugs purchased in the coverage gap phase of the benefit.

In this estimate, it is assumed that the dispensing and vaccine administration fees account for 0.072 percent of the gross covered brand drug costs used by non-LIS beneficiaries in the coverage gap. Therefore, a 75 percent reduction in cost-sharing for dispensing and vaccine

administration fees results in an overall reduction of 0.05 percent to 94.95 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:

$$\text{ICL} + \frac{\text{100\% beneficiary cost sharing in the gap}}{\text{weighted gap coinsurance factor}} \quad \textit{or} \quad \$3{,}820 + \frac{\$3{,}833.75}{88.7538\%} = \$8{,}139.54$$

- *ICL* is the Initial Coverage Limit equal to $3,820
- *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* $5,100 − $1,266.25 = $3,833.75

- Weighted gap coinsurance factor is calculated as follows:

  (Brand Gross Drug Cost Below Catastrophic [GDCB] % for non-LIS × 94.95% gap cost-sharing for applicable drugs) + (Generic GDCB % for non-LIS × 37% gap cost-sharing for non-applicable drugs)

  or

  (89.31% × 94.95%) + (10.69% × 37%) = 88.7538%

  - *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 drugs, as reported on the 2017 PDEs.
  - *Gap cost-sharing for applicable drugs* is the coinsurance incurred by applicable beneficiaries (i.e., non-LIS) for applicable 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

      94.95% = [(99.928% × 95%) + (0.072% × 25%)]
  - *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 drugs as reported on the 2017 PDEs.

- *Gap cost-sharing for non-applicable drugs* is the coinsurance incurred by applicable beneficiaries (i.e., non-LIS) for non-applicable drugs in the coverage gap.

Attachment VI. CMS-HCC and ESRD Risk Adjustment Factors

Table VI-1. 2019 CMS-HCC without Count Variables Model Relative Factors for Continuing Enrollees

Variable	Description Label	Community, NonDual, Aged	Community, NonDual, Disabled	Community, FBDual, Aged	Community, FBDual, Disabled	Community, PBDual, Aged	Community, PBDual, Disabled	Institutional
Female								
0-34 Years		-	0.225	-	0.326	-	0.357	0.898
35-44 Years		-	0.297	-	0.322	-	0.387	1.103
45-54 Years		-	0.331	-	0.345	-	0.392	1.041
55-59 Years		-	0.363	-	0.404	-	0.389	1.062
60-64 Years		-	0.413	-	0.462	-	0.388	1.065
65-69 Years		0.316	-	0.427	-	0.347	-	1.241
70-74 Years		0.381	-	0.520	-	0.401	-	1.148
75-79 Years		0.452	-	0.613	-	0.479	-	1.013
80-84 Years		0.540	-	0.762	-	0.564	-	0.882
85-89 Years		0.668	-	0.942	-	0.680	-	0.799
90-94 Years		0.823	-	1.087	-	0.818	-	0.669
95 Years or Over		0.831	-	1.158	-	0.917	-	0.502
Male								
0-34 Years		-	0.143	-	0.220	-	0.367	1.098
35-44 Years		-	0.184	-	0.209	-	0.258	0.999
45-54 Years		-	0.226	-	0.280	-	0.288	0.961
55-59 Years		-	0.272	-	0.374	-	0.317	1.014
60-64 Years		-	0.315	-	0.499	-	0.349	1.058
65-69 Years		0.301	-	0.478	-	0.358	-	1.284
70-74 Years		0.388	-	0.597	-	0.420	-	1.326
75-79 Years		0.472	-	0.724	-	0.502	-	1.316
80-84 Years		0.564	-	0.837	-	0.554	-	1.208
85-89 Years		0.707	-	1.058	-	0.678	-	1.122
90-94 Years		0.872	-	1.220	-	0.862	-	0.990

Variable	Description Label	Community, NonDual, Aged	Community, NonDual, Disabled	Community, FBDual, Aged	Community, FBDual, Disabled	Community, PBDual, Aged	Community, PBDual, Disabled	Institutional
95 Years or Over		1.021	-	1.359	-	1.077	-	0.822
Medicaid and Originally Disabled Interactions								
Medicaid		-	-	-	-	-	-	0.061
Originally Disabled, Female		0.248	-	0.168	-	0.133	-	0.001
Originally Disabled, Male		0.146	-	0.180	-	0.080	-	0.001
Disease Coefficients	**Description Label**							
HCC1	HIV/AIDS	0.344	0.294	0.604	0.410	0.491	0.213	1.723
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.428	0.527	0.534	0.658	0.393	0.411	0.332
HCC6	Opportunistic Infections	0.446	0.808	0.592	0.888	0.359	0.732	0.535
HCC8	Metastatic Cancer and Acute Leukemia	2.654	2.713	2.551	2.814	2.450	2.666	1.302
HCC9	Lung and Other Severe Cancers	1.027	0.919	1.007	1.028	1.004	0.899	0.623
HCC10	Lymphoma and Other Cancers	0.675	0.671	0.714	0.778	0.649	0.683	0.461
HCC11	Colorectal, Bladder, and Other Cancers	0.309	0.350	0.311	0.370	0.332	0.364	0.293
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.153	0.221	0.161	0.230	0.160	0.197	0.211
HCC17	Diabetes with Acute Complications	0.307	0.354	0.344	0.432	0.331	0.379	0.442
HCC18	Diabetes with Chronic Complications	0.307	0.354	0.344	0.432	0.331	0.379	0.442
HCC19	Diabetes without Complication	0.106	0.123	0.108	0.149	0.089	0.125	0.179
HCC21	Protein-Calorie Malnutrition	0.554	0.799	0.788	0.857	0.556	0.797	0.275
HCC22	Morbid Obesity	0.262	0.200	0.389	0.318	0.247	0.226	0.460
HCC23	Other Significant Endocrine and Metabolic Disorders	0.212	0.417	0.228	0.355	0.197	0.371	0.379
HCC27	End-Stage Liver Disease	0.913	1.126	1.136	1.184	0.783	0.950	0.873

Variable	Description Label	Community, NonDual, Aged	Community, NonDual, Disabled	Community, FBDual, Aged	Community, FBDual, Disabled	Community, PBDual, Aged	Community, PBDual, Disabled	Institutional
HCC28	Cirrhosis of Liver	0.381	0.365	0.421	0.416	0.426	0.382	0.486
HCC29	Chronic Hepatitis	0.153	0.329	0.040	0.320	0.190	0.263	0.486
HCC33	Intestinal Obstruction/Perforation	0.243	0.551	0.289	0.606	0.267	0.608	0.355
HCC34	Chronic Pancreatitis	0.308	0.625	0.373	0.826	0.394	0.656	0.423
HCC35	Inflammatory Bowel Disease	0.315	0.536	0.287	0.576	0.292	0.564	0.357
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.431	0.430	0.588	0.756	0.475	0.495	0.403
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.426	0.378	0.374	0.349	0.357	0.282	0.293
HCC46	Severe Hematological Disorders	1.394	3.597	1.237	4.334	1.269	4.166	0.802
HCC47	Disorders of Immunity	0.683	0.910	0.476	0.759	0.703	0.654	0.577
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.214	0.360	0.249	0.363	0.221	0.385	0.192
HCC54	Substance Use with Psychotic Complications	0.368	0.564	0.709	0.912	0.415	0.700	0.178
HCC55	Substance Use Disorder, Moderate/Severe, or Substance Use with Complications	0.368	0.283	0.524	0.358	0.400	0.282	0.178
HCC56	Substance Use Disorder, Mild, Except Alcohol and Cannabis	0.368	0.249	0.524	0.348	0.400	0.282	0.178
HCC57	Schizophrenia	0.606	0.372	0.697	0.398	0.589	0.327	0.188
HCC58	Reactive and Unspecified Psychosis	0.546	0.372	0.697	0.274	0.589	0.285	0.188
HCC59	Major Depressive, Bipolar, and Paranoid Disorders	0.353	0.176	0.365	0.141	0.350	0.123	0.188
HCC60	Personality Disorders	0.353	0.123	0.365	0.120	0.299	0.088	-
HCC70	Quadriplegia	1.338	1.031	1.141	1.032	1.083	1.185	0.562

Variable	Description Label	Community, NonDual, Aged	Community, NonDual, Disabled	Community, FBDual, Aged	Community, FBDual, Disabled	Community, PBDual, Aged	Community, PBDual, Disabled	Institutional
HCC71	Paraplegia	1.121	0.764	0.968	0.995	1.083	0.972	0.501
HCC72	Spinal Cord Disorders/Injuries	0.519	0.403	0.568	0.426	0.547	0.377	0.290
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	1.026	1.131	1.139	1.286	0.740	0.968	0.475
HCC74	Cerebral Palsy	0.354	0.105	-	-	0.135	-	-
HCC75	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	0.491	0.518	0.430	0.461	0.313	0.360	0.332
HCC76	Muscular Dystrophy	0.533	0.631	0.409	0.609	-	0.304	0.357
HCC77	Multiple Sclerosis	0.441	0.582	0.774	0.822	0.299	0.484	0.033
HCC78	Parkinson's and Huntington's Diseases	0.686	0.552	0.715	0.524	0.628	0.495	0.162
HCC79	Seizure Disorders and Convulsions	0.277	0.226	0.308	0.171	0.321	0.204	0.065
HCC80	Coma, Brain Compression/Anoxic Damage	0.575	0.370	0.592	0.213	0.783	0.246	-
HCC82	Respirator Dependence/Tracheostomy Status	1.051	0.873	2.198	1.554	0.886	0.854	1.626
HCC83	Respiratory Arrest	0.404	0.496	0.954	0.590	0.439	0.854	0.512
HCC84	Cardio-Respiratory Failure and Shock	0.314	0.435	0.517	0.590	0.392	0.394	0.313
HCC85	Congestive Heart Failure	0.310	0.404	0.355	0.441	0.306	0.376	0.204
HCC86	Acute Myocardial Infarction	0.220	0.306	0.410	0.508	0.333	0.434	0.366
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.219	0.306	0.318	0.489	0.302	0.434	0.366
HCC88	Angina Pectoris	0.143	0.132	0.036	0.191	0.162	0.182	0.366

Variable	Description Label	Community, NonDual, Aged	Community, NonDual, Disabled	Community, FBDual, Aged	Community, FBDual, Disabled	Community, PBDual, Aged	Community, PBDual, Disabled	Institutional
HCC96	Specified Heart Arrhythmias	0.271	0.276	0.390	0.344	0.267	0.305	0.253
HCC99	Intracranial Hemorrhage	0.276	0.257	0.443	0.613	0.281	0.223	0.108
HCC100	Ischemic or Unspecified Stroke	0.276	0.188	0.443	0.398	0.281	0.223	0.108
HCC103	Hemiplegia/Hemiparesis	0.498	0.331	0.540	0.359	0.503	0.368	0.016
HCC104	Monoplegia, Other Paralytic Syndromes	0.368	0.300	0.380	0.302	0.333	0.203	0.016
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	1.537	1.588	1.779	1.836	1.556	1.599	0.881
HCC107	Vascular Disease with Complications	0.401	0.503	0.585	0.714	0.482	0.501	0.302
HCC108	Vascular Disease	0.305	0.327	0.318	0.306	0.312	0.348	0.094
HCC110	Cystic Fibrosis	0.509	2.646	0.497	3.469	0.401	3.018	0.601
HCC111	Chronic Obstructive Pulmonary Disease	0.335	0.244	0.430	0.333	0.356	0.269	0.311
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.216	0.235	0.154	0.273	0.199	0.231	0.109
HCC114	Aspiration and Specified Bacterial Pneumonias	0.612	0.371	0.732	0.515	0.610	0.333	0.160
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.164	-	0.286	0.063	0.133	0.147	0.160
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.232	0.253	0.273	0.296	0.193	0.232	0.394
HCC124	Exudative Macular Degeneration	0.522	0.328	0.286	0.170	0.393	0.185	0.216
HCC134	Dialysis Status	0.474	0.461	0.729	0.671	0.481	0.538	0.472
HCC135	Acute Renal Failure	0.474	0.461	0.729	0.671	0.481	0.538	0.472
HCC136	Chronic Kidney Disease, Stage 5	0.284	0.227	0.251	0.333	0.276	0.265	0.245
HCC137	Chronic Kidney Disease, Severe (Stage 4)	0.284	0.089	0.251	0.125	0.271	0.023	0.201

Variable	Description Label	Community, NonDual, Aged	Community, NonDual, Disabled	Community, FBDual, Aged	Community, FBDual, Disabled	Community, PBDual, Aged	Community, PBDual, Disabled	Institutional
HCC138	Chronic Kidney Disease, Moderate (Stage 3)	0.068	0.012	0.014	-	0.038	-	0.092
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	2.112	2.157	2.512	2.646	2.144	2.574	0.838
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	1.153	1.295	1.536	1.462	1.250	1.019	0.308
HCC161	Chronic Ulcer of Skin, Except Pressure	0.551	0.645	0.776	0.650	0.580	0.604	0.308
HCC162	Severe Skin Burn or Condition	0.262	0.537	0.195	0.378	-	0.371	-
HCC166	Severe Head Injury	0.575	0.370	0.592	0.213	0.783	0.246	-
HCC167	Major Head Injury	0.143	0.043	0.213	0.089	0.101	0.080	-
HCC169	Vertebral Fractures without Spinal Cord Injury	0.508	0.403	0.568	0.426	0.547	0.377	0.251
HCC170	Hip Fracture/Dislocation	0.406	0.441	0.481	0.543	0.411	0.391	-
HCC173	Traumatic Amputations and Complications	0.249	0.251	0.256	0.612	0.230	0.263	0.095
HCC176	Complications of Specified Implanted Device or Graft	0.609	0.957	0.713	1.063	0.556	0.893	0.475
HCC186	Major Organ Transplant or Replacement Status	0.855	0.472	0.734	0.892	0.455	0.648	1.039
HCC188	Artificial Openings for Feeding or Elimination	0.581	0.818	0.803	0.846	0.573	0.805	0.518
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.567	0.487	0.837	1.007	0.738	0.684	0.365
Disease Interactions								
HCC47_gCancer	Immune Disorders*Cancer	0.847	0.490	0.843	0.718	0.661	0.633	-
Diabetes_CHF	Congestive Heart Failure*Diabetes	0.152	0.079	0.214	0.116	0.145	0.064	0.170
CHF_gCopdCF	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.191	0.190	0.256	0.239	0.196	0.215	0.191

Variable	Description Label	Community, NonDual, Aged	Community, NonDual, Disabled	Community, FBDual, Aged	Community, FBDual, Disabled	Community, PBDual, Aged	Community, PBDual, Disabled	Institutional
HCC85_gRenal_V23	Congestive Heart Failure*Renal	0.202	0.520	0.215	0.587	0.234	0.488	-
gCopdCF_CARD_RESP_FAIL	Cardiorespiratory Failure*Chronic Obstructive Pulmonary Disease	0.384	0.429	0.542	0.529	0.410	0.526	0.415
HCC85_HCC96	Congestive Heart Failure*Specified Heart Arrhythmias	0.111	0.325	0.156	0.414	0.132	0.348	-
gSubstanceAbuse_gPsychiatric_V23	Substance Use Disorder*Psychiatric	-	0.164	-	0.220	-	0.224	-
SEPSIS_PRESSURE_ULCER	Sepsis*Pressure Ulcer	-	-	-	-	-	-	0.140
SEPSIS_ARTIF_OPENINGS	Sepsis*Artificial Openings for Feeding or Elimination	-	-	-	-	-	-	0.480
ART_OPENINGS_PRESSURE_ULCER	Artificial Openings for Feeding or Elimination*Pressure Ulcer	-	-	-	-	-	-	0.347
gCopdCF_ASP_SPEC_BACT_PNEUM	Chronic Obstructive Pulmonary Disease*Aspiration and Specified Bacterial Pneumonias	-	-	-	-	-	-	0.216
ASP_SPEC_BACT_PNEUM_PRES_ULC	Aspiration and Specified Bacterial Pneumonias*Pressure Ulcer	-	-	-	-	-	-	0.465
SEPSIS_ASP_SPEC_BACT_PNEUM	Sepsis*Aspiration and Specified Bacterial Pneumonias	-	-	-	-	-	-	0.347
SCHIZOPHRENIA_gCopdCF	Schizophrenia*Chronic Obstructive Pulmonary Disease	-	-	-	-	-	-	0.415
SCHIZOPHRENIA_CHF	Schizophrenia*Congestive Heart Failure	-	-	-	-	-	-	0.128

Variable	Description Label	Community, NonDual, Aged	Community, NonDual, Disabled	Community, FBDual, Aged	Community, FBDual, Disabled	Community, PBDual, Aged	Community, PBDual, Disabled	Institutional
SCHIZOPHRENIA_SEIZURES	Schizophrenia*Seizure Disorders and Convulsions	-	-	-	-	-	-	0.573
Disabled/Disease Interactions								
DISABLED_HCC85	Disabled, Congestive Heart Failure	-	-	-	-	-	-	0.278
DISABLED_PRESSURE_ULCER	Disabled, Pressure Ulcer	-	-	-	-	-	-	0.546
DISABLED_HCC161	Disabled, Chronic Ulcer of the Skin, Except Pressure Ulcer	-	-	-	-	-	-	0.478
DISABLED_HCC39	Disabled, Bone/Joint Muscle Infections/Necrosis	-	-	-	-	-	-	0.451
DISABLED_HCC77	Disabled, Multiple Sclerosis	-	-	-	-	-	-	0.468
DISABLED_HCC6	Disabled, Opportunistic Infections	-	-	-	-	-	-	0.407

NOTES:

1. The denominator is $9,367.51.
2. In the "disease interactions" and "disabled interactions," the variables are defined as follows:
   Immune Disorders = HCC 47
   Cancer = HCCs 8-12
   Congestive Heart Failure = HCC 85
   Diabetes = HCCs 17-19
   Chronic Obstructive Pulmonary Disease = HCCs 110-112
   Renal = HCCs 134-138
   Cardiorespiratory Failure = HCCs 82-84
   Specified Heart Arrhythmias = HCC 96
   Substance Use Disorder = HCCs 54-56
   Psychiatric = HCCs 57-60
   Pressure Ulcer = HCCs 157-158
   Chronic Ulcer of Skin, except Pressure = HCC 161
   Bone/Joint/Muscle Infections/Necrosis = HCC 39
   Multiple Sclerosis = HCC 77
   Opportunistic Infections = HCC 6
   Sepsis = HCC 2
   Artificial Openings for Feeding or Elimination = HCC 188
   Aspiration and Specified Bacterial Pneumonias = HCC 114
   Schizophrenia = HCC 57
   Seizure Disorders and Convulsions = HCC 79

SOURCE: RTI International analysis of 2014/2015 Medicare 100% data and RTI International analysis of 2014/2015 Medicare 100% institutional sample.

Table VI-2. 2019 CMS-HCC without Count Variables Model Relative Factors for Aged and Disabled New Enrollees

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	0.804	0.969	-	-
35-44 Years	0.947	1.202	-	-
45-54 Years	1.015	1.305	-	-
55-59 Years	1.016	1.307	-	-
60-64 Years	1.122	1.408	-	-
65 Years	0.520	0.993	1.122	1.462
66 Years	0.515	0.897	1.174	1.887
67 Years	0.544	0.919	1.174	1.887
68 Years	0.597	0.950	1.174	1.887
69 Years	0.600	0.950	1.174	1.887
70-74 Years	0.690	0.985	1.174	1.887
75-79 Years	0.860	1.133	1.174	1.887
80-84 Years	1.013	1.352	1.174	1.887
85-89 Years	1.293	1.535	1.293	1.887
90-94 Years	1.293	1.701	1.293	1.887
95 Years or Over	1.293	1.701	1.293	1.887
Male				
0-34 Years	0.442	0.734	-	-
35-44 Years	0.657	1.059	-	-
45-54 Years	0.864	1.353	-	-
55-59 Years	0.903	1.418	-	-
60-64 Years	0.920	1.550	-	-
65 Years	0.517	1.144	0.920	1.811
66 Years	0.533	1.094	1.071	2.198
67 Years	0.582	1.151	1.123	2.198
68 Years	0.626	1.202	1.123	2.198
69 Years	0.690	1.202	1.319	2.198
70-74 Years	0.785	1.298	1.408	2.198
75-79 Years	1.059	1.407	1.408	2.198
80-84 Years	1.246	1.555	1.408	2.198
85-89 Years	1.497	1.777	1.497	2.198
90-94 Years	1.497	1.777	1.497	2.198
95 Years or Over	1.497	1.777	1.497	2.198

NOTES:

1. The denominator is $9,367.51.
2. For payment purposes, a new enrollee is a beneficiary who did not have 12 months of Part B eligibility in the data collection year. CMS-HCC new enrollee models are not based on diagnoses, but include factors for different age and sex combinations by Medicaid and the original reason for Medicare entitlement.

SOURCE: RTI International analysis of 2014/2015 100% Medicare data.

Table VI-3. Disease Hierarchies for the 2019 CMS-HCC without Count Variables Model

Hierarchical Condition Category (HCC)	If the Disease Group is Listed in this column…	…Then drop the Disease Group(s) listed in this column
	Hierarchical Condition Category (HCC) Label	
8	Metastatic Cancer and Acute Leukemia	9, 10, 11, 12
9	Lung and Other Severe Cancers	10, 11, 12
10	Lymphoma and Other Cancers	11, 12
11	Colorectal, Bladder, and Other Cancers	12
17	Diabetes with Acute Complications	18, 19
18	Diabetes with Chronic Complications	19
27	End-Stage Liver Disease	28, 29, 80
28	Cirrhosis of Liver	29
46	Severe Hematological Disorders	48
54	Substance Use with Psychotic Complications	55, 56
55	Substance Use Disorder, Moderate/Severe, or Substance Use with Complications	56
57	Schizophrenia	58, 59, 60
58	Reactive and Unspecified Psychosis	59, 60
59	Major Depressive, Bipolar, and Paranoid Disorders	60
70	Quadriplegia	71, 72, 103, 104, 169
71	Paraplegia	72, 104, 169
72	Spinal Cord Disorders/Injuries	169
82	Respirator Dependence/Tracheostomy Status	83, 84
83	Respiratory Arrest	84
86	Acute Myocardial Infarction	87, 88
87	Unstable Angina and Other Acute Ischemic Heart Disease	88
99	Intracranial Hemorrhage	100
103	Hemiplegia/Hemiparesis	104
106	Atherosclerosis of the Extremities with Ulceration or Gangrene	107, 108, 161, 189
107	Vascular Disease with Complications	108
110	Cystic Fibrosis	111, 112
111	Chronic Obstructive Pulmonary Disease	112
114	Aspiration and Specified Bacterial Pneumonias	115
134	Dialysis Status	135, 136, 137, 138
135	Acute Renal Failure	136, 137, 138
136	Chronic Kidney Disease, Stage 5	137, 138
137	Chronic Kidney Disease, Severe (Stage 4)	138
157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	158, 161

Hierarchical Condition Category (HCC)	If the Disease Group is Listed in this column…	…Then drop the Disease Group(s) listed in this column
158	Pressure Ulcer of Skin with Full Thickness Skin Loss	161
166	Severe Head Injury	80, 167

How Payments are Made and Counts are Calculated with a Disease Hierarchy:

EXAMPLE: If a beneficiary triggers Disease Groups 135 (Acute Renal Failure) and 136 (Chronic Kidney Disease, Stage 5), then DG 136 will be dropped. In other words, payment and payment HCC counts 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 and payment HCC counts will be based on DG 135 rather than DG 136.

Table VI-4. 2019 CMS-HCC without Count Variables Model Relative Factors for New Enrollees in Chronic Condition Special Needs Plans (C-SNPs)

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	1.513	1.776	-	-
35-44 Years	1.513	1.776	-	-
45-54 Years	1.513	2.007	-	-
55-59 Years	1.613	2.091	-	-
60-64 Years	1.683	2.119	-	-
65 Years	1.016	1.393	1.820	2.202
66 Years	1.016	1.393	1.820	2.202
67 Years	1.084	1.491	1.837	2.217
68 Years	1.120	1.563	1.837	2.241
69 Years	1.174	1.580	1.837	2.329
70-74 Years	1.319	1.788	2.004	2.416
75-79 Years	1.519	1.965	2.103	2.535
80-84 Years	1.743	2.174	2.453	2.724
85-89 Years	1.960	2.453	2.453	2.724
90-94 Years	2.148	2.633	2.453	2.724
95 Years or Over	2.148	2.633	2.453	2.724
Male				
0-34 Years	1.289	1.547	-	-
35-44 Years	1.289	1.547	-	-
45-54 Years	1.506	1.858	-	-
55-59 Years	1.634	2.037	-	-
60-64 Years	1.673	2.165	-	-
65 Years	0.994	1.533	1.676	2.175
66 Years	0.994	1.533	1.676	2.175
67 Years	1.029	1.651	1.729	2.176
68 Years	1.093	1.651	1.748	2.176
69 Years	1.151	1.651	1.800	2.176
70-74 Years	1.352	1.966	1.935	2.401
75-79 Years	1.585	2.125	2.065	2.481
80-84 Years	1.831	2.251	2.328	2.755
85-89 Years	2.087	2.581	2.328	2.755
90-94 Years	2.340	2.581	2.328	2.755
95 Years or Over	2.340	2.581	2.328	2.755

NOTES:

1. The denominator is $9,367.51.
2. For payment purposes, a new enrollee is a beneficiary who did not have 12 months of Part B eligibility in the data collection year. CMS-HCC new enrollee models are not based on diagnoses, but include factors for different age and sex combinations by Medicaid and the original reason for Medicare entitlement.

SOURCE: RTI International analysis of 2014/2015 100% Medicare data.

Table VI-5. ESRD Model Continuing Enrollee Dialysis Relative Factors

Variable	Description Label	Relative Factors
Female		
0-34 Years		0.618
35-44 Years		0.567
45-54 Years		0.522
55-59 Years		0.535
60-64 Years		0.553
65-69 Years		0.635
70-74 Years		0.653
75-79 Years		0.658
80-84 Years		0.671
85-89 Years		0.671
90-94 Years		0.671
95 Years or Over		0.671
Male		
0-34 Years		0.527
35-44 Years		0.502
45-54 Years		0.478
55-59 Years		0.495
60-64 Years		0.498
65-69 Years		0.562
70-74 Years		0.611
75-79 Years		0.634
80-84 Years		0.652
85-89 Years		0.663
90-94 Years		0.663
95 Years or Over		0.663
Medicaid, Originally Disabled, and Originally ESRD Interactions with Age and Sex		
Medicaid_Female_Aged		0.067
Medicaid_Female_NonAged (Age <65)		0.065
Medicaid_Male_Aged		0.122
Medicaid_Male_NonAged (Age <65)		0.090
Originally Disabled_Female[2]		-
Originally Disabled_Male[2]		-
Originally ESRD_Female[3]		−0.078

Variable	Description Label	Relative Factors
Originally ESRD_Male[3]		−0.049
Disease Coefficients		
HCC1	HIV/AIDS	0.154
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.081
HCC6	Opportunistic Infections	0.052
HCC8	Metastatic Cancer and Acute Leukemia	0.295
HCC9	Lung and Other Severe Cancers	0.169
HCC10	Lymphoma and Other Cancers	0.136
HCC11	Colorectal, Bladder, and Other Cancers	0.076
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.046
HCC17	Diabetes with Acute Complications	0.244
HCC18	Diabetes with Chronic Complications	0.091
HCC19	Diabetes without Complication	0.066
HCC21	Protein-Calorie Malnutrition	0.055
HCC22	Morbid Obesity	0.073
HCC23	Other Significant Endocrine and Metabolic Disorders	0.013
HCC27	End-Stage Liver Disease	0.204
HCC28	Cirrhosis of Liver	0.086
HCC29	Chronic Hepatitis	0.069
HCC33	Intestinal Obstruction/Perforation	0.072
HCC34	Chronic Pancreatitis	0.073
HCC35	Inflammatory Bowel Disease	0.053
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.061
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.072
HCC46	Severe Hematological Disorders	0.180
HCC47	Disorders of Immunity	0.097
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.059
HCC51	Dementia With Complications	0.097
HCC52	Dementia Without Complication	0.045
HCC54	Drug/Alcohol Psychosis	0.048
HCC55	Drug/Alcohol Dependence	0.048
HCC57	Schizophrenia	0.142

Variable	Description Label	Relative Factors
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.091
HCC70	Quadriplegia	0.274
HCC71	Paraplegia	0.200
HCC72	Spinal Cord Disorders/Injuries	0.102
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.117
HCC74	Cerebral Palsy	0.036
HCC75	Polyneuropathy	0.059
HCC76	Muscular Dystrophy	0.062
HCC77	Multiple Sclerosis	0.069
HCC78	Parkinson's and Huntington's Diseases	0.065
HCC79	Seizure Disorders and Convulsions	0.066
HCC80	Coma, Brain Compression/Anoxic Damage	0.043
HCC82	Respirator Dependence/Tracheostomy Status	0.242
HCC83	Respiratory Arrest	0.114
HCC84	Cardio-Respiratory Failure and Shock	0.044
HCC85	Congestive Heart Failure	0.082
HCC86	Acute Myocardial Infarction	0.131
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.116
HCC88	Angina Pectoris	0.048
HCC96	Specified Heart Arrhythmias	0.093
HCC99	Cerebral Hemorrhage	0.078
HCC100	Ischemic or Unspecified Stroke	0.078
HCC103	Hemiplegia/Hemiparesis	0.086
HCC104	Monoplegia, Other Paralytic Syndromes	0.077
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	0.321
HCC107	Vascular Disease with Complications	0.126
HCC108	Vascular Disease	0.065
HCC110	Cystic Fibrosis	0.072
HCC111	Chronic Obstructive Pulmonary Disease	0.072
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.066
HCC114	Aspiration and Specified Bacterial Pneumonias	0.063
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.013

Variable	Description Label	Relative Factors
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	-
HCC124	Exudative Macular Degeneration	0.055
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	0.277
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	0.161
HCC159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	0.147
HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	0.147
HCC161	Chronic Ulcer of Skin, Except Pressure	0.119
HCC162	Severe Skin Burn or Condition	0.042
HCC166	Severe Head Injury	0.043
HCC167	Major Head Injury	0.017
HCC169	Vertebral Fractures without Spinal Cord Injury	0.065
HCC170	Hip Fracture/Dislocation	0.050
HCC173	Traumatic Amputations and Complications	0.042
HCC176	Complications of Specified Implanted Device or Graft	-
HCC186	Major Organ Transplant or Replacement Status	0.154
HCC188	Artificial Openings for Feeding or Elimination	0.078
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.090
Disease Interactions		
SEPSIS_CARD_RESP_FAIL	Sepsis*Cardiorespiratory Failure	0.038
CANCER_IMMUNE	Cancer*Immune Disorders	0.025
DIABETES_CHF	Diabetes*Congestive Heart Failure	-
CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.022
COPD_CARD_RESP_FAIL	Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure	0.024
NonAged (Age <65)/Disease Interactions		
NONAGED_HCC6	NonAged, Opportunistic Infections	0.073
NONAGED_HCC34	NonAged, Chronic Pancreatitis	0.113
NONAGED_HCC46	NonAged, Severe Hematological Disorders	0.157
NONAGED_HCC54	NonAged, Drug/Alcohol Psychosis	0.133

Variable	Description Label	Relative Factors
NONAGED_HCC55	NonAged, Drug/Alcohol Dependence	0.122
NONAGED_HCC110	NonAged, Cystic Fibrosis	0.298
NONAGED_HCC176	NonAged, Complications of Specified Implanted Device or Graft	0.040

NOTES:

1. The CMS ESRD Dialysis Denominator used to calculate the relative factors is $82,113.76.
2. Originally Disabled indicates beneficiary originally entitled to Medicare for reasons of disability other than ESRD.
3. Originally ESRD indicates beneficiary originally entitled to Medicare due to ESRD. Beneficiaries who are Originally ESRD cannot be Originally Disabled.
4. In the "disease interactions," the variables are defined as follows:
   Sepsis = HCC 2.
   Cardiorespiratory Failure = HCCs 82-84.
   Cancer = HCCs 8-12.
   Immune Disorders = HCC 47.
   Diabetes = HCCs 17, 18, 19.
   Congestive Heart Failure = HCC 85.
   Chronic Obstructive Pulmonary Disease = HCCs 110-111.

SOURCE: RTI International analysis of 2014/2015 Medicare 100% ESRD claims and enrollment data.

Table VI-6. ESRD Model Demographic Relative Factors for New Enrollees in Dialysis Status

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	0.793	1.066	1.120	1.328
35-44 Years	0.793	1.028	1.120	1.328
45-54 Years	0.877	1.029	1.120	1.368
55-59 Years	0.917	1.049	1.120	1.368
60-64 Years	0.975	1.112	1.181	1.387
65-69 Years	1.121	1.295	1.236	1.409
70-74 Years	1.191	1.397	1.331	1.444
75-79 Years	1.191	1.397	1.380	1.488
80-84 Years	1.221	1.397	1.380	1.488
85 Years or Over	1.164	1.454	1.380	1.488
Male				
0-34 Years	0.700	0.897	1.001	1.246
35-44 Years	0.700	0.922	1.001	1.246
45-54 Years	0.759	0.950	1.001	1.271
55-59 Years	0.865	1.015	1.033	1.292
60-64 Years	0.905	1.064	1.033	1.361
65-69 Years	1.025	1.249	1.033	1.361
70-74 Years	1.127	1.382	1.220	1.474
75-79 Years	1.181	1.382	1.253	1.474
80-84 Years	1.175	1.382	1.253	1.474
85 Years or Over	1.161	1.485	1.253	1.474

NOTES:

1. The CMS ESRD Dialysis Denominator used to calculate the relative factors is $82,113.76.
2. Originally Disabled terms refer to beneficiaries originally entitled to Medicare for reasons of disability other than ESRD.

SOURCE: RTI International analysis of 2014/2015 Medicare 100% ESRD claims and enrollment data.

Table VI-7. ESRD Kidney Transplant CMS-HCC Model Relative Factors for Transplant Beneficiaries

	Beneficiaries	**Kidney Transplant** *Actual Dollars*	**Kidney Transplant Relative Risk Factor**
Month 1	9,606	$41,260.76	6.030
Months 2 and 3	18,651	6,126.29	0.895
Total (Actual Months 1-3)		**$53,493.60**	

NOTES:

1. Kidney transplant is identified by MS-DRG 652.
2. The transplant month payments were computed by aggregating the costs for each of the three monthly payments.
3. The transplant factor is calculated in this manner: (kidney transplant month's dollars/Dialysis Denominator) × 12. The CMS ESRD Dialysis Denominator value used was $82,113.76.

SOURCE: RTI International analysis of 2014/2015 Medicare 100% ESRD claims and enrollment data.

Table VI-8. ESRD Model Functioning Graft Relative Factors for Community Population

Variable	Description Label	Relative Factors
Functioning Graft Factors		
Aged 65+, with duration since transplant of 4-9 months		2.562
Aged <65, with duration since transplant of 4-9 months		2.174
Aged 65+, with duration since transplant of 10 months or more		1.121
Aged <65, with duration since transplant of 10 months or more		0.840
Female		
0-34 Years		0.196
35-44 Years		0.219
45-54 Years		0.256
55-59 Years		0.306
60-64 Years		0.360
65-69 Years		0.291
70-74 Years		0.350
75-79 Years		0.406
80-84 Years		0.480
85-89 Years		0.590
90-94 Years		0.724
95 Years or Over		0.737
Male		
0-34 Years		0.067
35-44 Years		0.076
45-54 Years		0.149
55-59 Years		0.226
60-64 Years		0.297
65-69 Years		0.274
70-74 Years		0.353
75-79 Years		0.425
80-84 Years		0.499
85-89 Years		0.625
90-94 Years		0.775
95 Years or Over		0.914
Medicaid and Originally Disabled Interactions with Age and Sex		
Medicaid_Female_Aged		0.275
Medicaid_Female_NonAged (Age <65)		0.137
Medicaid_Male_Aged		0.367
Medicaid_Male_NonAged (Age <65)		0.190

Variable	Description Label	Relative Factors
Originally Disabled_Female_Age ≥65		0.184
Originally Disabled_Male_Age ≥65		0.115
Disease Coefficients		
HCC1	HIV/AIDS	0.350
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.428
HCC6	Opportunistic Infections	0.426
HCC8	Metastatic Cancer and Acute Leukemia	2.627
HCC9	Lung and Other Severe Cancers	0.975
HCC10	Lymphoma and Other Cancers	0.668
HCC11	Colorectal, Bladder, and Other Cancers	0.298
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.156
HCC17	Diabetes with Acute Complications	0.243
HCC18	Diabetes with Chronic Complications	0.243
HCC19	Diabetes without Complication	0.094
HCC21	Protein-Calorie Malnutrition	0.593
HCC22	Morbid Obesity	0.278
HCC23	Other Significant Endocrine and Metabolic Disorders	0.234
HCC27	End-Stage Liver Disease	1.028
HCC28	Cirrhosis of Liver	0.384
HCC29	Chronic Hepatitis	0.243
HCC33	Intestinal Obstruction/Perforation	0.285
HCC34	Chronic Pancreatitis	0.282
HCC35	Inflammatory Bowel Disease	0.362
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.468
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.398
HCC46	Severe Hematological Disorders	1.325
HCC47	Disorders of Immunity	0.688
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.234
HCC51	Dementia With Complications	0.643
HCC52	Dementia Without Complication	0.328
HCC54	Drug/Alcohol Psychosis	0.352
HCC55	Drug/Alcohol Dependence	0.352
HCC57	Schizophrenia	0.442

Variable	Description Label	Relative Factors
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.260
HCC70	Quadriplegia	1.112
HCC71	Paraplegia	0.943
HCC72	Spinal Cord Disorders/Injuries	0.456
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	1.030
HCC74	Cerebral Palsy	-
HCC75	Polyneuropathy	0.284
HCC76	Muscular Dystrophy	0.544
HCC77	Multiple Sclerosis	0.546
HCC78	Parkinson's and Huntington's Diseases	0.583
HCC79	Seizure Disorders and Convulsions	0.221
HCC80	Coma, Brain Compression/Anoxic Damage	0.184
HCC82	Respirator Dependence/Tracheostomy Status	1.231
HCC83	Respiratory Arrest	0.540
HCC84	Cardio-Respiratory Failure and Shock	0.345
HCC85	Congestive Heart Failure	0.336
HCC86	Acute Myocardial Infarction	0.258
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.258
HCC88	Angina Pectoris	0.129
HCC96	Specified Heart Arrhythmias	0.303
HCC99	Cerebral Hemorrhage	0.252
HCC100	Ischemic or Unspecified Stroke	0.252
HCC103	Hemiplegia/Hemiparesis	0.467
HCC104	Monoplegia, Other Paralytic Syndromes	0.307
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	1.385
HCC107	Vascular Disease with Complications	0.431
HCC108	Vascular Disease	0.271
HCC110	Cystic Fibrosis	0.494
HCC111	Chronic Obstructive Pulmonary Disease	0.313
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.281

Variable	Description Label	Relative Factors
HCC114	Aspiration and Specified Bacterial Pneumonias	0.596
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.155
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.248
HCC124	Exudative Macular Degeneration	0.512
HCC134	Dialysis Status	–
HCC135	Acute Renal Failure	–
HCC136	Chronic Kidney Disease, Stage 5	–
HCC137	Chronic Kidney Disease, Severe (Stage 4)	–
HCC138	Chronic Kidney Disease, Moderate (Stage 3)	–
HCC139	Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)	–
HCC140	Unspecified Renal Failure	–
HCC141	Nephritis	–
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	2.492
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	1.285
HCC159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	0.955
HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	0.799
HCC161	Chronic Ulcer of Skin, Except Pressure	0.503
HCC162	Severe Skin Burn or Condition	0.370
HCC166	Severe Head Injury	0.184
HCC167	Major Head Injury	0.184
HCC169	Vertebral Fractures without Spinal Cord Injury	0.456
HCC170	Hip Fracture/Dislocation	0.350
HCC173	Traumatic Amputations and Complications	0.290
HCC176	Complications of Specified Implanted Device or Graft	0.599
HCC186	Major Organ Transplant or Replacement Status	0.075

Variable	Description Label	Relative Factors
HCC188	Artificial Openings for Feeding or Elimination	0.643
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.654
Disease Interactions		
SEPSIS_CARD_RESP_FAIL	Sepsis*Cardiorespiratory Failure	0.133
CANCER_IMMUNE	Cancer*Immune Disorders	0.773
DIABETES_CHF	Diabetes*Congestive Heart Failure	0.160
CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.227
CHF_RENAL	Congestive Heart Failure*Renal Disease	–
COPD_CARD_RESP_FAIL	Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure	0.453
NonAged (Age <65)/Disease Interactions		
NONAGED_HCC6	NonAged, Opportunistic Infections	0.561
NONAGED_HCC34	NonAged, Chronic Pancreatitis	0.534
NONAGED_HCC46	NonAged, Severe Hematological Disorders	2.791
NONAGED_HCC54	NonAged, Drug/Alcohol Psychosis	0.549
NONAGED_HCC55	NonAged, Drug/Alcohol Dependence	0.066
NONAGED_HCC110	NonAged, Cystic Fibrosis	2.746
NONAGED_HCC176	NonAged, Complications of Specified Implanted Device or Graft	–

NOTES:

1. The Denominator used to calculate the relative factors is $9,366.89.
2. The coefficients estimated for this model are the Functioning Graft add-on factors for being in a month after the 3 months accounted for in the Transplant segment of the ESRD system. Early months post-transplant incur higher Medicare spending than later months. The model differentiates the six months, months 4-9, from months further from the transplant period.
3. Originally Disabled terms refer to beneficiaries originally entitled to Medicare for reasons of disability other than ESRD.
4. In the "disease interactions," the variables are defined as follows:
   Sepsis = HCC 2.
   Cardiorespiratory Failure = HCCs 82-84.
   Cancer = HCCs 8-12.
   Immune Disorders = HCC 47.
   Diabetes = HCCs 17, 18, 19.
   Congestive Heart Failure = HCC 85.
   Chronic Obstructive Pulmonary Disease = HCCs 110-111.
   Renal Disease = HCCs 134-141.

SOURCE: RTI International analysis of 2014/2015 100% ESRD sample claims and enrollment data and 2014/2015 Medicare 100% sample.

Table VI-9. ESRD Model Functioning Graft Relative Factors for Institutionalized Population

Variable	Description Label	Relative Factors
Functioning Graft Factors		
Aged 65+, with duration since transplant of 4-9 months		2.562
Aged <65, with duration since transplant of 4-9 months		2.174
Aged 65+, with duration since transplant of 10 months or more		1.121
Aged <65, with duration since transplant of 10 months or more		0.840
Female		
0-34 Years		0.848
35-44 Years		1.061
45-54 Years		0.992
55-59 Years		1.014
60-64 Years		1.017
65-69 Years		1.212
70-74 Years		1.120
75-79 Years		0.988
80-84 Years		0.861
85-89 Years		0.780
90-94 Years		0.651
95 Years or Over		0.484
Male		
0-34 Years		1.055
35-44 Years		0.956
45-54 Years		0.924
55-59 Years		0.971
60-64 Years		1.013
65-69 Years		1.267
70-74 Years		1.306
75-79 Years		1.295
80-84 Years		1.188
85-89 Years		1.101
90-94 Years		0.969
95 Years or Over		0.799
Medicaid and Originally Disabled		
Medicaid		0.074
Originally Disabled_Age ≥65		-
Disease Coefficients		
HCC1	HIV/AIDS	1.708

Variable	Description Label	Relative Factors
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.274
HCC6	Opportunistic Infections	0.568
HCC8	Metastatic Cancer and Acute Leukemia	1.289
HCC9	Lung and Other Severe Cancers	0.604
HCC10	Lymphoma and Other Cancers	0.451
HCC11	Colorectal, Bladder, and Other Cancers	0.284
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.194
HCC17	Diabetes with Acute Complications	0.373
HCC18	Diabetes with Chronic Complications	0.373
HCC19	Diabetes without Complication	0.165
HCC21	Protein-Calorie Malnutrition	0.252
HCC22	Morbid Obesity	0.429
HCC23	Other Significant Endocrine and Metabolic Disorders	0.359
HCC27	End-Stage Liver Disease	0.863
HCC28	Cirrhosis of Liver	0.479
HCC29	Chronic Hepatitis	0.479
HCC33	Intestinal Obstruction/Perforation	0.346
HCC34	Chronic Pancreatitis	0.422
HCC35	Inflammatory Bowel Disease	0.341
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.375
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.274
HCC46	Severe Hematological Disorders	0.766
HCC47	Disorders of Immunity	0.549
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.173
HCC51	Dementia With Complications	-

Variable	Description Label	Relative Factors
HCC52	Dementia Without Complication	-
HCC54	Drug/Alcohol Psychosis	0.112
HCC55	Drug/Alcohol Dependence	0.112
HCC57	Schizophrenia	0.217
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.217
HCC70	Quadriplegia	0.512
HCC71	Paraplegia	0.435
HCC72	Spinal Cord Disorders/Injuries	0.256
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.446
HCC74	Cerebral Palsy	-
HCC75	Polyneuropathy	0.323
HCC76	Muscular Dystrophy	0.296
HCC77	Multiple Sclerosis	-
HCC78	Parkinson's and Huntington's Diseases	0.141
HCC79	Seizure Disorders and Convulsions	0.065
HCC80	Coma, Brain Compression/Anoxic Damage	-
HCC82	Respirator Dependence/Tracheostomy Status	1.602
HCC83	Respiratory Arrest	0.466
HCC84	Cardio-Respiratory Failure and Shock	0.311
HCC85	Congestive Heart Failure	0.186
HCC86	Acute Myocardial Infarction	0.392
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.392
HCC88	Angina Pectoris	0.392
HCC96	Specified Heart Arrhythmias	0.247
HCC99	Cerebral Hemorrhage	0.105
HCC100	Ischemic or Unspecified Stroke	0.105
HCC103	Hemiplegia/Hemiparesis	-
HCC104	Monoplegia, Other Paralytic Syndromes	-

Variable	Description Label	Relative Factors
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	0.754
HCC107	Vascular Disease with Complications	0.300
HCC108	Vascular Disease	0.086
HCC110	Cystic Fibrosis	0.435
HCC111	Chronic Obstructive Pulmonary Disease	0.299
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.299
HCC114	Aspiration and Specified Bacterial Pneumonias	0.143
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.143
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.388
HCC124	Exudative Macular Degeneration	0.209
HCC134	Dialysis Status	–
HCC135	Acute Renal Failure	–
HCC136	Chronic Kidney Disease, Stage 5	–
HCC137	Chronic Kidney Disease, Severe (Stage 4)	–
HCC138	Chronic Kidney Disease, Moderate (Stage 3)	–
HCC139	Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)	–
HCC140	Unspecified Renal Failure	–
HCC141	Nephritis	–
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	0.968
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	0.378
HCC159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	0.225
HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	0.225

Variable	Description Label	Relative Factors
HCC161	Chronic Ulcer of Skin, Except Pressure	0.225
HCC162	Severe Skin Burn or Condition	-
HCC166	Severe Head Injury	-
HCC167	Major Head Injury	-
HCC169	Vertebral Fractures without Spinal Cord Injury	0.237
HCC170	Hip Fracture/Dislocation	-
HCC173	Traumatic Amputations and Complications	0.061
HCC176	Complications of Specified Implanted Device or Graft	0.599
HCC186	Major Organ Transplant or Replacement Status	0.075
HCC188	Artificial Openings for Feeding or Elimination	0.482
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.339
Disease Interactions		
CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.190
CRFAIL_COPD	Cardiorespiratory Failure*Chronic Obstructive Pulmonary Disease	0.416
SEPSIS_PRESSURE_ULCER	Sepsis*Pressure Ulcer	0.226
SEPSIS_ARTIF_OPENINGS	Sepsis*Artificial Openings for Feeding or Elimination	0.452
ARTIF_OPENINGS_ PRESSURE_ULCER	Artificial Openings for Feeding or Elimination*Pressure Ulcer	0.295
DIABETES_CHF	Diabetes*Congestive Heart Failure	0.159
COPD_ASP_SPEC_ BACT_PNEUM	Chronic Obstructive Pulmonary Disease*Aspiration and Specified Bacterial Pneumonias	0.220
ASP_SPEC_BACT_PNEUM_ PRES_ULCER	Aspiration and Specified Bacterial Pneumonias*Pressure Ulcer	0.252
SEPSIS_ASP_SPEC_ BACT_PNEUM	Sepsis*Aspiration and Specified Bacterial Pneumonias	0.347
SCHIZOPHRENIA_COPD	Schizophrenia*Chronic Obstructive Pulmonary Disease	0.402

Variable	Description Label	Relative Factors
SCHIZOPHRENIA_CHF	Schizophrenia*Congestive Heart Failure	0.122
SCHIZOPHRENIA_SEIZURES	Schizophrenia*Seizure Disorders and Convulsions	0.541
NonAged (Age <65)/Disease Interactions		
NONAGED_HCC85	NonAged, Congestive Heart Failure	0.263
NONAGED_PRESSURE_ULCER	NonAged, Pressure Ulcer	0.528
NONAGED_HCC161	NonAged, Chronic Ulcer of the Skin, Except Pressure Ulcer	0.469
NONAGED_HCC39	NonAged, Bone/Joint Muscle Infections/Necrosis	0.447
NONAGED_HCC77	NonAged, Multiple Sclerosis	0.448
NONAGED_HCC6	NonAged, Opportunistic Infections	0.314

NOTES:

1. The Denominator used to calculate the relative factors is $9,366.89.
2. The coefficients estimated for this model are the Functioning Graft add-on factors for being in a month after the 3 months accounted for in the Transplant segment of the ESRD system. Early months post-transplant incur higher Medicare spending than later months. The model differentiates the six months, months 4-9, from months further from the transplant period.
3. Originally Disabled terms refer to beneficiaries originally entitled to Medicare for reasons of disability other than ESRD.
4. In the "Disease interactions" and "Non-Aged interactions," the variables are defined as follows:
   Sepsis = HCC 2.
   Cardiorespiratory Failure = HCCs 82-84.
   Diabetes = HCCs 17, 18, 19.
   Congestive Heart Failure = HCC 85.
   Chronic Obstructive Pulmonary Disease = HCCs 110-111.
   Pressure Ulcer = HCCs 157-160.
   Artificial Openings for Feeding or Elimination = HCC 188.
   Aspiration and Specified Bacterial Pneumonias = HCC 114.
   Schizophrenia = HCC 57.
   Seizure Disorders and Convulsions = HCC 79.
   Chronic Ulcer of Skin, except Pressure = HCC 161.
   Bone/Joint/Muscle Infections/Necrosis = HCC 39.
   Multiple Sclerosis = HCC 77.
   Opportunistic Infections = HCC 6.

SOURCE: RTI International analysis of 2014/2015 100% ESRD sample claims and enrollment data and 2014/2015 Medicare 100% institutional sample.

Table VI-10. ESRD Model Demographic Relative Factors for Functioning Graft New Enrollees Duration Since Transplant of 4-9 Months

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	2.978	3.143	–	–
35-44 Years	3.121	3.376	–	–
45-54 Years	3.189	3.479	–	–
55-59 Years	3.190	3.481	–	–
60-64 Years	3.307	3.582	–	–
65 Years	3.082	3.555	3.629	4.019
66 Years	3.077	3.459	3.629	4.019
67 Years	3.106	3.481	3.629	4.565
68 Years	3.159	3.512	3.846	4.565
69 Years	3.162	3.512	3.846	4.565
70-74 Years	3.252	3.547	3.846	4.565
75-79 Years	3.422	3.695	3.846	4.565
80-84 Years	3.576	3.914	3.846	4.565
85-89 Years	3.856	4.097	3.846	4.565
90-94 Years	3.856	4.263	3.846	4.565
95 Years or Over	3.856	4.263	3.846	4.565
Male				
0-34 Years	2.616	2.908	–	–
35-44 Years	2.831	3.233	–	–
45-54 Years	3.038	3.527	–	–
55-59 Years	3.077	3.592	–	–
60-64 Years	3.122	3.724	–	–
65 Years	3.079	3.706	3.388	4.373
66 Years	3.095	3.656	3.633	4.760
67 Years	3.144	3.713	3.685	4.760
68 Years	3.188	3.764	3.685	4.760
69 Years	3.252	3.764	3.961	4.760
70-74 Years	3.347	3.860	3.961	4.760
75-79 Years	3.621	3.969	3.961	4.760
80-84 Years	3.808	4.117	3.961	4.760
85-89 Years	4.038	4.339	3.961	4.760
90-94 Years	4.038	4.339	3.961	4.760
95 Years or Over	4.038	4.339	3.961	4.760

NOTES:

1. The relative factors are derived from the Graft New Enrollee model. The Denominator used to calculate the relative factors is $9,366.89.
2. Originally Disabled terms refer to beneficiaries originally entitled to Medicare for reasons of disability other than ESRD. In this model, Originally Disabled is defined only for beneficiaries age 65 and over.

SOURCE: RTI International analysis of 2014/2015 100% ESRD sample claims and enrollment data and 2014/2015 Medicare 100% sample.

Table VI-11. ESRD Model Demographic Relative Factors for Functioning Graft New Enrollees Duration Since Transplant of 10 Months or More

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	1.644	1.809	–	–
35-44 Years	1.787	2.042	–	–
45-54 Years	1.855	2.145	–	–
55-59 Years	1.856	2.147	–	–
60-64 Years	1.973	2.248	–	–
65 Years	1.641	2.114	2.188	2.578
66 Years	1.636	2.018	2.188	2.578
67 Years	1.665	2.040	2.188	3.124
68 Years	1.718	2.071	2.405	3.124
69 Years	1.721	2.071	2.405	3.124
70-74 Years	1.811	2.106	2.405	3.124
75-79 Years	1.981	2.254	2.405	3.124
80-84 Years	2.135	2.473	2.405	3.124
85-89 Years	2.415	2.656	2.405	3.124
90-94 Years	2.415	2.822	2.405	3.124
95 Years or Over	2.415	2.822	2.405	3.124
Male				
0-34 Years	1.282	1.574	–	–
35-44 Years	1.497	1.899	–	–
45-54 Years	1.704	2.193	–	–
55-59 Years	1.743	2.258	–	–
60-64 Years	1.788	2.390	–	–
65 Years	1.638	2.265	1.947	2.932
66 Years	1.654	2.215	2.192	3.319
67 Years	1.703	2.272	2.244	3.319
68 Years	1.747	2.323	2.244	3.319
69 Years	1.811	2.323	2.520	3.319
70-74 Years	1.906	2.419	2.520	3.319
75-79 Years	2.180	2.528	2.520	3.319
80-84 Years	2.367	2.676	2.520	3.319
85-89 Years	2.597	2.898	2.520	3.319
90-94 Years	2.597	2.898	2.520	3.319
95 Years or Over	2.597	2.898	2.520	3.319

NOTES:

1. The relative factors are derived from the Graft New Enrollee model. The Denominator used to calculate the relative factors is $9,366.89.
2. Originally Disabled terms refer to beneficiaries originally entitled to Medicare for reasons of disability other than ESRD. In this model, Originally Disabled is defined only for beneficiaries age 65 and over.

SOURCE: RTI International analysis of 2014/2015 100% ESRD sample claims and enrollment data and 2014/2015 Medicare 100% sample.

Table VI-12. List of Disease Hierarchies for the ESRD Model

DISEASE HIERARCHIES		
Hierarchical Condition Category (HCC)	**If the Disease Group is Listed in this column…**	**…Then drop the HCC(s) listed in this column**
	Hierarchical Condition Category (HCC) Label	
8	Metastatic Cancer and Acute Leukemia	9, 10, 11, 12
9	Lung and Other Severe Cancers	10, 11, 12
10	Lymphoma and Other Cancers	11, 12
11	Colorectal, Bladder, and Other Cancers	12
17	Diabetes with Acute Complications	18, 19
18	Diabetes with Chronic Complications	19
27	End-Stage Liver Disease	28, 29, 80
28	Cirrhosis of Liver	29
46	Severe Hematological Disorders	48
51	Dementia With Complications	52
54	Drug/Alcohol Psychosis	55
57	Schizophrenia	58
70	Quadriplegia	71, 72, 103, 104, 169
71	Paraplegia	72, 104, 169
72	Spinal Cord Disorders/Injuries	169
82	Respirator Dependence/Tracheostomy Status	83, 84
83	Respiratory Arrest	84
86	Acute Myocardial Infarction	87, 88
87	Unstable Angina and Other Acute Ischemic Heart Disease	88
99	Cerebral Hemorrhage	100
103	Hemiplegia/Hemiparesis	104
106	Atherosclerosis of the Extremities with Ulceration or Gangrene	107, 108, 161, 189
107	Vascular Disease with Complications	108
110	Cystic Fibrosis	111, 112
111	Chronic Obstructive Pulmonary Disease	112
114	Aspiration and Specified Bacterial Pneumonias	115
134	Dialysis Status	135, 136, 137, 138, 139, 140, 141
135	Acute Renal Failure	136, 137, 138, 139, 140, 141
136	Chronic Kidney Disease, Stage 5	137, 138, 139, 140, 141
137	Chronic Kidney Disease, Severe (Stage 4)	138, 139, 140, 141
138	Chronic Kidney Disease, Moderate (Stage 3)	139, 140, 141
139	Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)	140, 141
140	Unspecified Renal Failure	141
157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	158, 159, 160, 161
158	Pressure Ulcer of Skin with Full Thickness Skin Loss	159, 160, 161

DISEASE HIERARCHIES		
Hierarchical Condition Category (HCC)	**If the Disease Group is Listed in this column…**	**…Then drop the HCC(s) listed in this column**
159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	160, 161
160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	161
166	Severe Head Injury	80, 167

How Payments are Made with a Disease Hierarchy:

EXAMPLE: If a beneficiary triggers Disease Groups 8 (Metastatic Cancer and Acute Leukemia) and 9 (Lung and Other Severe Cancers), then DG 9 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 8 rather than DG 9.

SOURCE: RTI International.

Attachment VII. CY 2019 Final Call Letter

2019 Final Call Letter
Table of Contents

How to Use This Call Letter

The CY 2019 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 2019 bids.

CMS has designed the policies contained in this Call Letter to improve the overall management of the Medicare Advantage and Prescription Drug programs. CMS aims to expand flexibilities so that plans and providers are empowered to meet the needs of Medicare beneficiaries at the local level, while increasing beneficiary choice and improving the patient/physician relationship. The policies in the Call Letter also reflect CMS efforts to increase transparency in our decision-making and promote innovation.

If you have questions concerning this Call Letter, please contact: Kim Levin at Kimberlee.Levin@cms.hhs.gov (Part C issues), Lucia Patrone at Lucia.Patrone@cms.hhs.gov (Part D issues), or 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 such as the date bids are due to CMS, the date that organizations must inform CMS of their contract non-renewal, and dates for beneficiary mailings.

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 1 – February 14, 2018	Annual 45-Day Medicare Advantage Disenrollment Period (MADP).	✓			
January 9, 2018	Release of Contract Year CY 2019 Initial and Service Area Applications for MA/MA-PD/PDP, MMP, SNP, EGWP, and 1876 Cost Plan Expansions.	✓	✓	✓	✓
January 10, 2018	Model of Care (MOC) Renewal Submission period begins for SNP MOCs with approvals ending 12/31/2018.	✓			
January 2018	Industry Training and Technical Assistance for CY 2019 MOC Submissions.	✓			
January 2018	Industry training on 2019 Applications.	✓	✓	✓	✓
February 14, 2018	CY 2019 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 14, 2018	MOC Renewals Submissions for SNP MOCs with approvals ending as of 12/31/2018 are due in HPMS by 8pm EST.	✓			
Late February, 2018	Submission of meaningful use HITECH attestation for qualifying MA Employer Plans and MA-affiliated hospitals.	✓			
February, 2018	CMS releases instructional memo concerning updates to Parent Organization designations in HPMS.	✓	✓	✓	✓
February, 2018	Release of draft CY 2019 Formulary Reference File (FRF).	✓	✓	✓	✓
March 16, 2018	Parent Organization Update requests from MAOs and sponsors due to CMS (instructional memo released in February 2018).	✓	✓	✓	✓
Mid-Late March, 2018	Release of CY 2019 Formulary Reference File.	✓	✓	✓	✓

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
Late March 2018	Release of the Fiscal Soundness Module in HPMS.	✓	✓	✓	✓
March/April, 2018	CMS coordinates with MAOs and PDP Sponsors to resolve low enrollment issues for CY 2019.	✓	✓	✓	
Early April, 2018	CY 2019 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 satisfying MA and Part D requirements, such as meeting meaningful difference (if applicable) and Total Beneficiary Cost (TBC) requirements prior to bid submission.	✓	✓	✓	
Early April, 2018	Information about renewal options for CY 2019 (including HPMS crosswalk charts) provided to plans.	✓	✓		
April 2, 2018	Release of the 2019 Final Announcement of Medicare Advantage Capitation Rates and MA and Part D Payment Policies released, including the CY 2019 Call Letter.	✓	✓	✓	✓
April 2018	Conference call with stakeholders to discuss the Rate Announcement and CY 2019 Call Letter.	✓	✓	✓	✓
April 6, 2018	Release of the CY 2019 Plan Creation Module, PBP, and Bid Pricing Tool (BPT) software in HPMS.	✓	✓	✓	✓
April 10, 2018	Deadline for MAOs and cost plans to submit requests for full contract consolidations for CY 2018.	✓		✓	
Mid-April, 2018	Release of HPMS Memo: Contract Year 2019 Medicare Advantage Bid Review and Operations Guidance.	✓		✓	
April 16, 2018	Release of the CY 2019 Medication Therapy Management (MTM) Program Submission in HPMS (11:59 p.m. PDT).		✓		✓
April 18, 2018	CY 2019 Part D Formulary and Benefit Submission/Compliance Training.	✓	✓	✓	✓
Late April, 2018	Total Beneficiary Cost data for CY 2019 Bid Preparation Release.	✓			
April 30, 2018	Deadline for submission of CY 2019 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, 2018	Final ANOC/EOC, LIS rider, Part D EOB, formularies, transition notice, provider directory, pharmacy directory, and MMP models for CY 2019 available for all organizations.	✓	✓	✓	✓

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 May 2018	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.	✓	✓	✓	
May, 2018	2018 Medicare Advantage & Prescription Drug Plan Spring Conference & Webcast.	✓	✓	✓	✓
May 4, 2018	Release of the CY 2019 Bid Upload Functionality in HPMS.	✓	✓	✓	✓
May 14, 2018	Deadline for submission of CY 2019 MTM Program attestations in HPMS (11:59pm PDT).		✓		✓
May 14, 2018	Release of CY 2019 Formulary Submission Module in HPMS.	✓	✓	✓	✓
May 18, 2018	Release of CY 2019 Actuarial Certification Module in HPMS.	✓	✓	✓	
Mid-Late May, 2018	Release of CY 2019 Formulary Reference File Update.	✓	✓	✓	✓
May 25, 2018	Plans/Part D sponsors begin to upload agent/broker compensation information in HPMS.	✓	✓	✓	✓
May 31, 2018	Release of the 2017 DIR Submission Module in HPMS.	✓	✓	✓	✓
Late May, 2018	CMS sends qualification determinations to applicants based on review of the CY 2019 applications for new contracts or service area expansions.	✓	✓	✓	✓
June 1, 2018	Release of the CY 2019 Marketing Module in HPMS. Plans/Part D sponsors begin to submit 2019 marketing materials.	✓	✓	✓	✓
Mid to late June, 2018	Release of the CY 2019 Medicare Marketing Guidelines in HPMS.	✓	✓	✓	✓
June 2018	Release of state-specific marketing guidance for MMPs.				✓

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	Deadline for submission of CY 2019 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 2019 Medicare Plan Finder to submit PBPs (11:59 p.m. PDT). Deadline for submission of CY 2019 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 2019 contract non-renewal, service area reduction via HPMS from MA plans, MA-PD plans, MMPs, PDPs and Medicare cost-based contractors and cost- based sponsors. 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 2019.	✓	✓	✓	✓ *Non-bid related items only*
Early June to Late August, 2018	CMS completes review and approval of CY 2019 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, 2018	Window for submitting first round of crosswalk exception requests through HPMS.	✓	✓	✓	
June 8, 2018	Deadline for submission of CY 2019 Supplemental Formulary files, Free First Fill file, Partial Gap file, Excluded Drug file, Over the Counter (OTC) drug file, and Home Infusion file through HPMS (11:59 a.m. EDT).		✓		✓
June 8, 2018	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 8, 2018	Deadline for submission of Additional Demonstration Drug (ADD) file (MMPs only) (11:59 a.m. EDT).				✓
June, 2018	2018 MA and PDP Audit and Enforcement Conference and Webcast.	✓	✓	✓	✓
Late June, 2018	CMS sends an acknowledgement letter to all MA, MA-PD, MMP, PDP and Medicare cost-based plans that are non-renewing or reducing their service area.	✓	✓	✓	✓
Early July, 2018	2019 Plan Finder pricing test submissions begin.	✓	✓	✓	✓

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, 2018	Deadline for D-SNPs to upload required State Medicaid Agency Contract and Contract Matrix to HPMS.	✓			
Early July, 2018	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, 2018	Release of CY 2019 FRF Update in advance of the Limited Formulary Update Window.	✓	✓	✓	✓
Mid-Late July, 2018	CY 2019 Limited Formulary Update Window.	✓	✓	✓	✓
Late July, 2018	Submission deadline for agent/broker compensation information via HPMS.	✓	✓	✓	✓
July 2018	Second window for submitting HPMS crosswalk exceptions.	✓	✓	✓	
Late July / Early August, 2018	CMS releases the 2019 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, 2018	Rebate reallocation period begins after release of the above bid amounts.	✓	✓	✓	
No Later Than July 29, 2018	CMS informs currently contracted organizations of its decision to not renew a contract for 2019.	✓	✓	✓	
August 1, 2018	Plans expected to submit model Low Income Subsidy (LIS) riders in HPMS.	✓	✓	✓	
August 17, 2018	Deadline for organizations to complete the plan connectivity data in HPMS to ensure timely approval of contracts.	✓	✓	✓	✓
August 16-20, 2018	CY 2019 preview of the 2018 Medicare & You plan data in HPMS prior to printing of the CMS publication (not applicable to EGWPs).	✓	✓	✓	✓
August 22-24, 2018	First CY 2019 Medicare Plan Finder (MPF) Preview and Out- of-Pocket Cost (OOPC) Preview in HPMS.	✓	✓	✓	✓ *MPF only*
August 31, 2018	CY 2019 MTM Program Annual Review completed.		✓		✓
Late August, 2018	Contracting Materials submitted to CMS.	✓	✓	✓	

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
End of August/Early September, 2018	Plan preview periods of Part C & D Star Ratings in HPMS.	✓	✓	✓	
Early September, 2018	CMS begins accepting plan correction requests upon contract approval.	✓	✓	✓	
Mid-September, 2018	All 2018 contracts fully executed (signed by both parties: Part C/Part D Sponsor and CMS).	✓	✓	✓	
September 4-7, 2018	Second CY 2019 Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HPMS.	✓	✓	✓	✓ *MPF only*
September 16 - 30, 2018	CMS mails the 2019 Medicare & You handbook to Medicare beneficiaries.	✓	✓	✓	✓
Late September, 2018	D-SNPs that requested review for FIDE SNP determination notified as to whether they meet required qualifications.	✓			
Late September, 2018	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, 2018	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, MMPs, 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 2019 documents permitted to be sent prior to October 1, 2018.	✓	✓	✓	✓
October 1, 2018	Organizations may begin marketing their CY 2019 plan benefits. Note: Once an organization begins marketing CY 2019 plans, the organization must cease marketing CY 2018 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 2018 materials upon request, conduct one-on-one sales appointments, and process enrollment applications.	✓	✓	✓	✓

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 1, 2018	Tentative date for CY 2019 plan and drug benefit data to be displayed on Medicare Plan Finder on Medicare.gov (not applicable to EGWPs).	✓	✓	✓	✓
October 2, 2018	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, 2018.	✓	✓	✓	✓
October 11, 2018	Part C & D Star Ratings go live on medicare.gov on or around October 11, 2018.	✓	✓	✓	
October 15, 2018	Part D sponsors must post prior authorization and step therapy criteria on their websites for CY 2019.		✓		✓
October 15, 2018	2019 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, 2018	Release of the online CY 2020 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 12, 2018	Notices of Intent to Apply (NOIA) for CY 2020 due for MA and MA-PD plans, MMP, PDPs, and "800 series" EGWPs and Direct Contract EGWPs.	✓	✓		✓
Early November, 2018	First display of Plan Finder data for sponsors/MA organizations that submitted a plan correction request after bid approval.	✓	✓	✓	✓
Late November, 2018	Part C & D display measures data are posted in HPMS for plan preview.	✓	✓	✓	
December 1, 2018	Cost-based plans must publish notice of non-renewal, as per §417.494 of Title 42 of the CFR.			✓	
December 7, 2018	End of the Annual Election Period.	✓	✓		✓
Mid December, 2018	Part C & D display measures data on cms.gov updated.	✓	✓	✓	
2019					
January 1, 2019	Plan Benefit Period Begins.	✓	✓	✓	✓
January 1 – March 31, 2019	Annual Medicare Advantage Open Enrollment Period (MA OEP).	✓			
January 2019	Release of CY 2020 MAO/MA-PD/MMP/PDP/SAE/EGWP applications.	✓	✓		✓
January, 2019	Industry training on CY 2020 applications.	✓	✓	✓	✓

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
February 2019	Applications due for CY 2020.	✓	✓	✓	✓
June 3, 2019	CY 2020 Deadline for bid and formulary submission.	✓	✓	✓	✓ *Non-bid related items only*

Enhancements to the 2019 Star Ratings and Future Measurement Concepts

CMS publishes the Part C and D Star Ratings each year to measure 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.

CMS regularly reviews the measures and the methodology (used to generate the ratings) to incentivize plans and ensure the ratings 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 concerns about the Star Ratings. CMS works in collaboration with beneficiaries, stakeholders, measure developers, researchers, and other HHS collaborators to improve the Star Ratings.

As a result, we proposed enhancements to the 2019 Star Ratings as well as possible enhancements for the 2020 Star Ratings and other future measurement concepts. We appreciate the feedback we received on the draft CY 2019 Call Letter.

Except as noted below, the methodology and measures used to calculate the ratings will remain the same as the 2018 Star Ratings.

For reference, the list of measures and a description of the methodology for the 2018 Star Ratings are included in the Technical Notes available on the CMS webpage: https://go.cms.gov/partcanddstarratings.

In 2018, CMS's current Part C & D Star Ratings contractor, RAND Corporation, will be establishing a small Technical Expert Panel (TEP) comprised of representatives across various stakeholder groups to obtain feedback on the Star Ratings framework, topic areas, methodology, and operational measures. The TEP may also provide suggestions regarding the process(es) we use to review and ensure data integrity and how the Star Ratings should relate to audits and enforcement actions. RAND will analyze the suggestions from the TEP to provide feedback to

CMS on potential future enhancements. We appreciate commenters' support for the TEP. Recommendations from the TEP will be shared, and there will be additional opportunities for stakeholders to provide input more broadly.

Reminders for 2019 Star Ratings

CMS currently assigns stars for each numeric measure score by applying one of two methods: clustering or relative distribution with significance testing. Each method is described in detail in the Technical Notes. Relative distribution with significance testing is applied to determine valid star cut points for Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures. Clustering is applied to other Star Ratings measures. The cut points to determine star assignments for all measures and case-mix coefficients for the CAHPS survey and Health Outcomes Survey (HOS) will be updated for 2019 Star Ratings using the most current data available.

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

We provide various datasets and reports to plan sponsors throughout the year. Part C and D sponsors should regularly review their underlying measure data that are the basis for the Part C and D Star Ratings 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 2017 IRE data must be made by June 30, 2018 for the 2019 Star Ratings).

New Measures for 2019 Star Ratings

- **Statin Use in Persons with Diabetes (SUPD) (Part D).** This Pharmacy Quality Alliance (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 Medicare Enrollment Database (EDB) are excluded from the denominator of the SUPD measure for the entire year. Beneficiaries with end-stage renal disease (ESRD) at any time in the measurement year are also excluded. For the 2017 measurement year, CMS will expand its data sources for identifying all Part D enrollees with ESRD for exclusion from the measures to include ICD-10-CM codes found in both Part A & B claims and Risk Adjustment Processing System (RAPS) RxHCCs to use along with the EDB ESRD indicator that is currently used. This measure has been included as a display measure for the past two years. We will add the SUPD measure to the 2019 Star Ratings (based on 2017 data) with a weight of 1 for the first year since it is a first year measure. For subsequent years, we proposed a weight of 3 as is standard practice

for an intermediate outcome measure, as prescription fills are a proxy for patients taking their prescribed medications, and adherence is necessary to reach clinical/therapeutic goals; therefore, the measure will have a weight of 3 starting with the 2020 Ratings. Some commenters suggested that statin intolerant patients be excluded from the measure denominator; this feedback was shared with the measure developer, PQA.

- **Statin Therapy for Patients with Cardiovascular Disease (Part C).** This measure was developed by the National Committee for Quality Assurance (NCQA) as part of HEDIS and has been included as a display measure for two years. 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 2018 Technical Specifications for Health Plans Volume 2 for measure construction and technical specifications. We will include this measure in the 2019 Star Ratings as a process measure with a weight of 1, since it is based on one fill. The measure will continue to be weighted 1 in the future as recommended by commenters. CMS shared all comments received on this measure with NCQA.

Changes to Measures for 2019

- **Improvement measures (Part C & D).** After consideration of the comments about the improvement measures, we are finalizing our proposal with one modification. The measure Reducing the Risk of Falling will be included in the improvement measure calculations for the 2019 Star Ratings. We explain below how we are keeping this measure for the 2019 Star Ratings; its inclusion in the improvement measure is tied to that. The measures used to calculate the 2019 improvement measures are listed in Table 1.

Table 1: 2019 Star Ratings Improvement Measures

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

Part C or D	Measure	Measure Type	Weight	Improvement Measure
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	Reducing the Risk of Falling	Process Measure	1	Yes
C	Improving Bladder Control	Process Measure	1	Yes
C	Medication Reconciliation Post-Discharge	Process Measure	1	Yes
C	Plan All-Cause Readmissions	Outcome Measure	3	Yes
C	Getting Needed Care	Patients' Experience and Complaints Measure	1.5	Yes
C	Getting Appointments and Care Quickly	Patients' Experience and Complaints Measure	1.5	Yes
C	Customer Service	Patients' Experience and Complaints Measure	1.5	Yes
C	Rating of Health Care Quality	Patients' Experience and Complaints Measure	1.5	Yes
C	Rating of Health Plan	Patients' Experience and Complaints Measure	1.5	Yes
C	Care Coordination	Patients' Experience and Complaints Measure	1.5	Yes
C	Complaints about the Health Plan	Patients' Experience and Complaints Measure	1.5	Yes
C	Members Choosing to Leave the Plan	Patients' Experience and Complaints Measure	1.5	Yes
C	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
C	Statin Therapy for Patients with Cardiovascular Disease	Process Measure	1	No
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	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

Part C or D	Measure	Measure Type	Weight	Improvement Measure
D	Medication Adherence for Hypertension (RAS antagonists)	Intermediate Outcome Measure	3	Yes
D	Medication Adherence for Cholesterol (Statins)	Intermediate Outcome Measure	3	Yes
D	MTM Program Completion Rate for CMR	Process Measure	1	Yes
D	Statin Use in Persons with Diabetes	Intermediate Outcome Measure	1	No

- **Medication Adherence (ADH) for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications (Part D).** Beneficiaries with ESRD are excluded from the measure per the PQA measure specifications. For the 2017 measurement year, CMS will expand its data sources for identifying all Part D enrollees with ESRD for exclusion from the measures to include ICD-10-CM codes found in both Part A & B claims and Risk Adjustment Processing System (RAPS) RxHCCs along with the EDB ESRD indicator (currently used).

- **Medication Adherence (ADH) for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications, and Medication Adherence for Cholesterol (Statins) (Part D).** The Proportion of Days Covered (PDC) is adjusted for inpatient (IP) stays and hospice enrollment for MA-PDs and PDPs, and skilled nursing facility (SNF) stays for PDPs. In applying the adjustment, first we identify the start and end dates of relevant types of stays for beneficiaries included in the adherence measures. The start date is currently the admission date, and the end date is one day before the discharge date. The discharge date is not included in the PDC adjustment. The days of the relevant stays that occur during the beneficiary's measurement period are removed from the numerator and denominator of the PDC calculation. In addition, we shift the days' supply from Part D prescription fills that overlap with the stay to uncovered days after the end of the relevant stay, if applicable. This assumes the beneficiary receives the relevant medication from a different source during the stay and "stockpiles" the Part D prescription fills for later use.

  We found that in cases where the beneficiary has consecutive stays where the admission date of the second stay is one day after the discharge date, one day would not be removed from the PDC calculation. In the draft 2019 Call Letter, we proposed to concatenate consecutive stays to create a single admission and discharge date for the PDC adjustment. A commenter suggested a simpler approach to count the day of discharge in the PDC adjustment, which we will implement for the 2017 measurement year for the 2019 Star Ratings.

- **MPF Price Accuracy (Part D).** We had proposed enhancements to the MPF Price Accuracy measure to be first published as a display measure in 2020, and then to be considered to be applied to the Star Rating measure for 2022, pending rulemaking. Since we are not making these changes to the 2019 Star Rating measure, we have

moved this topic to the subsection "Forecasting to 2020 and Beyond: Potential Changes to Existing Measures".

- **Members Choosing to Leave the Plan (Part C & D).** We will expand the exclusions for this existing measure to include plan benefit package (PBP) service area reductions (SARs) that result in the unavailability of PBPs that the enrollee is eligible to move to within the contract. Commenters to the draft Call Letter expressed support for this new exclusion and asked for clarification about how disenrollments related to the cost contract transitions would be handled. The exclusions meeting the following specific scenarios will be added:

    - The area reduced is part of non-Special Need Plan (SNP) PBPs and the only PBPs remaining in the contract that cover the area are SNP PBPs.

    - The area reduced is part of a SNP PBP and there are no non-SNP PBPs or another SNP PBP within the contract of the same SNP type that cover the area.

    - Cost contract disenrollments into the transition MA contract (H contract) will be excluded from the calculation of the cost contract disenrollment rate; however, movement out of that transition MA contract will not be excluded from the calculated disenrollment rate of the transition MA contract.

    We note that a contract-level SAR removes an area from being offered in all PBPs marketed by the contract. A PBP-level SAR removes an area from a single PBP, but that area must still be available under some other PBP marketed by the contract.

- **Reducing the Risk of Falling (Part C).** This current measure, collected through the Medicare HOS, assesses the percentage of beneficiaries who discussed falls, balance concerns, or walking with their healthcare provider and received fall risk intervention(s) from a provider. CMS proposed expanding the denominator and removing the measure from the 2019 and 2020 Star Ratings. The measure for the 2019 ratings is based on survey data collected in 2017. Although several commenters supported the proposed change, none offered recommendations on the specifications. Many, however, raised concerns that removing the measure could send the wrong message to plans and beneficiaries, specifically, that fall prevention is not important and does not need to be measured, and that plans will not be held accountable for their performance in this area. These commenters strongly urged CMS to keep the measure in the 2019 and 2020 Star Ratings. CMS also clarified that the denominator expansion applies to the Discussing Fall Risk indicator only, not to the measure. Therefore, CMS will retain the Reducing the Risk of Falling measure in the 2019 and 2020 Star Ratings. If any future substantive changes are considered for Star Ratings for 2021 or after, we will propose these through the regulatory process.

Removal of Measure from Star Ratings

- **Beneficiary Access and Performance Problems (BAPP) (Part C & D).** The BAPP measure is based on CMS's sanctions, civil money penalties (CMP) as well as Compliance Activity Module (CAM) data (this includes: notices of non-compliance, warning letters [with or without business plan], and ad-hoc corrective action plans (CAP) and the CAP severity). After several solicitations for public comment on the BAPP measure and considering comments from MA plans, advocates, and other stakeholders,[8] CMS proposed in the CY2018 Advance Notice/draft Call Letter a number of revisions to the BAPP measure. In response to that proposal, commenters expressed overwhelming support to implement a revision to the measure decoupling audits and enforcement actions from Star Ratings. The commenters cited reasons for recommending such revisions 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, submitted strong concerns about the proposal, including decoupling the BAPP measure from audit results. Based on the feedback, the strong support for a change to the measure specification, and concerns for providing additional notice and time to prepare for the significant changes, CMS decided to retain the current BAPP measure in the 2018 Star Ratings. We signaled in the 2018 Call Letter, an intention for 2019 Star Ratings: to remove from the BAPP measure all enforcement actions and reductions for plans under sanction due to audit findings; to propose to retire the current BAPP measure; and to introduce a new measure for the display page (described in the next paragraph).

  There was mixed reaction to the removal of the BAPP measure from the Star Ratings. Beneficiary advocacy groups strongly opposed the removal of the BAPP measure from the Star Ratings, stating this will mask plan behaviors that could pose a serious threat to the health and safety of beneficiaries. Although there were exceptions, most sponsors supported the removal of the BAPP measure from Star Ratings. Some commenters asked for more information about the revised BAPP measure proposed to be published on the display page. For the 2019 Star Ratings, CMS will move forward with retiring the current BAPP measure. As proposed, the new measure for the display page will modify the BAPP measure to only include Compliance Activity Module (CAM) data using the same methodology that has been used in the past to calculate the measure deduction for the CAM score. The only difference is that the CAM score will be the only deduction. The revised BAPP measure will be on the display page for the 2019 Star Ratings. We will continue to explore how to highlight performance issues on the Medicare Plan Finder.

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[8] Please refer to the CY2018 Advance Notice and CY2018 Rate Announcement for a summary of the history and comments received before the CY2018 Advance Notice proposal.

Data Integrity

Data used for the Part C and D Star Ratings must be accurate and reliable. CMS's longstanding policy has been to reduce a contract's measure rating to one 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 or inappropriate processing, or if implementation of incorrect practices impacted specific measure(s). Examples 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's 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 conduct reviews to identify incomplete or biased Star Ratings measure data.

The Part C and D Reporting Requirements measures (SNP Care Management (Part C) and Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) (Part D)) are calculated using data reported by plan sponsors and validated via an independent data validation using CMS standards. Since CMS first included these measures in the display measures, and then in the Star Ratings, we have used results from our Data Validation process to identify if plan-reported data were inaccurate and therefore could not be used for Star Ratings. Specifically, as listed in the Star Ratings Technical Notes, we do not rate the performance of contracts that do not score at least 95% on data validation for these reporting sections or are not compliant with data validation standards/sub-standards for at least one of the data elements used to calculate the measures. The contract's measure score is reduced

to 1 star. In line with changes made to the Data Validation scoring methodology for some standards/sub-standards to use a Likert scale, we will define a contract as being non-compliant if either it receives a "No" or a 1, 2, or 3 on the 5-point Likert scale in the specific data element's data validation.

Scaled Reductions for Appeals IRE Data Completeness Issues

At present, there are four Star Ratings appeal measures that rely on data submitted to the IRE. Two of the measures are Part C measures (Plan Makes Timely Decisions about Appeals and Reviewing Appeals Decisions), and two are Part D measures (Appeals Auto-Forward and Appeals Upheld). We proposed a new process to determine and apply reductions to these specific appeals measures based on findings that the underlying data are inaccurate, biased, or incomplete.

The completeness of the IRE data is critical to allow accurate measurement of the appeals measures. All plans are responsible and held accountable for ensuring high quality and complete data to maintain the validity and reliability of the measures.

For verification and validation of the Part C and D appeals measures, CMS has relied primarily on the use of audit findings and targeted reviews. Contracts identified during an audit review to have systematic issues with the completeness of the IRE data have had their appeals measures reduced to one star. Plans and sponsors have expressed concern with the use of the audit findings as the sole source of information because of the perceived inequity of the application of the reductions that only audited contracts may face. Each year, a subset of contracts, not all contracts, are audited. Further, if a reduction due to IRE data integrity was applied, it resulted in a measure-level Star Rating of one star for the appeals measures.

In response to stakeholder concerns about both CMS's prior practice of reducing measure ratings to one star based on any finding of data inaccuracy, incompleteness, or bias, and the potential inequity in application of the data integrity policy related to audit findings, CMS initiated the Timeliness Monitoring Project (TMP) in CY 2017.[9] All contracts submitted data during the first year of the project. The first submission for the TMP was for the measurement year 2016 related to Part C organization determinations and reconsiderations and Part D coverage determinations and redeterminations. The timeframe for the submitted data was dependent on the enrollment size of the contract with smaller contracts submitting data from a three-month period, medium-sized contracts submitting data from a two-month period, and larger contracts submitting data

[9] This project was discussed in the November 28, 2016 HPMS memo, "Industry-wide Appeals Timeliness Monitoring" as well as the December 02, 2016 follow-up email. https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Industry-wide-Timeliness-Monitoring.pdf https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Industry-wide-Appeals-Timeliness-Monitoring-Memo-November-28-2016.pdf.

from a one-month period.[10] CMS reviewed and examined the data from the first collection of TMP data, but did not use it in the determination of appeals-related reductions for the 2018 Star Ratings.

CMS is finalizing and adopting its proposal to use statistical criteria to reduce a contract's Star Rating for data that are not complete or lack integrity using TMP or audit data. The reduction will be applied to the measure-level Star Rating for the applicable appeals measures. Because there are varying degrees of data issues, we will use a methodology for reductions that reflects the degree of the data accuracy issue for a contract instead of a one-size-fits-all approach. The methodology will employ scaled reductions (one-star, two-star, three-star, or four-star reduction) based on the degree of missing IRE data. Contracts with the highest IRE data quality issues (i.e., largest percentage of missing or compromised data) will receive the largest reductions, while contracts with a lower degree of missing IRE data will receive a smaller reduction. The most severe reduction for IRE data completeness issues will be a four-star reduction, thus resulting in a measure-level Star Ratings of one star for the associated appeals measures. If a contract receives a reduction due to missing Part C IRE data, the reduction will be applied to both of the contract's Part C appeals measures. Likewise, if a contract receives a reduction due to missing Part D IRE data, the reduction will be applied to both of the contract's Part D appeals measures. If a contract fails to submit TMP data for CMS's review to ensure the completeness of their IRE data, they will receive one star in this measure. We believe that it is appropriate to apply a negative inference in such cases related to the performance reflected in the data that the MA organization or Part D plan sponsor has refused to provide for purposes of our oversight of compliance with the appeals requirements and monitoring of performance. This is similar to how CMS treats measures dependent on contracts' completion of data validation of plan-reported data. Further, we will use multiple data sources whenever possible to determine whether the IRE data are complete and if not, the severity of the missingness and/or data issues.

CMS's scaled reduction methodology will be a three-stage process using the TMP data or audit for the means to determine: first, whether a contract may be subject to a potential reduction for the Part C or Part D appeals measures; second, as the basis for the determination of the estimated error rate; and finally, whether the estimated value is statistically greater than the cut points for the scaled reductions of 1, 2, 3, or 4 stars.

Once the scaled reduction for a contract is identified using the methodology, the reduction will be applied to the contract's associated appeals measure-level Star Ratings. Since the minimum measure-level Star Rating is one star, if the difference between the associated appeals measure-level Star Rating (before the application of the reduction) and the identified scaled reduction is

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[10] Contracts with a mean annual enrollment of less than 50,000 are required to submit data for a three-month time period. Contracts with a mean enrollment of at least 50,000 but, at most 250,000 are required to submit data for a two-month time period. Contracts with a mean enrollment greater than 250,000 are required to submit data for a one-month period.

less than one, the contract will receive a measure-level Star Rating of one star for the appeals measure.

The error rate for the Part C and Part D appeals measures - using the TMP or audit data and the projected number of cases not forwarded to the IRE for a 3-month period - will be used to identify contracts that may be subject to an appeals-related IRE data completeness reduction. A minimum error rate establishes a threshold for the identification of contracts that may be subject to a reduction. The establishment of the threshold allows the focus of the possible reductions on contracts with error rates that have the greatest potential to distort the signal of the appeals measures. Since the timeframe for the TMP or audit data is dependent on the enrollment size of the contract, with smaller contracts submitting data from a three-month period, medium-sized contracts submitting data from a two-month period, and larger contracts submitting data from a one-month period, the use of a projected number of cases allows a consistent time period for the application of the criteria.

The calculated error rate formula (Equation 1) for the Part C measures will be determined by the quotient of number of cases not forwarded to the IRE and the total number of cases that should have been forwarded to the IRE. The number of cases that should have been forwarded to the IRE is the sum of the number of cases in the IRE during the TMP or audit data collection period and the number of cases not forwarded to the IRE during the same period.

$$\text{Part C Calculated Error Rate} = \frac{\text{Number of cases not forwarded to the IRE}}{\text{Total number of cases that should have been forwarded to IRE}} \qquad \textbf{Equation (1)}$$

The calculated error rate formula (Equation 2) for the Part D measures will be determined by the quotient of the number of untimely cases not auto-forwarded to the IRE and the total number of untimely cases.

$$\text{Part D Calculated Error Rate} = \frac{\text{Number of untimely cases not auto-forwarded to the IRE}}{\text{Total number of untimely cases}} \qquad \textbf{Equation (2)}$$

Given the different lengths of TMP or audit data collected and evaluated (based on contract size), the number of non-forwarded cases in a three-month period per contract is projected. The projected number of cases not forwarded to the IRE in a three-month period will be calculated by multiplying the number of cases found not to be forwarded to the IRE based on the TMP or audit data, by a constant determined by the associated time period. Contracts with mean annual enrollments greater than 250,000 that submitted data from one-month, will have a constant of 3.0. Contracts with mean enrollments between 50,000 and 250,000 that submitted data from a two-month period, will have their number of cases found not to be forwarded to the IRE (based on the TMP or audit data) multiplied by the constant 1.5. Small contracts with mean enrollments less than 50,000 that submitted data for a three-month period will have their number of cases found not to be forwarded to the IRE multiplied by the constant 1.0.

Contracts will be subject to a possible reduction due to lack of data completeness if both conditions are met:

1. The calculated error rate is 20% or more.
2. The projected number of cases not forwarded to the IRE is at least 10 in a 3-month period.

The requirement for a minimum number of cases is needed to address statistical concerns with precision and small numbers. If a contract meets only one of the conditions, the contract will not be subject to reductions for IRE data completeness issues. If a contract is subject to a possible reduction based on the aforementioned conditions, a confidence interval estimate for the true error rate for the contract will be calculated using a Score Interval (Wilson Score Interval) at a confidence level of 95%. The midpoint of the score interval is determined using Equation 3.

$$Midpoint = Calculated\ Error\ Rate \times \left(\frac{Total\ Number\ of\ Cases}{Total\ Number\ of\ Cases + z^2}\right) + \frac{1}{2}\left(\frac{z^2}{Total\ Number\ of\ Cases + z^2}\right) \quad \textbf{Equation (3)}$$

The z score that corresponds to a level of statistical significance of 0.05, commonly denoted as $z_{\alpha/2}$ but for ease of presentation represented here as z. (The z value that is used for the purpose of the calculation of the interval is 1.959964.).

For the Part C appeals measures, the midpoint of the confidence interval will be calculated using Equation 3 along with the calculated error rate from the TMP or audit data, which is determined by Equation 1. The total number of cases in Equation 3 is the number of cases that should have been in the IRE for the Part C TMP or audit data.

For the Part D appeals measures, the midpoint of the confidence interval will be calculated using Equation 3 along with the calculated error rate from the TMP or audit data, which is determined by Equation 2. The total number of cases in Equation 3 is the total number of untimely cases for the Part D appeals measures.

Letting the calculated error rate be represented by $\hat{p}$ and the total number of cases represented as n, Equation 3 can be streamlined as follows (Equation 4):

$$Midpoint = \hat{p}\left(\frac{n}{n+z^2}\right) + \frac{1}{2}\left(\frac{z^2}{n+z^2}\right) \quad \textbf{Equation (4)}$$

The lower bound of the confidence interval estimate for the error rate is calculated using Equation 5 below:

$$Lower\ Bound = Midpoint - z \times \sqrt{\frac{1}{n+z^2}\left[\hat{p}(1-\hat{p})\left(\frac{n}{n+z^2}\right) + \frac{1}{4}\left(\frac{z^2}{n+z^2}\right)\right]}$$ **Equation (5)**

For each contract subject to a possible reduction, the lower bound of the interval estimate of the error rate will be compared to each of the thresholds in Table 2. If the contract's calculated lower bound is higher than the threshold, the contract will receive the reduction that corresponds to the highest threshold that is less than the lower bound. In other words, the contract's lower bound is used to determine whether the contract's error rate is significantly greater than the thresholds of 20%, 40%, 60%, and 80% to determine the scaled reduction. The scaled reductions are in Table 2. The reductions due to IRE data completeness issues are applied after the calculation of the measure-level Star Rating for the appeals measures (using the available data provided by the sponsoring organization to the IRE). The reduction applies to the Part C appeals measures or the Part D appeals measures.

A contract's lower bound could be statistically significantly higher than more than one threshold. The reduction will be determined by the highest threshold that the contract's lower bound exceeds. For example, if the lower bound for a contract is 64.560000%, the contract's estimated value is significantly greater than the thresholds of 20%, 40%, and 60% because the lower bound value 64.560000% is greater than each of these thresholds. The lower bound for the contract's confidence interval is not greater than 80%. The contract will be subject to the reduction that corresponds to the 60% threshold which is 3 stars.

Table 2: Thresholds and Associated Reductions

Thresholds Using the Lower Bound of Confidence Interval Estimate of the Error Rate	Reduction for Incomplete IRE Data (Stars)
20%	1
40%	2
60%	3
80%	4

For the 2019 Star Ratings, CMS will implement the data integrity policy as proposed in the draft Call Letter. Commenters expressed overall support for the new process for using scaled reductions for IRE data completeness issues. Commenters preferred the proposed new methodology and perceived it as a tailored approach compared to the one-size-fits-all reduction

used for 2018 and prior ratings on these measures. Some commenters expressed concern about the use of a relatively new data source (TMP data) for this purpose. CMS is committed to working closely with sponsoring organizations to address any concerns about the data. We plan to provide sponsoring organizations with a preview of the relevant data before the Star Ratings are finalized.

2019 Star Ratings Program and the Categorical Adjustment Index

CMS's interim response to address the within-contract disparity in performance associated with a contract's percentages of beneficiaries with low income subsidy and dual eligible (LIS/DE) and disability status revealed in our comprehensive research conducted over multiple years culminated in the creation of the Categorical Adjustment Index (CAI). The CAI was first implemented in the 2017 Star Ratings Program. The values and abridged details of the methodology are provided in the annual Medicare Part C & D Star Rating Technical Notes available on the CMS webpage at https://go.cms.gov/partcanddstarratings. Additional details of the CAI methodology can be found in the CAI Methodology Supplement available at the same link.

There continues to be additional work in the research community on both identifying the impact of social risk factors on health outcomes and how to best address the impact on clinical quality measurement such that comparisons across contracts yield accurate representations of true differences in quality as opposed to reflections of changes in the composition of beneficiaries in contracts. The final report of the findings of the two-year trial period by National Quality Forum (NQF) that temporarily lifted the restriction and allowed risk-adjustment of performance measures for socioeconomic status (SES) and other demographic factors was released in July 2017.[11] NQF has recommended a three-year initiative to further examine and consider social risk adjustment to allow evidence as to whether a change in their longstanding policy prohibiting risk adjustment for SES and other demographic factors should be revised.

We continue to engage the NCQA and PQA to review and determine if any measures are sensitive to the composition of the enrollees in a plan and whether case-mix adjustment of individual measures would be appropriate. The PQA examined their medication adherence measures, which are currently used in the Star Ratings Program, for potential risk adjustment[12]. Beginning in 2018, the PQA included draft recommendations on risk adjustment of the three medication adherence measures: Medication Adherence for Diabetes

[11] NQF's Final Report can be accessed using the following link: http://www.qualityforum.org/Publications/2017/07/Social_Risk_Trial_Final_Report.aspx

[12] The PQA summary can be accessed at: SDS Risk Adjustment PQA PDC CMS Part D Stars

Medications, Medication Adherence for Hypertension, and Medication Adherence for Cholesterol in the 2018 PQA Measure Manual. The draft recommendations are as follows:

- All three adherence measures should be risk adjusted for sociodemographic status (SDS) characteristics to adequately reflect differences in patient populations.
- The measures should be adjusted for the following beneficiary-level SDS characteristics: age, sex, dual eligibility/LIS status, and disability status.
- The three adherence measures should be stratified by the beneficiary-level SDS characteristics listed above to allow health plans to identify disparities and understand how their patient population mix is affecting their measure rates.

The PQA indicated that these draft recommendations will be finalized in 2019 once PQA completes the NQF measure endorsement maintenance of the measures (NQF Endorsed # 0541). If finalized, CMS will consider how to implement the PQA recommendations in the future for these Star Ratings measures (for 2020 measurement year or beyond).

NCQA has also completed its examination of a subset of the HEDIS measures used in the Star Ratings Program. NCQA has received approval from the Committee on Performance Measurement (CPM) to implement stratified reporting of four of the measures used in the Star Ratings Program: Breast Cancer Screening, Colorectal Cancer Screening, Comprehensive Diabetes Care – Eye Exam Performed, and Plan All-Cause Readmissions.[13] The measures will be stratified using the following subgroups: both LIS/DE and disabled, not LIS/DE and not disabled; LIS/DE and not disabled; not LIS/DE and disabled; and other. An overall (i.e., non-stratified) result will also be required to be reported for this measure. The change to the specification will be applicable to MA contracts to meet the MA program's reporting requirements. At present, NCQA is designing the reporting requirements and anticipates the change in its specification in the 2019 HEDIS Volume 2. CMS is considering how to best incorporate the information provided by the stratified reporting in future years of the Star Ratings.

The Office of the Assistant Secretary for Planning and Evaluation (ASPE), as required in the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act, P.L. 113-185), released the first in a two-part series of Reports to Congress (RTC) in December 2016.[14] In it, ASPE analyzed the effect of social risk factors on health outcomes of Medicare beneficiaries. ASPE reviewed a number of CMS programs, including MA. CMS has

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[13] A summary of the NCQA analysis and recommendations can be accessed using the link that follows: http://www.ncqa.org/hedis-quality-measurement/research/hedis-and-the-impact-act

[14] 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.

carefully reviewed the report and is considering the feasibility of the considerations presented in ASPE's RTC for MA contracts and sponsors, as well as the impact on the use of the ratings for beneficiaries. ASPE's second report is due in the fall of 2019. In the meantime, CMS continues to be in dialogue with ASPE to discuss potential options for future MA Star Ratings.

CMS remains 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 issue - quality and payment. The Star Ratings are a reflection of the quality of a contract and thus, the response to address the LIS/DE/disabled effect revealed in our research must not distort the meaning and value of the quality ratings. Further, the long-term solution must recognize the unique challenges of serving vulnerable populations. While the measure stewards continue their work, CMS will continue to consider all feasible options that exist for a long-term response.

Since its inception, the application of the CAI has resulted in a modest movement of the Star Ratings. In 2017, nineteen MA-PDs had their overall Star Rating increase a half-star after the overall CAI was applied to their unadjusted overall Star Rating. Nine contracts had their overall rating change from 3.5 to 4.0 stars after the overall CAI was applied. For MA-only and MA-PDs, seven contracts increased a half-star after the Part C summary CAI was applied to their unadjusted Part C summary rating. Sixteen MA-PDs contracts increased a half-star after Part D CAI was applied to their unadjusted Part D summary rating. In 2017, the movement for stand-alone PDPs was bidirectional. Nine PDPs decreased a half-star and three increased a half-star after the PDP-specific CAI values were applied to their unadjusted Part D summary rating.

For the 2018 Star Ratings, the impact of the CAI resulted in primarily positive movement of the ratings. A total of eleven MA-PDs saw their overall Star Rating increase by a half-star and one MA-PD's overall rating decreased by a half-star after the overall CAI was applied to its unadjusted overall Star Rating. Six contracts had their overall rating change from 3.5 to 4.0 after the CAI was applied. For MA-only and MA-PDs, eleven contracts increased a half-star and 4 decreased a half-star after the Part C summary CAI values were applied. A total of 4 MA-PD contracts increased a half-star after the Part D MA-PD summary CAI was applied to their unadjusted Part D summary rating. The movement for stand-alone PDPs was directional only. Six PDPs decreased a half-star after the PDP-specific CAI values were applied to their unadjusted Part D summary rating.

For the 2019 Star Ratings Program, CMS will continue using the interim analytical adjustment, the CAI. The overall methodology will remain unchanged for 2019.

As stated in the CY 2017 Call Letter (CY 2017 Rate Announcement, Attachment VII, pages 131-133), the CAI values will be updated annually and published in the final Call Letter

while the CAI is implemented. The CAI values are determined using the previous Star Ratings year's measurement period, which allows the release of the CAI values well in advance of the first Star Ratings preview period. Thus, the 2019 CAI values were determined using data from the 2018 Star Ratings.

LIS/DE status for the categorization of the contracts for the 2019 Star Ratings will be based on the Medicare enrollment data from CY 2017. The disability status of an enrollee will be determined using information from the Social Security Administration (SSA) and Railroad Retirement Board (RRB) record systems for CY 2017. Disability status will be determined using the original reason for entitlement code (OREC).

For the 2019 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 2016 measurement period data and evaluated the variability of within-contract differences in performance for a similar subset of Star Ratings measures examined last year[15]. 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://go.cms.gov/partcanddstarratings. The decision criteria used to select measures from the candidate measure set[16] for adjustment was (1) a median absolute difference between LIS/DE and non-LIS/DE beneficiaries of 5 percentage points or more and/or (2) the LIS/DE subgroup performed better or worse than the non-LIS/DE subgroup in all contracts.

The measures selected for adjustment for the 2019 Star Ratings include seven Part C measures and two Part D measures[17]. For MA (MA-only, MA-PD) and 1876 contracts, the Part C measures selected for adjustment for the 2019 Star Ratings include: Annual Flu Vaccine, Breast Cancer Screening, Diabetes Care – Blood Sugar Controlled, Medication Reconciliation Post-

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[15] The 19 clinical quality measures that comprised the subset of the Star Ratings measures examined for the 2019 CAI included: adult BMI assessment, annual flu vaccine, breast cancer screening, colorectal cancer screening, controlling blood pressure, diabetes care – blood sugar controlled, diabetes care – eye exam, diabetes care – kidney disease monitoring, improving bladder control, medication reconciliation post-discharge, MTM Program Completion Rate for CMR, monitoring physical activity,osteoporosis management in women who had a fracture, plan all-cause readmissions, reducing the risk of falling, rheumatoid arthritis management, medication adherence for diabetes medications, medication adherence for hypertension, medication adherence for cholesterol. See footnote 10 regarding inclusion of the measure reducing the risk of falling.

[16] The criteria for the candidate measure set is detailed in the CAI Methodology Supplement available at: https://go.cms.gov/partcanddstarratings

[17] Since the publication of the draft Call Letter, based on comments received, the decision was made to retain the measure *Reducing the Risk for Falling* in the 2019 Star Ratings. Subsequently, the measure was added to the candidate measure set as a potential adjusted measure. The measure did meet the selection criteria based on the analysis of the within-contract disparity and will be one of the measures. The 2019 CAI values have been recalculated using the previously identified adjusted measures and including *Reducing the Risk of Falling.*

Discharge, Osteoporosis Management in Women who had a Fracture, Reducing the Risk of Falling, and Plan All-Cause Readmissions[18]. For MA-PDs and PDPs, the two Part D measures selected for adjustment for the 2019 Star Ratings include: Part D Medication Adherence for Hypertension and MTM Program Completion Rate for CMR.

2019 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 3 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 ten equal-sized groups. Table 4 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 9.486205%, the contract's LIS/DE initial category is L3. The exceptions for the upper limit exclusion for an initial group are the tenth initial category for LIS/DE and the fifth quintile for disability.

[18] Using the CAI measure selection criteria, plan all-cause readmissions was selected for adjustment for the 2019 Star Ratings. The adjustment of the plan all-cause readmissions measure scores for LIS/DE and disabled included case-mix weights that are part of the HEDIS measure specification and weighted effects coding to account for the different numbers of LIS/DE and non-LIS/DE beneficiaries per contract as well as, the unequal numbers of disabled and non-disabled beneficiaries in the data.

Table 3: 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 6.147316
L2	6.147316 to less than 9.486205
L3	9.486205 to less than 11.709700
L4	11.709700 to less than 14.743797
L5	14.743797 to less than 19.979137
L6	19.979137 to less than 26.817676
L7	26.817676 to less than 39.929156
L8	39.929156 to less than 69.752170
L9	69.752170 to less than 100.00000
L10	100.000000

Table 4: 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 15.059848
D2	15.059848 to less than 20.932235
D3	20.932235 to less than 27.405248
D4	27.405248 to less than 38.060705
D5	38.060705 to less than or equal to 100.000000

Table 5 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 5: Final Adjustment Categories and CAI Values for the Overall Rating

Final Adjustment Category	LIS/DE Initial Group	Disability Quintile	CAI Value
A	L1	D1 – D3	−0.031461
B	L2 - L4	D1 - D4	−0.005122
	L5	D1 - D2	
	L1	D4	
C	L6 - L7	D1 - D3	0.007895
	L8 - L9	D1	
	L5	D3 - D4	
	L6	D4	
	L1 - L5	D5	
D	L10	D1	0.035958
	L8	D2 - D5	
	L7	D4	
	L9 - L10	D2	
	L6 - L7	D5	
E	L9 - L10	D3 - D4	0.091276
	L9	D5	
F	L10	D5	0.131385

Tables 6 and 7 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 rating.

Table 6: 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 5.992616
L2	5.992616 to less than 8.988495
L3	8.988495 to less than 11.438062
L4	11.438062 to less than 14.634338
L5	14.634338 to less than 19.378661
L6	19.378661 to less than 26.317568
L7	26.317568 to less than 39.614595
L8	39.614595 to less than 69.705289
L9	69.705289 to less than 100.00000
L10	100.000000

Table 7: 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 14.826108
D2	14.826108 to less than 20.812509
D3	20.812509 to less than 27.249755
D4	27.249755 to less than 38.009950
D5	38.009950 to less or equal to 100.000000

Table 8 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 8: Final Adjustment Categories and CAI Values for the Part C Summary Rating

Final Adjustment Category	LIS/DE Initial Group	Disability Quintile	CAI Value
A	L1 - L4	D1 - D2	−0.005385
	L1 - L2	D3	
B	L5 - L7	D1 - D5	0.009151
	L8 - L9	D1	
	L3 - L4	D3 - D5	
	L1 - L2	D4 - D5	
C	L8 - L10	D2 - D3	0.037128
	L10	D1	
	L8	D4 - D5	
D	L9 - L10	D4	0.063253
	L9	D5	
E	L10	D5	0.109867

Tables 9 and 10 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 9: 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 6.086006
L2	6.086006 to less than 9.486205
L3	9.486205 to less than 11.818672
L4	11.818672 to less than 15.062762
L5	15.062762 to less than 20.400000
L6	20.400000 to less than 28.005752
L7	28.005752 to less than 41.258946
L8	41.258946 to less than 72.787572
L9	72.787572 to less than 100.000000
L10	100.00000

Table 10: 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 15.064161
D2	15.064161 to less than 21.113304
D3	21.113304 to less than 27.887822
D4	27.887822 to less than 39.190317
D5	39.190317 to less than 100.000000

Table 11 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 11: 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 - L3	D1	−0.031272
	L1	D2 - D3	
B	L4 - L8	D1 - D3	−0.007584
	L9	D1 - D2	
	L2 - L3	D2 - D3	
C	L1 - L6	D4 - D5	0.015478
	L7	D4	
D	L9 - L10	D3 - D4	0.086029
	L10	D1 - D2	
	L8	D4	
	L7 - L9	D5	
E	L10	D5	0.142243

Tables 12 and 13 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 12: 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 1.669196
L2	1.669196 to less than 4.001965
L3	4.001965 to less than 15.204859
L4	15.204859 to less than or equal to 100.000000

Table 13: 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 7.415977
D2	7.415977 to less than 12.842575
D3	12.842575 to less than 19.147148
D4	19.147148 to less than or equal to 100.000000

Table 14 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 are 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 14: 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 - D3	−0.243619
B	L2 - L3	D1 - D4	−0.119773
	L1	D4	
C	L4	D1 - D4	0.047909

In response to the draft Call Letter, CMS received acclaim for our efforts to address the sensitivity of the Star Ratings to the composition of enrollees in a contract, as well as support for the use of the CAI as an interim adjustment. However, while the feedback was overwhelmingly positive, CMS received some recommendations to enhance the current CAI methodology. Many commenters believe the adjustment should have a greater impact on a contract's ratings.

To realize a more robust adjustment, some commenters suggested increasing the adjusted measure set by changing the selection criteria for adjusted measures. Ideas included: selecting measures in a cumulative fashion using the measures selected from the current year and the prior years, thus measures could be added based on the analysis for the current year's CAI analysis while retaining all measures used in the previous years; eliminating the second set of selection rules that uses the within-contract disparity analysis; or adding additional case-mix adjustment to the measures in the Star Ratings Program. Other commenters suggested a hold-harmless provision that would be applicable to: highly-rated contracts (a contract that has 4 or more stars for their highest rating when calculated without the improvement measures and with all applicable adjustments (CAI and the reward factor)), contracts with low percentages of LIS/DE or disabled enrollees, or contracts that would be subject to a negative adjustment.

CMS remains committed to our fundamental principles, which include incentivizing contracts to provide the best quality of care to all of their enrollees and providing accurate information to beneficiaries to allow comparisons among contracts for plan choice. A hold-harmless provision for the CAI that specifically targets contracts with limited LIS/DE populations or contracts that would realize a negative impact does not align with the underlying principles of the Star Ratings Program or the fundamental design principles of the CAI. Such a provision could have the unintended consequence of limiting quality improvement and innovation for the care of the LIS/DE/disabled population, as well as distorting the signal of the Star Ratings. As noted earlier, the measures stewards have reviewed the measures and will be re-specifying a subset of their measures. Only the measure steward can re-specify a measure and thus, a change to the case-mix adjustment by CMS for the measures in the Star Ratings is not possible. However, a modification to the selection rules for the adjusted measure set does align with the foundation of the CAI.

For the 2019 Star Ratings, CMS will implement the CAI using the methodology developed in prior years. The 2019 CAI values that will be implemented will be based on the updated values provided in the final Call Letter that include the measure Reducing the Risk of Falling. For the 2020 Star Ratings, CMS will consider modifying the selection rules by including all measures in the candidate measure set for adjustment and eliminating the selection of measures based on the analysis of the dispersion of the within-contract disparity of all contracts required to report.

Additional Adjustment to Address Lack of an LIS Indicator for Enrollees in Puerto Rico

Puerto Rico has a unique healthcare market with a large percentage of low-income individuals in both Medicare and Medicaid and a complex legal history that affects its healthcare system in many ways. Puerto Rican beneficiaries are not eligible for LIS. As a result, the CAI has been adjusted for application to contracts that operate solely in Puerto Rico (i.e., contracts with service areas entirely in Puerto Rico).

For the 2017 Star Ratings an additional adjustment for Puerto Rico-only contracts was applied to make the application of the CAI equitable for contracts operating solely in Puerto Rico in light of the lack of LIS. The additional adjustment resulted in a modified value for the percentage of LIS/DE for contracts operating solely in Puerto Rico. The adjustment resulted in a modified percentage of LIS/DE beneficiaries that was subsequently used to categorize contracts into the final adjustment category for the CAI. The model developed for the 2019 Star Ratings LIS/DE indicator will be available in Attachment O in the 2019 Medicare Part C & D Star Rating Technical Notes. The details of the LIS/DE indicator methodology are available in the CAI Methodology Supplement available at http://go.cms.gov/partcanddstarratings.

For the 2019 Star Ratings, CMS will continue to employ the additional adjustment for contracts operating solely in Puerto Rico (using the most recent data available at the time of development of the model for the 2019 Star Ratings). CMS will use the data sources identified in the draft Call Letter for this purpose.

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 2019 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.

Disaster Implications

Natural disasters such as hurricanes and wildfires can directly affect Medicare beneficiaries and providers, as well as the Parts C and D organizations that provide them with important medical care and prescription drug coverage. These disasters may negatively affect the underlying

operational and clinical systems that CMS relies on for accurate performance measurement in the Star Ratings program. With slight additions to the proposed policy, we will adjust the 2019 and 2020 Star Ratings to take into account the effects of extreme and uncontrollable circumstances that occurred during the performance period, such as the disasters (Hurricanes Harvey, Irma, and Maria, and the wildfires in California) that occurred during the 2017 performance period. CMS is also concerned that certain natural disasters and emergencies that continue into early 2018 may interfere in plans' ability to conduct surveys needed for 2019 Star Ratings. There was overwhelming support for CMS's proposal to adjust Star Ratings for the widespread disasters and overall support for our approach. A small number of commenters asked for clarification on several topics:

- ongoing communication issues in Puerto Rico and subsequent impact on the Call Center measures.
- whether CMS would apply hold harmless rules for the appeals measures since the disasters did impact these processes, and
- how CMS will handle new measures for the 2019 Star Ratings.

A few commenters wanted more clarification about the two thresholds (that is, the thresholds for applying certain additional adjustments) chosen for these policies. Below we describe the final policies for identifying affected contracts, and adjusting the Star Ratings measures.

Identification of Affected Contracts

We will first identify MA and Part D contracts affected by extreme and uncontrollable circumstances that may have affected their performance on Star Ratings measures or their ability to collect the necessary measure-level data. These "affected contracts" will be the contracts eligible for the adjustments detailed below to take into account the effects of the extreme and uncontrollable circumstances.

Affected contracts are:

(1) Contracts operating solely in Puerto Rico (i.e., serving only residents of Puerto Rico) for the 2019 Star Ratings;[19]

OR

[19] We noted, in our subsequent review, that the proposal for contracts that cover only service areas in Puerto Rico were defined as always affected by extreme and uncontrollable circumstances under this policy. However, this designation is intended only for the 2019 Star Ratings in light of the specific circumstances of 2017 and 2018 in Puerto Rico. For the 2020 Star Ratings (unless otherwise addressed in the Call Letter for those Ratings), Puerto Rico contracts will be treated the same as contracts in other areas when determining which contracts are affected contracts for purposes of these adjustments.

(2) Contracts that meet all of these criteria:

a. The service area is within an "emergency area" during an "emergency period" as defined in Section 1135(g) of the Act.

b. The service area is within a county, parish, U.S. territory or tribal area designated in a major disaster declaration under the Stafford Act and the Secretary exercised[20] authority under Section 1135 of the Act based on the same triggering event(s).

c. At least one enrollee under the contract resides in a FEMA-designated Individual Assistance area at either the time of the survey (for CAHPS and HOS adjustments to survey responses) or the time of the disaster (for all other adjustments). For some adjustments, a certain percentage (25% or 60%) of the enrollees under the contract must reside in a FEMA-designated Individual Assistance area at the time of the disaster.

The policy is tailored to the specific areas experiencing the extreme and uncontrollable circumstance in order to avoid over-adjustment or adjustments that are unnecessary. Health and drug plans can serve enrollees across large geographic areas, and thus they may not be impacted in the same manner as healthcare providers such as hospitals or medical centers located in specific physical locations. For purposes of this policy, a narrower geographic scope than the full emergency area ensures that the Star Ratings adjustments focus on the specific geographic areas that experienced the greatest adverse effects from the extreme and uncontrollable circumstance and are not applied to areas sustaining little or no adverse effects. We will identify an area as having experienced extreme and uncontrollable circumstances if it is within an "emergency area" and "emergency period" as defined in Section 1135(g) of the Act, and also is within a county, parish, U.S. territory or tribal government designated in a major disaster declaration under the Stafford Act and the Secretary exercised[21] authority under Section 1135 of the Act based on the same triggering event(s) (https://www.phe.gov/emergency/news/healthactions/section1135/Pages/default.aspx). Major disaster areas are identified and can be located on Federal Emergency Management Agency (FEMA) website at https://www.fema.gov/disasters.

Table 15 lists all of the Section 1135 waivers that could affect the 2019 Star Ratings. Some of the entries do not qualify for consideration of having an extreme or uncontrollable circumstance.

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[20] Based on our review of the timing of the various declarations under the Stafford Act and Section 1135, we believe that requiring one declaration to precede the other unnecessarily limits our policy, so we are finalizing this criterion with a slight adjustment.

[21] Based on our review of the timing of the various declarations under the Stafford Act and Section 1135, we believe that requiring one declaration to precede the other unnecessarily limits our policy, so we are finalizing this criterion with a slight adjustment.

For example, no counties in Florida and Louisiana have FEMA Major Disaster Declarations associated with Hurricane Nate.

Table 15: List of Section 1135 Waivers issued in relation to the FEMA Major Disaster Declarations

Section 1135 Waiver Date Issued	Waiver or Modification of Requirements Under Section 1135 of the Social Security Act	FEMA Major Disaster Declaration	FEMA Incident Type	Affected State	Incident Start Date	Incident End Date	Declared Major Disaster
12/11/2017	CA as the result of wildfires	DR-4353	Flood, Mud/Landslide, Wildfire	CA	12/04/2017	12/04/2017	01/02/2018
10/15/2017	CA as the result of wildfires	DR-4344	Fire	CA	10/08/2017	10/31/2017	10/10/2017
10/8/2017	AL as the result of hurricane Nate	DR-4349	Hurricane – Nate	AL	10/06/2017	10/10/2017	11/16/2017
10/8/2017	FL as the result of hurricane Nate	None	N/A	N/A	N/A	N/A	N/A
10/8/2017	LA as the result of hurricane Nate	None	N/A	N/A	N/A	N/A	N/A
10/8/2017	MS as the result of hurricane Nate	DR-4350	Hurricane – Nate	MS	10/06/2017	10/10/2017	11/22/2017
09/19/2017	PR as the result of hurricane Maria	DR-4339	Hurricane – Maria	PR	09/17/2017	11/15/2017	09/20/2017
09/19/2017	VI as the result of hurricane Maria	DR-4340	Hurricane – Maria	VI	09/16/2017	09/22/2017	09/20/2017
09/08/2017	SC as the result of hurricane Irma	DR-4346	Hurricane – Irma	SC	09/06/2017	09/13/2017	10/16/2017
09/08/2017	GA as the result of hurricane Irma	DR-4338	Hurricane – Irma	GA	09/07/2017	09/20/2017	09/15/2017
09/07/2017	FL as the result of hurricane Irma	DR-4337	Hurricane – Irma	FL	09/04/2017	10/18/2017	09/10/2017
09/06/2017	PR as the result of hurricane Irma	DR-4336	Hurricane – Irma	PR	09/05/2017	09/07/2017	09/10/2017
09/06/2017	VI as the result of hurricane Irma	DR-4335	Hurricane – Irma	VI	09/05/2017	09/07/2017	09/07/2017
08/28/2017	LA as the result of hurricane Harvey	DR-4345	Hurricane – Harvey	LA	08/27/2017	09/10/2017	10/16/2017
08/26/2017	TX as the result of hurricane Harvey	DR-4332	Hurricane – Harvey	TX	08/23/2017	09/15/2017	08/25/2017

To ensure the policy is applied to those contracts most likely to have experienced the greatest adverse effects, it is narrowed to apply to contracts with at least one enrollee residing in an area declared as an Individual Assistance area because of the disaster declaration. Individual

Assistance includes assistance to individuals and households, crisis counseling, disaster case management, disaster unemployment assistance, disaster legal services, and the disaster Supplemental Nutrition Assistance Program. We focus on enrollees residing in counties eligible for Individual Assistance because of a major disaster, because most Star Ratings measures are based on services provided directly to beneficiaries in their local area. Therefore, adjustments to the Star Ratings are most appropriately targeted to contracts serving beneficiaries who were eligible for individual and household assistance because of the disaster declaration.

Table 16 lists the Individual Assistance counties from the relevant FEMA Major Disaster Declarations. Some of the FEMA Major Disaster Declarations do not trigger our policy for adjusting CY2019 Star Ratings, because there are no counties designated as Individual Assistance areas (for example, DR-4345 Hurricane Harvey was a Major Disaster Declaration but there are no Individual Assistance areas in Louisiana as a result).

Table 16: Individual Assistance counties in FEMA Major Disaster Declared States

FEMA Declaration	State	FEMA Individual Assistance Counties
DR-4332	Texas	Aransas, Austin, Bastrop, Bee, Brazoria, Caldwell, Calhoun, Chambers, Colorado, DeWitt, Fayette, Fort Bend, Galveston, Goliad, Gonzales, Grimes, Hardin, Harris, Jackson, Jasper, Jefferson, Karnes, Kleberg, Lavaca, Lee, Liberty, Matagorda, Montgomery, Newton, Nueces, Orange, Polk, Refugio, Sabine, San Jacinto, San Patricio, Tyler, Victoria, Walker, Waller, Wharton
DR-4335	Virgin Islands	St. John, St. Thomas
DR-4336	Puerto Rico	Canovanas, Catano, Culebra, Dorado, Fajardo, Loiza, Luquillo, Toa Baja, Vega Baja, Vieques
DR-4337	Florida	Alachua, Baker, Bradford, Brevard, Broward, Charlotte, Citrus, Clay, Collier, Columbia, DeSoto, Dixie, Duval, Flagler, Gilchrist, Glades, Hardee, Hendry, Hernando, Highlands, Hillsborough, Indian River, Lafayette, Lake, Lee, Levy, Manatee, Marion, Martin, Miami-Dade, Monroe, Nassau, Okeechobee, Orange, Osceola, Palm Beach, Pasco, Pinellas, Polk, Putnam, Sarasota, Seminole, St. Johns, St. Lucie, Sumter, Suwannee, Union, Volusia
DR-4338	Georgia	Camden, Charlton, Chatham, Coffee, Glynn, Liberty, McIntosh
DR-4339	Puerto Rico	Adjuntas, Aguada, Aguadilla, Aguas Buenas, Aibonito, Anasco, Arecibo, Arroyo, Barceloneta, Barranquitas, Bayamon, Cabo Rojo, Caguas, Camuy, Canovanas, Carolina, Catano, Cayey, Ceiba, Ciales, Cidra, Coamo, Comerio, Corozal, Culebra, Dorado, Fajardo, Florida, Guanica, Guayama, Guayanilla, Guaynabo, Gurabo, Hatillo, Hormigueros, Humacao, Isabela, Jayuya, Juana Diaz, Juncos, Lajas, Lares, Las Marias, Las Piedras, Loiza, Luquillo, Manati, Maricao, Maunabo, Mayaguez, Moca, Morovis, Naguabo, Naranjito, Orocovis, Patillas, Penuelas, Ponce, Quebradillas, Rincon, Rio Grande, Sabana Grande, Salinas, San German, San Juan, San Lorenzo, San Sebastian, Santa Isabel, Toa Alta, Toa Baja, Trujillo Alto, Utuado, Vega Alta, Vega Baja, Vieques, Villalba, Yabucoa, Yauco
DR-4340	Virgin Islands	St. Croix, St. John, St. Thomas

FEMA Declaration	State	FEMA Individual Assistance Counties
DR-4344	California	Butte, Lake, Mendocino, Napa, Nevada, Orange, Sonoma, Yuba
DR-4345	Louisiana	None
DR-4346	South Carolina	None
DR-4349	Alabama	None
DR-4350	Mississippi	None
DR-4353	California	Los Angeles, San Diego, Santa Barbara, Ventura

To determine whether a contract was impacted (such as that it would be an "affected contract" eligible for adjustments), we will compare the number of enrollees in the Individual Assistance area at the time of the disaster compared to the number of enrollees outside the Individual Assistance area. This ensures that the adjustments are limited to contracts that we believe may have experienced a real impact from the disaster in terms of operations or ability to serve enrollees. Using the Individual Assistance major disaster declaration as a requirement for the extreme and uncontrollable event policy also ensures that the policy applies only when the event is extreme, meriting the use of special adjustments to the Star Ratings.

The Hurricanes Harvey, Irma, and Maria, and the recent California wildfires trigger the extreme and uncontrollable circumstance policy as there were areas identified as "emergency areas" for "emergency periods" under Section 1135(g) as a result of these natural disasters; there were Stafford Act declarations of a major disaster applicable to them; the Secretary did exercise authority under Section 1135 of the Act as a result of these disasters; and there are enrollees residing in FEMA-designated Individual Assistance areas. During the measurement year for the 2019 Star Ratings, the effects of Hurricanes Harvey, Irma, and Maria, as well as the California wildfires were significant for Medicare beneficiaries, as well as for the Parts C and D organizations that provide important medical care and prescription drug coverage for them. We will limit relief to these major disasters since they affected large regions of the United States, leading to issues accessing medical care and prescription drug coverage. Further, plans complete many preventive screenings at the end of the calendar year so disasters in this period may have an inordinate impact on 2019 Star Ratings. Finally, beneficiaries responding to CMS surveys early in 2018 will be reflecting predominately on events in late 2017 so these disasters may impact survey results.

For the CY2019 Star Ratings, contracts operating solely in Puerto Rico (i.e., with service areas limited to Puerto Rico) will be treated as affected contracts without further analysis because of the extent of damage in that area. Several areas remain without electricity in Puerto Rico and there are reports of significant population movement as a result of Hurricane Maria that are unique in scope to Puerto Rico compared to the other Individual Assistance areas designed by FEMA during 2017. As noted below, some of the adjustments are also specific to contracts operating in Puerto Rico.

Contracts that do not meet the definition of an "affected contract" or the parameters discussed below will not be eligible for any adjustments under this policy.

CAHPS Adjustments:

For CAHPS, CMS will take into account the effects of these disasters in the following ways for affected contracts:

(1) For contracts that operate solely in Puerto Rico, we will make the 2018 survey optional, given substantial ongoing issues contacting enrollees in Puerto Rico and the continuing loss of electricity and damage to infrastructure in several areas. If a contract in Puerto Rico chooses not to administer the 2018 survey, it will receive the contract's 2018 CAHPS Star Ratings for the 2019 Star Ratings. If a contract in Puerto Rico choses to administer the 2018 survey, it will receive the higher of the 2018 or 2019 Star Rating (and corresponding measure score) for each CAHPS survey measure (including the annual flu vaccine measure). We are finalizing this relief because of concerns that an adjustment to the 2018 survey results consistent with our policy for other affected contracts may not capture all possible impacts of the major disasters given the possibility of unusual response patterns due to the scope of the disasters, and we do not know what performance would have been observed in the absence of these disasters.

(2) For other affected contracts, the MA organization will be required to administer the 2018 CAHPS survey unless the contract requested and we approved an exception because a substantial number of their enrollees have been displaced due to a FEMA-designated disaster in 2017 making it practically impossible to contact the required sample for the survey. Our adjustment is two-fold: one adjustment for affected contracts and an additional adjustment for affected contracts with at least 25% of enrollees residing in FEMA-designated Individual Assistance areas.[22]

[22] In connection with the adjustments, the draft Call Letter in some places referred to affected contracts "with more than 25% of enrollees residing in the FEMA-designated Individual Assistance areas." We intended the policy to apply to contracts with *at least* 25% of enrollees residing in those areas. We have corrected the description of the threshold in this final Call Letter so it is consistent throughout the document.

The CAHPS scores for affected contracts will be adjusted to account for the impact of the disaster. A CAHPS respondent will be considered to reside in a FEMA-designated disaster area if the respondent lives in a FEMA-designated Individual Assistance area at the time of the survey. This adjustment for non-Puerto Rico contracts will pool across contracts to develop separate estimates for each disaster. Unlike the usual procedures for case-mix adjustment, the coefficients will be estimated in a difference-in-differences manner (controlling for the previous year's scores in the same contracts). In particular, the estimated effect of a disaster will be the mean CAHPS score change from the previous year in affected counties minus the mean CAHPS score change from the previous year in unaffected counties, both estimated from only the contracts that have sample in both the affected counties and unaffected counties. This approach distinguishes changes that were specific to the affected areas from overall trends in CAHPS scores and only adjusts for the change in CAHPS scores that is specific to the affected areas. We will only adjust if the effects are in a consistent direction and adjustment is advantageous to contracts.

In addition, affected contracts with at least 25% of beneficiaries residing in affected Individual Assistance areas at the time of the disaster will receive the higher of the 2018 or the adjusted 2019 Star Rating (and corresponding measure score) for each CAHPS measure (including the annual flu vaccine measure). We chose the 25% cutoff based on analysis of the distribution of the data for the percent of enrollees per contract in the Individual Assistance areas at the time of the disasters. The 25% was chosen based on the distribution since no contracts were near this cut off and it would avoid including contracts with very few enrollees impacted. The measure-level scores for contracts with very few enrollees impacted should not be adversely affected by these disasters. If a small percentage of enrollees was impacted by a disaster, it should not have a significant impact on measure scores.

Further, contracts operating solely in Puerto Rico will be excluded from 2019 Star Ratings cut point calculations for CAHPS measures. Cut points for contracts operating solely in Puerto Rico will have their cut points calculated using only data collected in 2018.

HOS Adjustments:

For the HOS survey, we will follow similar procedures as CAHPS but the adjustment will be to the 2020 Star Ratings instead of the 2019 Star Ratings. This is because the HOS data collection is lagged. The 2019 Star Ratings are based on data collected from April through June 2017. The data collected in 2018 are used for the 2020 Star Ratings and reflect experiences over the past 12 months, so responses may reflect experiences during 2017 disasters.

(1) For contracts solely operating in Puerto Rico, we will make the 2018 HOS survey optional, given substantial ongoing issues contacting enrollees in Puerto Rico, the continuing loss of electricity and damage to infrastructure in several areas. If a contract in Puerto Rico chooses not to administer the 2018 HOS Cohort 21 Baseline and Cohort 19 Follow-up surveys, it will receive the previous year's Star Ratings (and corresponding measure score) for HOS and HEDIS-HOS measures in the 2020 Star Ratings. If a contract in Puerto Rico chooses to administer the 2018 HOS surveys, we will assign it the higher of the current or previous year's Star Rating (and corresponding measure score) for each HOS and HEDIS-HOS measure in the 2020 Star Ratings.

(2) For affected contracts, the MA organization will be required to administer the 2018 HOS surveys unless the contract requests and CMS approves an exception because a substantial number of the contract enrollees have been displaced due to a FEMA-designated disaster in 2017 (i.e., Hurricanes Harvey, Irma, Maria, or the California wildfires) and it would be practically impossible to contact the required sample for the survey.

The HOS scores for affected contracts will be adjusted to account for the impact of the disaster. A HOS respondent will be considered to reside in a FEMA-designated disaster area if the respondent lives in a FEMA-designated Individual Assistance area at the time of the survey. The adjustment for non-Puerto Rico contracts will pool across contracts to develop separate estimates for each disaster. Unlike the usual procedures for case-mix adjustment, the coefficients will be estimated in a difference-in-differences manner (controlling for the previous year's scores in the same contracts). We will only adjust if the effects are in a consistent direction and adjustment is advantageous to contracts.

In addition, affected contracts with at least 25% of beneficiaries residing in affected Individual Assistance areas at the time of the disaster will receive the higher of the current or previous year's Star Rating for each HOS and HEDIS-HOS measure (and corresponding measure score) in the 2020 Star Ratings. We chose the 25% cutoff based on analysis of the distribution of the data for the percent of enrollees per contract in the Individual Assistance areas at the time of the disasters. Please see discussion above for more details.

Our policy for cut points for non-CAHPS measures is addressed below.

HEDIS Adjustments:

For HEDIS reporting in June 2018 that covers the 2017 measurement year for the 2019 Star Ratings, contracts operating solely in Puerto Rico will have the option to report "NA" for all HEDIS measures; all other affected contracts will be required to report HEDIS data to CMS unless the MA organization of an affected contract requests and receives from CMS an exception given the inability to obtain both administrative and medical record data. All contracts in disaster areas can work with NCQA to request modifications to the samples for measures that require

medical record review. If a Puerto Rico contract reports an "NA" for any of the Star Ratings measures, the contract will receive the 2018 Star Ratings for that measure. If a Puerto Rico contract chooses to report any of the HEDIS measures, the contract will receive the higher of the 2018 or 2019 Star Rating (and corresponding measure score) for each HEDIS measure reported.

For affected contracts that have service areas outside of Puerto Rico with at least 25% of beneficiaries in a FEMA-designated Individual Assistance area at the time of the disaster, we will take the higher of the 2018 or 2019 Star Ratings (and corresponding measure score) for each HEDIS measure. Please see discussion above for the selection of the 25% cutoff.

Other Star Ratings Measure Adjustments:

For all other measures for affected contracts with at least 25% of beneficiaries in a FEMA-designated Individual Assistance area at the time of the disaster, we will take the higher of the 2018 or 2019 measure Star Rating (and then use the corresponding measure score).

As proposed with three significant modifications, we will exclude from this adjustment policy the following measures: Part C Call Center – Foreign Language Interpreter and TTY Availability and Part D Call Center – Foreign Language Interpreter and TTY Availability. First, given the continuing loss of electricity and damage to infrastructure in several areas of Puerto Rico, we are excluding the Call Center measures from the calculation of the 2019 Star Ratings for contracts that operate solely in Puerto Rico. Second, unlike our proposal, we will not exclude appeals measures from adjustment under the final disaster policy. These changes are in response to comments on these topics and explained in more detail below. Third, we are adopting a hold harmless adjustment/policy for new measures.

We will exclude the Call Center measures from the adjustments for affected contracts that do not operate solely in Puerto Rico because these measures and the underlying performance are completely in the plan's control; we believe therefore that there should be no impact from the declaration of a disaster on plan performance in these areas. We will exclude the Call Center measures from the 2019 Star Ratings for contracts solely serving Puerto Rico given ongoing communication issues in Puerto Rico related to the loss of electricity and damage to infrastructure.

Several commenters described how disasters may influence their appeals data, for example if plans' call centers or administrative offices are located in a disaster area or if beneficiaries had issues contacting the plan in order to initiate appeals processes. We found these arguments compelling, so we are no longer excluding the appeals measures from adjustments. For the appeals measures for contract with at least 25% of beneficiaries in a FEMA-designated Individual Assistance area at the time of the disaster, we will do a comparison of the 2018 and 2019 measure-level Star Ratings and use the higher of the two.

Several commenters also pointed out that our policy did not cover new 2019 Star Ratings measures. We agree that new measures should also be addressed. Also, our policy of using 2018 Star Ratings is not applicable for new measures since we cannot compare with the prior years' Star Ratings. Therefore, we will implement a hold harmless provision for *new* Star Ratings measures if the inclusion of all applicable new measure(s) brings the highest rating down. That is, for affected contracts with at least 25% of beneficiaries in a FEMA-designated Individual Assistance area at the time of the disaster, all the new measures will be excluded from the calculation of the highest rating if their inclusion brings a contract's summary (or in the case of MA-PD contracts, the overall) rating down.

Currently, contracts must have data for at least half of the attainment measures used to calculate the Part C or Part D improvement measures to be eligible to receive a rating in each improvement measure. For contracts that revert back to the data underlying the 2018 Star Rating for a particular measure, that measure will be excluded from both the count of measures (for the determination of whether the contract has at least half of the measures needed to calculate the relevant improvement measure) and the applicable improvement measures for the 2019 and 2020 Star Ratings. That is, we will follow our usual rule where to receive a Star Rating in the improvement measures a contract must have measure scores for both years in at least half of the required measures used to calculate the Part C improvement or Part D improvement measures. The use of the data from the 2018 Star Ratings means that there is no measure score from the 2019 Star Ratings, so the usual rule would eliminate the measure from consideration.

Cut Points for Non-CAHPS Measures:

Currently, the Star Rating for each non-CAHPS measure is determined by applying a clustering algorithm to the measures' numeric value scores from all contracts required to submit the measure. The cut points are derived from this clustering algorithm. We will exclude from this clustering algorithm the numeric values for affected contracts with 60% or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the disaster. These contracts will be excluded to ensure that any impact of the disaster on their measure-level scores will not have an impact on the cut points for other contracts. However, these cut points calculated for all other non-affected contracts will be used to assess these affected contracts' 2019 measure Star Ratings. We will compare the 2019 measure Star Ratings to the contracts' 2018 measure Star Ratings to determine which is higher, and therefore used for the impacted contracts' 2019 Star Ratings calculations, per above. We examined the data from the 2018 Star Ratings to see how the performance of the affected contracts (that is, the contracts identified to be excluded) differs from other contracts. When these affected contracts are removed from the distribution of measure-level scores, the distribution of the remaining contracts looks very similar to the distribution of 2018 Star Ratings, which suggests the affected contracts are randomly distributed among the rating levels.

Similarly, affected contracts with 60% or more of their enrollees impacted will also be excluded from the determination of the performance summary and variance thresholds for the Reward Factor. However, these contracts will still be eligible for the Reward Factor based on the mean and variance calculations of other contracts.

We identified and are finalizing the 25% enrollment threshold based on our analysis of the data. We observed that contracts tend either to have very few enrollees impacted or most of their enrollees impacted. If one out of four enrollees was impacted during the period of the year when the disaster hit, we believe there is a small chance that scores may have been impacted. If very few enrollees in a contract lived in impacted areas during the disaster period, the measure-level scores should not be impacted. We believe the 25% threshold for using the prior year's rating is generous and preserves the accuracy of the ratings for plan choice. The selection of the exclusion of numeric measures scores from contracts with 60% or more enrollees impacted from the determination of the cut points was chosen through an analysis of the distribution of the percent of enrollees impacted by contract across all contracts impacted. The 60% was chosen since there was a break in the distribution. Our approach in selecting 60% is conservative in case scores are impacted in contracts where a clear majority or all of the enrollees are impacted.

2019 CMS Display Measures

Display measures on CMS.gov are not part of the Star Ratings. These may include measures that are transitioned from inclusion in 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's 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 2018 display measures will continue to be shown as display measures on CMS.gov in 2019 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.

New 2019 Display Measure

- **Plan Makes Timely Decisions about Appeals (Part C).** We will display a new appeals measure which includes cases dismissed by the IRE because the plan has subsequently approved coverage/payment (using 2017 data). Currently, we exclude all cases dismissed/withdrawn by the IRE from the timely appeals measure. However, plans' performance may be artificially improved as a result, especially if the dismissal were directly related to the plans' (untimely) approval. The new measure will include dismissed but not withdrawn cases. Inclusion of cases where the plan has subsequently approved for coverage/payment that are dismissed at the IRE level could provide a more accurate

assessment of plans' timeliness in their Part C appeals processing. The inclusion of dismissals would only apply to cases dismissed by the IRE because the plan issued an untimely favorable decision. We will post this modified measure that includes dismissed cases on the 2019 and 2020 display pages; we intend also to add this revised measure to the 2021 Star Ratings. At that time the current "Plan Makes Timely Decisions about Appeals" measure would be retired.

Changes to Existing Display Measures

- **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, where hospitalizations represent a failure to prevent a serious complication. However, concerns raised by experts and stakeholders have led NCQA to consider updating the specifications to include hospital stays that are considered "observation stays" to improve completeness of the measure. That is, observation stays can also represent a failure to prevent serious complications. Therefore, we will retain this measure as a 2019 display page measure. We will propose through rulemaking moving it to Star Ratings with a weight of 1 for the 2022 Star Ratings. In subsequent years, we intend to weight it 3 as an outcomes measure. Please refer to the NCQA HEDIS 2018 Technical Specifications for Health Plans Volume 2 for measure construction and technical specifications, as well as to more recent communications from NCQA as to updates in specifications. CMS shared all comments received on this measure with NCQA.

- **High Risk Medication (Part D).** The 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. This measure will remain on the display page for 2019 (based on 2017 data), and we will use the updated PQA HRM drug list for that display. We will also adopt the specification change made by the PQA to measure specifications for the numerator (beneficiaries with at least two fills of the same HRM drug on different dates of service) for the 2019 display measure.

- **Drug-Drug Interactions (DDI) (Part D).** The PQA DDI measure is the percent of Part D beneficiaries who received a prescription for a target medication during the measurement period who were also dispensed a concurrent prescription for a contraindicated medication with or subsequent to the initial prescription. As discussed in the 2018 Call Letter, the PQA updated the DDI measure drug list. CMS will implement the revised list for the 2019 display measure using 2017 PDE data.

- **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. For the 2017 measurement year, the APD measure includes an overall measure rate and breakouts for community-only (COMM) residents and long-term nursing home (LTNH) residents. CMS will display the rates for the two population breakouts on the 2019 display page (in addition to the overall APD rate currently displayed). We will assess adding the APD measure to the Star Ratings in the future, which would be proposed through rulemaking.

- **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.

  The PQA's Measure Update Panel and Quality Metrics Expert Panel 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. We will add only the OHDMP measure to the 2019 Part D display page (using 2017 data) because Measure 3 mirrors the criteria used in the Overutilization Monitoring System (OMS) before revisions were

implemented in 2018, whereas the other two measures do not. All three measures will continue to be reported to Part D plan sponsors through the Patient Safety reports.

Although most commenters this year supported these changes and adding the measure to the display page, some commenters raised concerns about the measure specifications and requested that CMS delay adding the measures to the display page or Star Ratings. For example, commenters suggested that: 1) the PQA lower the threshold in the opioid measures to align with the March 2016 Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain[23], 2) consider changes to align with CMS policy, 3) exclude beneficiaries receiving palliative care or end-of-life care, and 4) count prescribers associated with the same Tax Identification Number (TIN) as a single prescriber. Measure specification comments were shared with the PQA.

Due to the timing of their measure development and NQF endorsement process, the PQA has not yet revised its measures. It is our understanding that the PQA will discuss additional changes in 2018 along with a timeline for testing potential modifications. We will monitor updates to the measure specifications made by the PQA and consider the revised measure for adoption (as a display measure with subsequent use as a Star Ratings measure) after advance notice through a future Call Letter. CMS will re-assess including the existing measures in the display page and in the Star Ratings when the PQA updates them.

Note, additional proposals to the Medicare Part D opioid overutilization policy are discussed under the heading "Improving Drug Utilization Review Controls" in the Medicare Part D section.

- **Transition Monitoring (Part D).** Since 2015, CMS has produced two display measures using the results from the Transition Monitoring Program Analysis (TMPA). We will no longer display two separate contract-level measures, one for drugs within the classes for clinical concern and one for all other drugs. Instead, the results will be consolidated into one failure rate and display measure. This change aligns with the display measure for the Formulary Administration Analysis (FAA). Previously, the data was displayed as a percentage with one decimal place. In order to provide the most accurate results, beginning with the 2019 display measure, the data will be displayed as a percentage with two decimal places.

- **Formulary Administration Analysis measure (Part D).** This display measure, added in 2018, uses the results of the 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.

[23] See https://www.cdc.gov/drugoverdose/prescribing/guideline.html.

Previously the data for this measure was displayed as a percentage with one decimal place. In order to provide the most accurate results, beginning with the 2019 display measure, the data will be displayed as a percentage with two decimal places.

- **Timely Effectuation of Appeals (Part D).** This measure is defined as the percent of appeals requiring effectuation that the plan effectuated in a timely manner (timely is defined as effectuation of the decision within one day for expedited appeals, and effectuation of the decision within three days for standard appeals). If the IRE does not receive a notice of effectuation before the report generation date, the IRE will count the effectuation as non-timely. Previously, this measure included all data applicable to the time period being reported as of the date the report is generated by the IRE. Data may change based on the report date. Discrepancies may also result if the IRE received the effectuation notice late, even though the plan's effectuation was timely. Reopenings of appeals may extend into the following contract year which can impact effectuation data. In order to allow for these factors, we will modify this measure to be defined as all appeals received by the IRE in the measure timeframe. To account for reopenings and appeals that straddle the contract year, all decisions from this time period will be included up to May 1st of the following contract year. For example, the CY 2019 display measure's timeframe will be IRE cases received from 1/1/18 – 12/31/18 with decisions on those appeals made before 5/1/19. Effectuations for appeals decided on or after May 1, 2019 that correspond to an appeal received 1/1/18 – 12/31/18 will not be reflected in these data and the timeliness of the reconsideration will be used. Additionally, we will exclude the results of appeals that occur beyond Level 2 (i.e., Administrative Law Judge or Medicare Appeals Council appeals) from this measure.

Display Measures being Retired

- **Enrollment Timeliness (Part C and D).** The measure assesses the timeliness of enrollment transactions using the number of plan generated enrollment transactions submitted to CMS within 7 calendar days of the application date and the total number of plan generated enrollment transactions submitted to CMS. Beginning in 2012, CMS has been displaying and monitoring the values of enrollment timeliness. Overall, contracts are receiving extremely high rates for this measure (96 percent on average). For the 2019 Star Ratings, we will discontinue the display of the measure. We encourage contracts to continue to track their enrollment timeliness.

- **Appropriate Monitoring of Patients Taking Long-term Medications and Asthma Medication Ratio (Part C).** NCQA removed the Medicare population from these measures. Therefore, we will discontinue display of these measures in 2019. CMS shared all comments received on this measure with NCQA.

Forecasting to 2020 and Beyond

The following describes potential 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 2020 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.

In the Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (CMS-4182-P) proposed rule published in the Federal Register on November 28, 2017 (82 FR 56336), we stated that new measures or measures with substantial changes would be proposed through the Federal Register rulemaking process for the 2021 Star Ratings or beyond (82 FR 56378) while the Advance Notice/Call Letter process would continue to be used for the 2019 and 2020 Star Ratings.

Potential Changes to Existing Measures

- **Controlling High Blood Pressure (Part C)**. Due to the release of new hypertension treatment guidelines from the American College of Cardiology and American Heart Association, NCQA is evaluating potential updates to the Controlling High Blood Pressure measure for HEDIS 2019. Additionally, NCQA is exploring modifications to the denominator criteria of the measure to improve feasibility and reduce burden, and potential administrative approaches for meeting numerator criteria. CMS shared all comments received on this measure with NCQA.

- **Plan All-Cause Readmissions (Part C).** NCQA is exploring several revisions to the HEDIS Plan All-Cause Readmissions measure based on feedback it has received from the field and stakeholders. These revisions may impact the definition of the denominator, numerator, and risk adjustment model for data collected in 2019. The specific revisions being explored 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 for this measure. NCQA is also considering stratifying this measure to separate those individuals with high frequency of index hospital stays. These changes are pending NCQA's analyses. CMS is also proposing to combine the rates for ages 18-64 and ages 65+ for the revised PCR measure. The revised measure would use NCQA's new recommendation of 150 as the minimum denominator value for data to be used. The revised measure would be part of the display page for 2020 and 2021 and would be proposed through rulemaking for the 2022 Star Ratings with a weight of 1 for the first year and a weight of 3 thereafter. The current Plan All-Cause Readmissions measure will remain in the Star Ratings through 2019.

NCQA is also considering a possible stratification of the Plan All-Cause Readmissions measure to identify the percentage of hospital discharges that result in an unplanned hospital readmission during or after a skilled nursing facility stay for MA contracts. As noted below an alternate strategy would be to report readmissions from skilled nursing facilities as a new measure. CMS shared all comments received on this measure with NCQA.

- **Initiation and Engagement in Alcohol or Drug Dependence (AOD) Treatment (Part C).** NCQA modified this measure to include data on the use of MAT in the denominator and numerator components of the measure. This measure will continue to be included on the display page. CMS shared all comments received on this measure with NCQA.

- **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 provided by the MAO as an 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 to (reasonable replacements for) in-person visits for relevant clinical areas. CMS shared all comments received on this measure with NCQA.

- **Cross-Cutting Exclusions for Advanced Illness (Part C).** NCQA is evaluating the clinical appropriateness and feasibility of excluding individuals with advanced illness from selected HEDIS measures. While HEDIS 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 assessing the need for having exclusions for selected HEDIS measures for patients with advanced illness where providing certain treatments and services may not be appropriate. NCQA is exploring which specific illnesses and healthcare utilization may warrant an exclusion, and to which measures the exclusion should be applied. If approved, updates to HEDIS measures for any additional exclusions would be incorporated in HEDIS 2019. CMS shared all comments received on this measure with NCQA.

- **Medication Adherence (ADH) for Cholesterol (Statins) (Part D).** The PQA updated this measure for 2018 to exclude beneficiaries with ESRD. CMS will apply this exclusion to the 2020 Star Ratings (based on 2018 data), in the same manner that the ESRD exclusion is currently applied to the Medication Adherence (ADH) for Hypertension (RAS

Antagonists), Medication Adherence for Diabetes Medications, and Statin Use in Persons with Diabetes measures.

- **Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) Measure (Part D).** The PQA updated this measure for 2018 to include a new denominator exception as follows:

  For patients eligible for CMR with fewer than 61 days of continuous enrollment in the MTM program:
    - Exclude them from the denominator if they did not receive a CMR within this timeframe.
    - Include them in the denominator and the numerator if they received a CMR within this timeframe.

  For example, if the patient was enrolled in the MTM program and eligible for CMR on November 2 of the measurement year, the patient would not be included in the denominator if the CMR were not received as of December 31, because there would have been fewer than 61 days of continuous eligibility during the contract year. If the patient received a CMR by December 31, the patient would be included in the denominator and the numerator.

  We will apply this denominator exception to the 2020 Star Ratings (based on 2018 data).

- **MPF Price Accuracy (Part D).** CMS proposed to make enhancements to the MPF Price Accuracy measure to better measure the reliability of a contract's MPF advertised prices. In response to the industry's requests for information about the impact of these changes to future Star Ratings, CMS will first publish the modified measure as a display measure for 2020 and 2021 and will consider adding this measure for the 2022 Star Ratings through rulemaking. Pending such a change, the current MPF measure will continue in the Star Ratings using the same methodology used for the 2018 Star Ratings. Most commenters supported this approach. Those opposed requested CMS remove this type of evaluation entirely from Star Ratings and Display measures. It is important to continue evaluation of sponsors' pricing data used by beneficiaries. Also, removing this measure from the Star Ratings before 2022 would potentially lower sponsors' overall Star Ratings given most contracts receive high ratings in this measure. We will implement the following changes for the 2020 and 2021 display of this measure (please see Appendix 1 for a more detailed methodology):

1. Factor both how much and how often prescription drug event (PDE) prices exceeded the prices reflected on the MPF by calculating a contract's measure score as the mean of the contract's Price Accuracy and Claim Percentage scores, based on the below indexes:
    - The Price Accuracy index compares point-of-sale PDE prices to plan-reported MPF prices and determines the magnitude of differences found. Using each PDE's date of service, the price displayed on MPF is compared to the PDE price. The Price Accuracy

index is computed as:

(Total amount that PDE is higher than MPF + Total PDE cost) / (Total PDE cost).

- The Claim Percentage index measures the percentage of all PDEs that meet the inclusion criteria with a total PDE cost higher than total MPF cost to determine the frequency of differences found. The Claim Percentage index is computed as:

  (Total number of claims where PDE is higher than MPF) / (Total number of claims)

- The best possible Price Accuracy index is 1 and the best possible Claim Percentage index is 0. This indicates that a plan did not have PDE prices greater than MPF prices.
- A contract's measure score is computed as:
  - Price Accuracy Score = 100 – ((Price Accuracy Index - 1) x 100)
  - Claim Percentage Score = (1 – Claim Percentage Index) x 100
  - Measure Score = (0.5 x Price Accuracy Score) + (0.5 x Claim Percentage Score)

2. Increase the claims included in the measure:
   - Expand the days' supply of claims included from 30 days to include claims with fills of 28-34, 60-62, or 90-100 days.
   - Identify additional retail claims using the PDE-reported Pharmacy Service Type code. Claims for pharmacies that are listed as retail in the MPF Pharmacy Cost file and also have a pharmacy service type on the PDE of either Community/Retail or Managed Care Organization (MCO) will be included.

3. Round a drug's MPF cost to 2 decimal places for comparison to its PDE cost. The PDE cost must exceed the PF cost by at least one cent ($0.01) in order to be counted towards the accuracy score (previously, a PDE cost which exceeded the MPF cost by $0.005 was counted). A contract may submit an MPF unit cost up to 5 digits, but PDE cost is always specified to 2 decimal places.

   In this measure, a contract's score is not lowered if PDEs are priced lower than MPF displayed pricing. Only price increases are counted in the numerator for this measure.

   The enhancements are largely those which had been previously finalized in the 2018 Call Letter. Rounding a drug's MPF cost will resolve the identified measurement error that resulted in CMS not implementing these changes for 2018 Star Ratings.[24] Simulations of

[24] Please see the HPMS memo released on August 9, 2017, "First Plan Preview of 2018 Star Ratings Data" https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Preview-2018-Star-Ratings-Data.pdf

these changes using 2016 MPF and PDE data found MA-PD and PDP performance to be similarly high, where the mean measure score is 91. The bottom 10th percentile of MA-PDs scored 81, and PDPs scored 85. Recent simulations using preliminary (non-final) 2017 PDE data confirmed that on average, contracts with higher scores in the current methodology would continue to perform similarly under the new specifications. Additionally, the number of PDEs included would increase by over 50%, and more contracts would meet the minimum claim criteria for the measure. We will continue to provide contracts their preliminary as well as final MPF Price Accuracy reports, which contain claim level information. We will also begin sharing with contracts information about their Accuracy scores using the new specifications.

- **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 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's goal is to not penalize participants or non-participants in either model.

  For the MA-VBID Model test, CMS is considering the option of excluding VBID participants' data when calculating the cut points for relevant measures starting with the 2020 Star Ratings. 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.

Potential New Measures for 2020 and Beyond

- **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. We plan to propose to include this measure with the four indicators on the 2020 display measure for possible inclusion in the 2022 Star Ratings. CMS shared all comments received on this measure 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 an 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 after 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 shared all comments received on this measure with NCQA. We plan to propose to include this measure on the 2020 display page for possible inclusion in the 2022 Star Ratings.

- **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. We have identified potential new care coordination measures and are currently testing them for possible future implementation. We will provide more details at a later date.

- **Opioid Overuse (Part C).** For HEDIS 2018, NCQA is collecting data on Use of Opioids at High Doses and Use of Opioids from Multiple Providers. These measures are adapted from the PQA's opioid measures (discussed above).

  For HEDIS 2019, NCQA will be testing a new measure concept that addresses members who were previously naïve to opioids who become long-term or "chronic" users. In addition to understanding the feasibility and utility of reporting this measure concept at the health plan level, testing of this concept will focus on exploring different definitions of "opioid naïve" and "chronic use," as well as identifying populations that warrant exclusion from the measure. NCQA is also considering testing of a second measure concept that addresses the concurrent prescription of opioids and central nervous system (CNS) depressants. If this concept is pursued further, testing would focus on understanding the feasibility and utility of the measure, identifying populations to be excluded, and defining both the list of drugs included and the concurrent overlap period. CMS shared all comments received on these measures with NCQA. Until the measures are developed such that we can review and test the specifications and evaluate any overlap with other opioid measures, we have no plans to add these to the display page or Star Ratings.

- **Assessment of Care for People with Multiple High-Risk Chronic Conditions (Part C).** NCQA is considering a new measure concept that would adapt the current Care for Older Adults measure by expanding the number of indicators and broadening the populations covered by the set of measures. Care for Older Adults currently has four indicators and is reported by MA Special Needs Plans (SNPs) only. The new measure, Assessment of Care for People with Multiple High-Risk Chronic Conditions, would apply to all Medicare plans and would target the population of people with two or more high-risk chronic conditions. Using the same denominator introduced in the HEDIS 2018 first-year measure Follow-Up After Emergency Department Visit for People with Multiple High-Risk Chronic Conditions, the new measure would assess the percentage of members who had an expanded assessment during the measurement year. The following components may be included in the measure: physical function assessment, cognitive function assessment, pain assessment, fall risk assessment, goals of care discussion, and advance care planning. The measure concept is currently undergoing testing to assess feasibility, alignment with current practice, and gaps in care. CMS shared all comments received on this measure with NCQA.

- **Depression Screening and Follow-Up for Adolescents and Adults (Part C).** NCQA developed a measure assessing 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 is part of NCQA's new effort to collect data using an Electronic Clinical Data System (ECDS). Depending on the results during the first year of implementation, CMS

may consider this measure for the display page and Star Ratings in the future. CMS shared all comments received on this measure with NCQA.

- **Unhealthy Alcohol Use Screening and Follow-Up (Part C).** NCQA adapted the 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. This measure is part of NCQA's new effort to collect data using an ECDS. Depending on the results during the first year of implementation, CMS may consider this measure for the display page and Star Ratings in the future. CMS shared all comments received on this measure with NCQA.

- **Readmissions from Post-Acute Care (Part C).** NCQA is pursuing opportunities to measure acute facility readmissions during or following a skilled nursing facility (SNF) stay for Medicare beneficiaries. Eleven percent of beneficiaries require skilled nursing following an acute facility stay. A readmission event during or after a SNF stay may be the result of inadequate provider communication during care transitions and poor discharge planning. NCQA is exploring the development of a new measure or, as noted above, the potential adaption of the Plan All-Cause Readmissions (PCR) measure to evaluate acute facility readmissions among Medicare beneficiaries during or after a SNF stay. If approved, the new measure or revisions to the current PCR measure would be included in HEDIS 2019. CMS shared all comments received on this measure with NCQA. We acknowledge the challenges of creating this measure including appropriate risk adjustment. We will take this into consideration if the measure is developed, in making a decision about proposing it for inclusion in the Star Ratings program.

- **Adult Immunization Measure (Part C).** For HEDIS 2018, NCQA added the Pneumococcal Vaccination Coverage for Older Adults measure to the ECDS reporting domain. Measures in the HEDIS ECDS domain are calculated using electronic data from administrative claims, electronic medical records, case management systems and registries. For HEDIS 2019, NCQA will build off the pneumococcal measure and evaluate the relevance, scientific soundness, and feasibility of a composite measure for HEDIS that assesses the receipt of routine adult vaccinations. The measure developer is focusing on four specific vaccines: influenza vaccine; tetanus, diphtheria, and pertussis (Tdap) or tetanus and diphtheria (Td) booster vaccine; herpes zoster vaccine; and pneumococcal vaccine. If approved, the new measure would be included in HEDIS 2019. CMS shared all comments received on this measure with NCQA. Depending on results of implementation, CMS will determine the use of this new composite measure for the display page and Star Ratings for the future.

- **Anxiety (Part C).** NCQA is exploring the feasibility and acceptability of developing quality measures assessing care for those with anxiety disorders for inclusion in HEDIS. The approach is to conduct feasibility assessments and evidence reviews, which includes the consideration of clinical practice guidelines, evidence-based treatment, and symptom monitoring tools for all types of anxiety disorders. Recognizing the high prevalence of co-occurring anxiety and depression, NCQA is assessing the need for new anxiety quality measures or amended depression quality measures. Any new anxiety quality measures or changes for the depression measures would be included in HEDIS 2020 at the earliest. CMS shared all comments received on this measure with NCQA.

- **Polypharmacy Measures (Part D).** The PQA developed and endorsed three measures that identify potentially harmful concurrent drug use or polypharmacy. CMS reviewed these measures for potential inclusion in Patient Safety reporting, display page, or Star Ratings in the future.

  Polypharmacy: Use of Multiple Anticholinergic (ACH) Medications in Older Adults (Poly-ACH): This measure assesses the percentage of individuals 65 years and older with concurrent[25] use of two or more unique ACH medications. To be included in the denominator, a beneficiary must have at least two fills of the same ACH medication with unique dates of service during the treatment period. Any beneficiary with a hospice indicator during the measurement year was excluded. Lower rates represent better performance. We tested the PQA specifications using 2016 PDE data as of May 6, 2017. We adjusted the measure for member-years and evaluated the number of contracts with greater than 30 member-years in the denominator. There were 743 active Part D contracts in 2016 (671 MA-PDs, 67 PDPs, and 5 employer direct contracts).

  Of the 743 active Part D contracts in 2016, eight contracts had no members eligible for the Poly-ACH measure (N=735). There were 621 MA-PD and PDP contracts that had greater than 30 member-years in the denominator, and about 16% of MA-PDs and 10% of PDP contracts did not meet the greater than 30 member-year denominator criterion. The table below provides the Part D contract distributions by contract type and member-year (M-Y) criterion.

[25]The days of concurrent use is the sum of the number of days with overlapping days supply of the target medications. Concurrent use is defined as overlapping days for 30 or more (cumulative) days for both polypharmacy measures.

Table 17: Distribution of the Poly-ACH Measure Rates, Part D, 2016

Part D Contracts			Percentiles							
Type	Group	Count	Min	10%	25%	50%	75%	90%	95%	Max
All		735	0.0%	4.3%	6.0%	7.3%	10.1%	13.9%	17.5%	51.3%
MA-PD	All	667	0.0%	4.1%	5.9%	7.3%	10.3%	14.4%	17.6%	51.3%
PDP	All	63	0.0%	5.8%	6.6%	7.6%	9.4%	11.3%	12.2%	20.0%
MA-PD	>30 M-Y	561	0.0%	5.0%	6.1%	7.3%	9.9%	13.0%	15.7%	30.8%
PDP	>30 M-Y	60	5.0%	5.8%	6.6%	7.6%	9.3%	11.1%	12.1%	12.7%

As the PQA measure manual notes, medication combinations in this measure are those for which serious adverse effects have been reported among older adults. It is generally accepted that a high burden of anticholinergic use is consistently associated with cognitive impairment and increased risk of dementia in older adults. The rate distributions show variability in use across both MA-PD and PDP contracts suggesting an opportunity for improvement to reduce the use of multiple concurrent ACH medications within Part D enrolled older adults.

Polypharmacy: Use of Multiple Central Nervous System (CNS)-Active Medications in Older Adults (Poly-CNS): This measure assesses the percentage of individuals 65 years and older with concurrent use of three or more unique CNS-active medications. To be included in the denominator, a beneficiary must have at least two fills of the same CNS-active medication with unique dates of service during the treatment period. Any beneficiary with a hospice indicator during the measurement year was excluded. Lower rates represent better performance.

We also tested the Poly-CNS PQA measure specifications using 2016 PDE data. We adjusted the measure for member-years and evaluated the number of contracts with greater than 30 member-years in the denominator. A total of 736 out of 743 Part D contracts in 2016 (668 MA-PDs, 63 PDPs, and 5 employer direct contracts) had a beneficiary who met the eligibility requirements for the Poly-CNS measure. When the greater than 30 member-year denominator criterion was applied, the total number of MA-PD and PDP contracts decreased to 698. Over 5% of MA-PD contracts and 9% PDP contracts were excluded. However, the distributions did not change, so those rates are not shown in the table below.

Table 18: Distribution of the Poly-CNS Measure Rates, Part D, 2016

Part D Contracts		Percentiles							
Type	Count	Min	10%	25%	50%	75%	90%	95%	Max
All	736	0.0%	4.8%	5.9%	7.7%	11.5%	16.9%	20.3%	44.4%
MA-PD	668	0.0%	4.7%	5.9%	7.7%	11.7%	17.0%	20.7%	44.4%
PDP	63	0.0%	5.4%	6.4%	7.8%	10.2%	14.3%	17.6%	28.5%

According to the American Geriatrics Society, there is moderate evidence to avoid concurrent use of three or more CNS agents in older adults due to an increased risk of falls and possible fractures. Based on the analysis, variability exists across Part D contracts on the use of multiple concurrent CNS medications. Again, CMS believes this measure represents an opportunity to identify and reduce concurrent use of multiple CNS medications and improve the health of Medicare Part D enrollees.

Many commenters supported both the Poly-ACH and Poly-CNS measures. We will begin reporting the two measures in the Patient Safety reports for the 2018 measurement year. We plan to add the measure to the display page for 2021 (2019 data) and 2022 (2020 data). We will consider this measure for the 2023 Star Ratings (2021 data), which would be proposed through rulemaking.

Some commenters suggested extension of the minimum overlapping days supply in the measure specifications, which was shared with the PQA. Other commenters were concerned with some overlap between the HRM display measure and the new Polypharmacy measures. We will consider retiring the HRM measure for the 2021 display page after opportunity for public comment. Other commenters were concerned about overlap with the Concurrent Use of Opioids and Benzodiazepines measure (discussed below). However, the measures target different populations so there is not complete overlap even if there is potential for enrollees who use both benzodiazepines and opioids to be counted under both measures. The Poly-CNS measure analyzes the percentage of older adults (65 and older) with concurrent use of three or more unique CNS-active medications, which can include both benzodiazepines and opioids. The Concurrent Use of Opioids and Benzodiazepines measure assesses the percentage of individuals 18 years and older with concurrent use of prescription opioids and benzodiazepines. To be in the denominator, beneficiaries must have two claims for opioids.

Concurrent[26] Use of Opioids and Benzodiazepines: This measure assesses the percentage of individuals 18 years and older with concurrent use of opioids and benzodiazepines.

We tested the measure specifications using 2016 PDE data. We adjusted the measure for member-years and evaluated the number of contracts with greater than 30 member-years in the denominator. A total of 680 Part D contracts (MA-PD, PDP, and employer direct contracts) met the eligibility requirements for the Concurrent Use of Opioids and Benzodiazepine measure. The rate associated with the top 5% of PDP contracts was 42.9% while MA-PD contracts had a higher rate of 51.4%.

[26] Concurrent use is defined as an overlapping supply for an opioid and a benzodiazepine for 30 or more cumulative days.

Table 19: Distribution of the Concurrent Use of Opioids and Benzodiazepines Measure Rates, Part D, 2016

Contracts		Percentiles							
Type	**Count**	**Min**	**10%**	**25%**	**50%**	**75%**	**90%**	**95%**	**Max**
All	680	4.1%	13.2%	16.5%	20.9%	25.3%	30.1%	33.7%	51.4%
PDP	61	9.6%	13.2%	15.7%	21.1%	25.6%	31.0%	35.5%	42.9%
MA-PD	614	4.1%	13.2%	16.5%	20.9%	25.2%	30.1%	33.7%	51.4%

Most commenters supported this measure, and we will begin reporting the Concurrent Use of Opioids and Benzodiazepines measure in the Patient Safety reports for the 2018 measurement year. We plan to add the measure to the display page for 2021 (2019 data) and 2022 (2020 data). We will consider this measure for the 2023 Star Ratings (2021 data) pending rulemaking. While most supported use of the measure, some commenters did express concerns about it, citing some overlap with the Poly-CNS measure and situations where the medication use may be appropriate. Another commenter suggested that the metric only measures new concurrent use; this was shared with the PQA.

Note: see additional proposals within the Improving Drug Utilization Review Controls in Medicare Part D section.

- **Additional PQA Medication Adherence Measures (Part D).** We evaluated two additional PQA endorsed medication adherence measures within the Medicare Part D population using 2016 PDE data. We adjusted the measure for member-years. There were 743 active Part D contracts in 2016 (671 MA-PDs, 67 PDPs, and 5 employer direct contracts).

  Adherence to Non-Warfarin Oral Anticoagulants (ADH- NWOA): This measure is defined as the percentage of individuals 18 years and older who met the Proportion of Days Covered (PDC) threshold of 80 percent during the measurement period. The PQA measure manual states that adherence to all anticoagulants is important, and adherence to non-warfarin anticoagulants may be more critical to monitor since there is not a surrogate lab value such as the international normalized ratio (INR).

  Individuals who filled at least two prescriptions for a NWOA on two unique dates of service at least 180 days apart during the treatment period and who received greater than 60 days' supply of the medication during the treatment period were included in the measure. The prescriptions can be for the same or different medications. Higher rates signify better performance.

Table 20: Distribution of the ADH-NWOA Measure Rates, Part D, 2016

Contracts		Percentiles							
Type	**Count**	**Min**	**10%**	**25%**	**50%**	**75%**	**90%**	**95%**	**Max**
All	714	0.0%	60.9%	69.4%	76.9%	85.0%	100.0%	100.0%	100.0%
MA-PD	647	0.0%	60.6%	68.6%	76.4%	85.1%	100.0%	100.0%	100.0%
PDP	62	50.0%	73.5%	75.9%	79.4%	85.3%	87.3%	89.9%	100.0%

The ADH-NWOA rates for all contracts ranged from 0.0% to 100% except for PDP contracts where the minimum rate was 50.0%. Over 50% of the MA-PD and PDP contracts had rates below 76% and 79%, respectively. Many of the low and high rates were associated with contracts with low denominator member-years. Overall, 462 or 37% of MA-PD and PDP contracts had 30 or fewer member-years in the denominator.

Adherence to Non-Infused Disease Modifying Agents Used to Treat Multiple Sclerosis (ADH-MS): This measure assesses the percentage of individuals 18 years and older who met the Proportion of Days Covered (PDC) threshold of 80% during the measurement period. The denominator includes patients who filled at least two prescriptions for non-infused disease modifying agents for the treatment of multiple sclerosis on two unique dates and who received at least 56 days' supply of the medication during the treatment period. The prescriptions can be for the same or different medications. Higher rates signify better performance.

Of the 743 Part D contracts, 144 or 19% contracts had no members eligible for the ADH-MS measure in 2016. The table below reports the Part D contract rate distribution by contract type.

Table 21: Distribution of ADH-MS Measure Rates, Part D, 2016

Contracts		Percentile							
Types	**Count**	**min**	**10%**	**25%**	**50%**	**75%**	**90%**	**95%**	**Max**
All	599	0.0%	56.0%	68.5%	76.2%	85.2%	100.0%	100.0%	100.0%
MA-PD	535	0.0%	51.0%	67.9%	76.0%	85.5%	100.0%	100.0%	100.0%
PDP	59	0.0%	68.4%	72.5%	76.6%	80.5%	100.0%	100.0%	100.0%

The minimum and maximum rates for all contracts and contract types was 0.0% to 100%. Over half of the contracts had rates below 76% and the top 10% of contracts had rates at 100%. Similar to the ADH-NWOA rates, many of the high and low contract rates were associated with low denominator member-years (512 or 69% of MA-PD and PDP contracts had 30 or fewer member-years in the denominator).

Although we found some variability between the contract rates for both the ADH-NWOA and ADH-MS measures, many contracts had low member-year denominators. The low prevalence of multiple sclerosis in many Part D contracts resulted in 19% of contracts having no members eligible for the ADH-MS measure and over 25% of contracts having a 100% adherence rate. Although the prevalence of NWOA use is much higher and only 4% of contracts had no members eligible for ADH-NWOA measure, many contracts had small denominators (less than 30 member-years). A total of 512 (69%) and 276 (37%) of MA-PD and PDP contracts had 30 or fewer member-years in the denominator for the ADH-MS and ADH-NWOA measures, respectively.

Low denominators can affect the utility of a measure to assess contract performance. Currently, four adherence measures are already included in the Patient Safety reports (three are included in Star Ratings). Therefore, as we proposed, we will not add these adherence measures to the Patient Safety reports, the display page, or Star Ratings at this time. Most commenters supported this proposal in the draft Call Letter and reiterated concerns that the small denominators indicated the measure would not be a reliable indicator of performance or that the measures did not provide the full clinical picture. However, some commenters supported these measures conceptually given the high cost of these medications and the importance of adherence for achieving positive outcomes. Therefore, we will consider including these measures within the quarterly outlier reports to Part D contracts through the Patient Safety Analysis Website in the future, along with the beneficiary-level data so contracts can focus adherence improvement efforts for these members.

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 will continue to analyze existing ratings measures to determine if measure scores are “topped out” or showing high performance across all contracts. In making decisions to transition such measures to the display page, CMS does not have a strict formula. Although some measures may show uniform high performance across contracts with 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.

- CMS and measure developers are exploring additional measurement concepts for future work, such as functional status, and use of non-pharmacological or non-opioid pain management interventions, which will require use of non-claims data.

- Effective processing of Part C organization determinations and reconsiderations and Part D coverage determination and redeterminations by sponsors are critical areas of the MA and Part D program. CMS requirements for these processes provide key beneficiary protections for access to healthcare and prescription drugs. We have included 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 sponsoring organizations as described earlier. In addition to the current measures of sponsoring organizations' timeliness and reliable decision-making, we remain interested in potentially evaluating sponsoring organizations' compliance with effectuating appeals and provider outreach requirements, as well as appropriate clinical decision-making and notification to beneficiaries.

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, and PDPs are due the first Monday in June and shall be in a form and manner specified by the Secretary. For CY 2019, the bid submission deadline is June 4, 2018 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 tool).

All MA, MA-PD, PDP, and cost-based plans are responsible for confirming that complete and accurate bids are submitted by the June deadline. Employer Group Waiver Plans are subject to the submission requirements that have not been waived. 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) 2018 Bid Upload Functionality in HPMS," dated May 5, 2017).

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 program requirements include:

- 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 2019 Call Letter.
- 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 4, 2018 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. 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.

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 2018 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 2018.

We received a few comments expressing concerns about CMS issuing compliance actions for minor data input errors. Potential CMS compliance actions discussed in this section may result from failure to meet established thresholds and items that rise to the level of requiring a plan correction after bid approval (i.e., not minor data input errors). MA organizations are encouraged to conduct a quality review prior to bid submission, and are permitted to make minor changes during the bid review process.

Validation Audits

CMS conducts program audits of Medicare Advantage Organizations (MAOs), Prescription Drug Plans (PDPs), and Medicare-Medicaid Plans (MMPs), (collectively, "sponsoring organizations") that participate in these programs. These program audits measure a sponsoring organization's compliance with the terms of its contract with CMS, in particular the requirements associated with access to medical services, drugs, and other beneficiary protections required by Medicare. CMS requires sponsoring organizations that have been audited and found to have deficiencies to undergo a validation audit to ensure correction.

Since 2016, pursuant to 42 CFR §§422.503(d)(2)(iv) and 423.504(d)(2)(iv), CMS has required that when an audit demonstrates that a sponsoring organization has failed to comply with program requirements, the sponsoring organization must hire an independent auditor to conduct a validation audit to demonstrate correction of conditions cited during the initial audit. CMS's current guidance titled "Program Audit Validation Close-Out" is available on CMS's Part C and Part D Compliance and Audits webpage, in the "Program Audits" section at the following link: https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.html.

On July 18, 2017, CMS hosted a listening session to solicit industry input on ways in which the program audit validation process could be improved. Sponsoring organizations and independent auditing firms provided valuable feedback during that session and via email in the weeks following the event. Based on the feedback, CMS solicited comment in the draft Call Letter on several process improvements and enhancements to the program audit validation process that are intended to promote consistency and decrease burden on sponsoring organizations.

CMS received widespread support from sponsoring organizations, health insurance plans, pharmacy healthcare providers, consumer advocacy groups, and independent auditing firms for each of the provisions relating to Validation Audits. Commenters noted that the process improvements would promote consistency, efficiencies, and lessen administrative burdens. Therefore, we will finalize the changes identified below and incorporate them into the validation process in 2019 unless otherwise noted.

The guidance document entitled "Program Audit Validation Close-Out" will be updated later to reflect all changes finalized in the Final 2019 Call Letter. This document is available at: https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.html.

Threshold for Requiring an Independent Validation Audit

CMS currently requires sponsoring organizations that have more than five program audit conditions in their final audit report to hire an independent auditing firm to conduct a validation

audit. CMS conducts the validation audits of sponsoring organizations that fall below this threshold.

In the CY 2019 draft Call Letter, we requested comments on whether this threshold should be increased or decreased, or limited to conditions that may cause adverse impacts to beneficiaries. We also considered modifying the threshold used to determine when a sponsoring organization must hire an independent auditing firm. We noted our intent to exclude Compliance Program Effectiveness (CPE) conditions from the threshold calculation; sponsoring organizations with more than five non-CPE conditions cited in their final audit report would be required to hire an independent auditing firm.

Finally, we clarified that although we intended to exclude CPE conditions from the threshold calculation used in determining whether a sponsoring organization would be required to hire an independent auditing firm, the requirement to validate correction of CPE conditions would not be eliminated. Once a sponsoring organization meets or exceeds the threshold, thus requiring an independent audit, all conditions, including CPE conditions, identified during the program audit must be validated by the independent auditor. Likewise, if the sponsoring organization's audit results were below the threshold, CMS would conduct the validation of all conditions, including CPE.

The majority of commenters supported removal of CPE conditions from the threshold in determining when a sponsoring organization must hire an independent auditing firm, indicating that this change would reduce administrative burden. Some commenters indicated that they did not believe CPE conditions directly or adversely impact beneficiaries and that CMS should only include conditions that would have beneficiary impact in its threshold for triggering a validation audit.

In the CY 2019 draft Call Letter, we estimated that the number of sponsoring organizations that would be required to hire an independent auditing firm would decrease by approximately three percent by implementing a threshold of more than five non-CPE conditions. We have since updated our estimates using 2017 program audit data. Based on that analysis, we estimate that the number of sponsoring organizations that would be required to hire an independent auditing firm would decrease by approximately eleven percent by implementing a threshold of more than five non-CPE conditions. After consideration of the comments and this analysis, CMS will proceed with excluding CPE conditions in its threshold for determining whether or not a sponsoring organization will be required to hire an independent validation auditor as a result of program audits conducted in 2019.

Conflict of Interest Limitations on Independent Auditing Firms

Currently, when an independent validation audit is required, the sponsoring organization must ensure that the independent auditing firm is free of any conflicts of interest. Examples of conflicts of interest include consultants who provide management consulting to the sponsoring

organization, assist the sponsoring organizations with audit-related operations, and/or assist with the correction of the sponsoring organization's audit conditions. However, consultants used by the sponsoring organization to conduct "mock audits", "pre-assessments" or prior independent audits, or those who have never provided consult or assistance with the correction of audit findings for the sponsoring organization are not considered to have a conflict of interest.

As noted, in the CY 2019 draft Call Letter, sponsoring organizations are not precluded from selecting the same independent auditing firm that is used for their annual external CPE audit, as long as the firm has not provided consulting services or assistance with the correction of audit findings. Sponsoring organizations with specific questions as to whether a potential conflict of interest exists should contact their CMS validation lead for individual guidance.

CMS also solicited comment on collecting information from independent auditing firms in the validation work plan that will be helpful in assessing potential conflicts of interest.

Commenters expressed overall support for our clarification pertaining to conflict of interest but also requested that CMS provide further clarification. One commenter requested that CMS clarify its definition of "management consulting." One commenter requested that CMS continue to share examples of scenarios that would or would not pose conflicts of interest for further clarity and to ensure transparency.

We clarify that the term "management consulting" was intended to refer to consulting firms that provide sponsoring organizations general consulting services. We refer readers to the CMS guidance document titled "Program Audit Validation Close-Out" for examples of scenarios that CMS has previously considered conflicts of interest as well as those that do not pose an obvious conflict. That document is available on CMS' website at: https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.html. We also encourage sponsoring organizations to talk with their CMS validation lead for individualized guidance regarding conflict of interest concerns.

Commenters also suggested that a sponsoring organization's assessment of potential conflicts of interest must be complete prior to entering into a contract with an audit firm. The commenters cautioned that waiting to share the conflict of interest assessment with CMS via the validation work plan would be too late. We appreciate these comments and agree that it is critical for a sponsoring organization to identify and resolve any potential conflicts of interest prior to entering into a contract with the firm that will conduct the independent validation audit. We clarify that the summary of any Medicare-related work previously performed for the sponsoring organization by the independent auditing firm, within the proposed validation work plan template, is intended to provide CMS with information demonstrating and ensuring *the absence* of any conflict of interest. The sponsoring organization's obligation to assess conflict of interest would occur much earlier in the process. Specifically, the sponsoring organization would be

responsible for fully vetting an auditing firm (including an analysis to ensure no conflicts of interest) prior to entering into a contract for the validation audit.

We thank commenters for their careful consideration and response to our solicitation of comments on this guidance. CMS will proceed with this guidance about the conflict of interest limitations. We refer sponsoring organizations to the CMS "Program Audit Validation Close-Out" guidance on CMS' website.

Required use of CMS Validation Audit Work Plan Template

As outlined in CMS's current guidance, essential elements must be included in validation audit work plans and reports but the format and design are left to the discretion of the independent auditing firm.

In the CY 2019 draft Call Letter, we identified our intent to create a work plan template for validation audits; sponsoring organizations undergoing independent validation audits in 2019 would be required to submit the template. We further noted that in accordance with the Paperwork Reduction Act of 1995 (the PRA), we intend to include the draft template in an upcoming Federal Register proposed information collection.

We identified the type of information that will be submitted in the template:

- A summary of any Medicare-related work previously performed for the sponsoring organization by the independent auditing firm. This information will be useful to CMS in assessing potential conflicts of interest.
- A list of all staff (including credentials) that will complete the audit, including which program areas of the audit require registered clinicians (physician, Registered Nurse, pharmacist). A minimum of two auditors per program area would be required in order to satisfy the requirement for a complete and full independent review.
- Expectations for the timeframe of universe periods.
- Expectations for sampling cases for both universe integrity testing and to evaluate case compliance related to a specific condition; these expectations would be used to ensure the reliability of the independent audit findings.
- A copy of the independent auditing firm's proposed audit report template/format.

Commenters expressed support for the creation of a validation work plan template, identifying anticipated benefits such as improved consistency and efficiency in the validation process and assurance that conditions are addressed with the appropriate scope and methodology. Commenters also indicated that a standardized work plan template would help stabilize cost and resource estimates from audit firms. Some commenters recommended that the template should

be as detailed as possible, clarify the minimum number of auditors required per program area, and identify which sections of the audit require registered clinicians (e.g., physician, Registered Nurse, pharmacist). We intend to include these suggested clarifications in the draft template. CMS will move forward with including the work plan template in an upcoming proposed information collection via notice in the Federal Register.

Timeframe to Complete Validation Audits

Currently, sponsoring organizations have 150 calendar days from the date that all of their program audit Corrective Action Plans (CAPs) are accepted by CMS to complete a validation audit and submit the independent audit report to CMS for review. In the CY 2019 draft Call Letter, we identified our intent to extend the timeframe by 30 days and solicited comment on the new 180-day timeframe for completion of the validation audit and submission of the independent audit report to CMS for review.

We received many comments in support of our proposal to extend the timeframe for completing a validation audit from 150 days to 180 days. Commenters stated that the extended timeframe would allow additional time to ensure full remediation of any deficiencies identified during the program audit. However, several commenters indicated that 180 days is still not sufficient. One commenter suggested it would take 180 days for a sponsoring organization to submit their auditing firm's validation work plan to CMS but that additional time would be needed to complete the audit and submit the report to CMS. Several commenters requested clarification on whether CMS would continue to consider written requests submitted by sponsoring organizations for ad hoc extensions of the 180-day timeframe on a case-by-case basis.

We appreciate the commenters' input and will extend the timeframe for validation audits to 180 days. We further clarify that sponsoring organizations may continue to submit written requests for extensions of the 180 day timeframe. These requests must include an explanation of the reasons why the organization would not be able to meet the original timeline. CMS will continue to consider these requests on a case-by-case basis.

Commenters also requested that CMS consider applying the extended timeframe for completion of the validation audit for the current year (2018) rather than waiting until 2019 reasoning that the sponsoring organizations scheduled for validation audits in 2018 would benefit from the timeframe extension. We agree and will make the change effective as of the publication date of the Final 2019 Call Letter so that sponsoring organizations subject to a 2018 program audit will have 180 days for validation audit completion and submission of the independent audit report to CMS.

Submitting Independent Audit Report to CMS

CMS currently requires a sponsoring organization to submit its independent auditing firm's validation audit report to CMS along with any additional information the sponsoring

organization would like CMS to consider. The report should be submitted to CMS as received from the independent auditing firm (i.e., without modification by the sponsoring organization). CMS encourages sponsoring organizations to submit additional documentation addressing any concerns with, or rebuttals to, the auditor's report.

In the 2019 draft Call Letter, we sought comment on requiring the sponsoring organization to copy the independent auditor on that submission.

We received limited, but supportive comments to add this requirement. Commenters noted it helps to ensure the auditing firm's audit report remains intact upon submission to CMS. Commenters also appreciated the clarification that sponsoring organizations are encouraged to include any supporting documentation and rebuttals when submitting their audit firm's report.

We are proceeding with this minor change to the submission requirements and to demonstrate completion of a complete and full independent review under §§ 422. 503(d)(2)(iv) and 423. 504(d)(2)(iv) and will require sponsoring organizations to copy the independent auditor on the submission to CMS.

Plan Finder Civil Money Penalty (CMP) Icon or Other Type of Notice

While CMS currently makes its Civil Money Penalty (CMP) information public via the CMS website, we are concerned that beneficiaries typically do not go to this website when evaluating plans for enrollment. In the CY 2019 draft Call Letter, CMS solicited comment on displaying an icon or other type of notice on Medicare Plan Finder for sponsoring organizations that received a CMP from CMS. The expectation was the icon or notice would provide current and prospective enrollees with general information about a CMP and a link to the CMP letter on the CMS website.

There were numerous comments from stakeholders that expressed concern with the inclusion of the CMP icon on Plan Finder. For example, there were concerns that the CMP icon would create confusion among beneficiaries and that it would not accurately reflect a sponsoring organization's current performance. Therefore, based on feedback received on the proposal, CMS has decided not to move forward with displaying the CMP icon or other type of notice on Medicare Plan Finder at this time.

There were a few comments that strongly supported the inclusion of the CMP icon, stating that it supports greater transparency and provides beneficiaries with information to help make enrollment decisions during the annual election period. We agree that transparency on plan performance is important and, therefore, CMS will consider the comments submitted by stakeholders in developing alternate approaches to communicate its CMP information to beneficiaries.

We also received some comments related to the posting of our CMP actions on the enforcement website. Currently, all CMPs resulting from the same program audit year are posted on the enforcement website at the end of February. Some commenters suggested that CMS should post CMPs in "real time" and not wait until the end of February. Given that the non-compliance underlying the program audit CMPs (for a given year) is discovered around the same time period, CMS will continue to post all of the program audit CMPs at the same time in order for the organizations impacted to be compared fairly and equally to each other. However, CMS continues to post information about its other enforcement actions such as intermediate sanctions and CMPs for other non-compliance on a continuous basis. CMS does not post information about enforcement or CMP actions against sponsoring organizations by any other government agencies (such as the OIG).

Enforcement Actions for Provider Directories

In the 2017 Call Letter, CMS provided guidance on the future of provider directory requirements and best practices. Inaccurate provider directories can impede access to care and bring into question the adequacy and validity of the Medicare Advantage Organization's (MAO's) network as a whole. In addition, CMS notified the industry that monitoring activities around provider directories could result in compliance and enforcement actions if non-compliance is detected. Since then, CMS has received several inquiries as to when CMS would impose enforcement actions for provider directory violations.

As reiterated in the 2019 draft Call Letter, CMPs and other enforcement actions may be imposed against MAOs that have received a compliance notice or notices for violations that have gone uncorrected. In addition, CMS (similar to other government agencies with enforcement authority) has the discretion to take enforcement actions when egregious instances of non-compliance are discovered.

We received many comments expressing support for the proposal to impose enforcement actions for non-compliant provider directories. Commenters supported CMS' efforts to improve the accuracy of provider directories, as it is essential to ensure enrollees have access to the care they need. We also received comments regarding the challenges of keeping provider directories accurate and updated. Based on feedback received, CMS will continue to work with MAOs on guidance around provider directories, but will also consider imposing enforcement actions for egregious instances of provider directory non-compliance. If CMS imposes CMPs for provider directory errors, CMS would initially calculate penalty amounts on a per determination basis.

Audit of the Sponsoring Organization's Compliance Program Effectiveness

The regulations at 42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F) require sponsoring organizations to establish and implement a system for routine monitoring and identification of compliance risks, including internal and external audits and other monitoring. CMS has provided guidance on these requirements in Section 50.6.5 of Chapter 9 of the Prescription Drug

Benefit Manual and Chapter 21 of the Medicare Managed Care Manual. To demonstrate that a compliance system is effective and that monitoring is routine, sponsoring organizations are required to audit the effectiveness of the compliance program and the results must be shared with the governing body. Audits of the compliance program should occur at least annually. These audits involve extensive resources and entail conducting a review of processes and outcomes, discussions with employees and first-tier, downstream and related entities (FDRs), and preparing documentation and demonstrating compliance with program requirements. CMS performs program audits of 30-40 sponsoring organizations every year, and these audits include a review of compliance program effectiveness. This includes assessing whether the sponsoring organization is compliant with establishing and maintaining compliance programs, which include measures to prevent, detect, and correct Parts C or D program noncompliance and fraud, waste and abuse. When selected for a CMS program audit, sponsoring organizations were still required to perform an internal annual compliance program effectiveness (CPE) audit as part of the routine monitoring required by the regulations. Many sponsoring organizations use our CMS CPE audit protocols during their own internal audits, which may result in a duplication of effort during a year when a sponsoring organization is selected for a program audit.

In the draft 2019 draft Call Letter, CMS solicited comment on allowing a CPE program audit to satisfy the sponsoring organization's annual internal compliance program audit in the subsequent calendar year. This one-year exemption will allow time for sponsoring organizations to complete all activities associated with the CMS program audit. This includes ensuring that operational issues are appropriately addressed and corrective actions are fully undertaken and effective before conducting the sponsoring organization's next internal CPE audit. Sponsoring organizations, advocates, and independent auditing firms were supportive of this proposal and noted that this will significantly reduce administrative burden and duplicative efforts. Numerous commenters requested clarification regarding the start of the one-year timeframe. Therefore, we are clarifying that sponsoring organizations are not required to conduct their internal CPE audit in the calendar year following the year the CMS program audit is initiated. For example, if a CMS program audit began at any point in 2019, sponsoring organizations are not expected to conduct an internal CPE audit until 2021. Based on the overwhelming support, CMS will proceed with this change in guidance for 2019, including the clarification for the one-year timeframe. CMS plans to make corresponding changes to the manual guidance in Chapter 9 of the Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual.

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 collaborate with private payers to test innovations in health plan design for CMS beneficiaries.

In response to these efforts, the Medicare Advantage Value-Based Insurance Design (MA-VBID) and the Part D Enhanced Medication Therapy Management (MTM) model tests 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 2019 Star Ratings and Future Measurement Concepts.

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 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 approved 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 is testing whether the additional flexibility provided to MAOs to develop and offer interventions can improve health outcomes and lower expenditures for Medicare Advantage enrollees.

For more information, including a description of other changes to the model test's design for CY 2019, 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. CMS appreciates this feedback and will consider all suggestions when assessing potential model enhancements in the future. CMS will also revise the model consistent with Section 50321 of the Bipartisan Budget Act of 2018 (P.L. 115-123).

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's Part D Enhanced MTM model for 2018. 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, including to encourage further pharmacist involvement in Enhanced MTM programs being tested. CMS appreciates this feedback and will consider all suggestions when assessing potential model enhancements in the future.

New Medicare Card Project (formerly the Social Security Number Removal Initiative, SSNRI)

The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (PL 114-10 s.501) included a mandate to remove the current Health Insurance Claim number (HICN) from Medicare cards by April 2019. This is a reminder that, beginning in April 2018, the current Social Security Number based HICN will be replaced with a new Medicare number, the Medicare Beneficiary Identifier (MBI). MBIs will be assigned to all Medicare recipients, and new Medicare cards will be mailed to beneficiaries beginning in April 2018.

During the transition period, (April 1, 2018 to December 31, 2019), Medicare plans can use either the HICN or the MBI to exchange data with CMS. CMS will continue to disseminate information related to this change to Medicare health and drug plans as it becomes available. More information can be found at (https://www.cms.gov/Medicare/New-Medicare-Card/index.html). Questions can be sent to NewMedicareCardSSNRemoval@cms.hhs.gov.

Section II – Part C

Special Needs Plans (SNPs) Permanently Reauthorized

Special Needs Plans (SNPs) were first authorized by Congress in 2003 for a certain period of years. Congress reauthorized SNPs several times and on February 9, 2018, section 50311(a) of the Bipartisan Budget Act of 2018 (Public Law No. 115-123) permanently reauthorized SNPs. The legislation also added new requirements for integration of SNPs for dually eligible beneficiaries. We anticipate that additional guidance will be forthcoming as CMS evaluates the changes necessary as result of the statutory changes.

Expanding use of Electronic Health Data for MA Enrollees

In March, CMS launched Blue Button 2.0, which puts patients in charge of their own health data. Blue Button 2.0 provides secure beneficiary-directed data transport in a structured Fast Healthcare Interoperability Resources (FHIR) format that is developer-friendly. This will enable beneficiaries to connect their data to applications, services, and research programs they trust. Blue Button 2.0 uses open source code that is available for all plans at https://bluebutton.cms.gov/developers/. CMS recommends and encourages plans to adopt data release platforms for their enrollees that meet or exceed the capabilities of CMS's Blue Button

2.0. CMS is contemplating future rulemaking in this area to require the adoption of such platforms by MA plans beginning CY2020.

Overview of CY 2019 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)).

Medicare-Medicaid Plans in a capitated model under the Medicare-Medicaid Financial Alignment Initiative are not subject to the review criteria summarized in the table below and benefit review guidance for these plans will be provided separately. In addition, guidance for MMPs is in Section IV, "Medicare-Medicaid Plans."

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 4, 2018 deadline. Any organization whose bid fails the Part C Service Category Cost Sharing, PMPM Actuarial Equivalent Cost Sharing, Meaningful Difference (if applicable, see below), 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 CMS uses to review the bids of the various plan types identified in the column headings.

Table 22: 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 (if applicable) 42 C.F.R. § 422.254(a)(4) and §422.256(b)(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), §422.100(f)(2) and (f)(6)	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 2019 and has provided guidance on these requirements in each applicable section below. Consistent with last year, MAOs also must address other requirements in their bids, 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 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 of SNP plans that have fewer than 100 enrollees and that have been in existence for three or more years [as of March 2018 (three annual election periods)]. This notice represents CMS's 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, did not receive this notification. Please note that 42 C.F.R. §422.514 is a minimum enrollment requirement that is applied at the contract level as part of the MA application process and is independent of this plan-level requirement.

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 2019, 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. 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 CMS renewal/non-renewal guidance (see HPMS memo: Information about Renewal Options for 2019, to be issued in early April 2018 and/or section 50 of Chapter 16B) to determine whether a low enrollment plan may be consolidated with another plan(s). CMS will continue to evaluate and implement low enrollment requirements on an annual basis.

Meaningful Difference (Substantially Duplicative Plan Offerings)

Pursuant to 42 C.F.R. §422.254(a)(4) and §422.256(b)(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 proposed to eliminate the meaningful difference requirement beginning in CY 2019 as part of the Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the

PACE Program (CMS-4182-P) proposed rule, which was published in the Federal Register on November 28, 2017 (82 FR 56336). CMS will provide guidance and instructions in the final rule or a HPMS memorandum regarding the meaningful difference requirement for CY 2019.

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 methodology for developing the CY 2019 out-of-pocket costs (OOPC) model is consistent with last year's methodology. For more information, please reference the HPMS memorandum dated December 21, 2017 titled "Medicare Plan Finder (MPF) Plan Version of Out-of-Pocket Cost (OOPC) Model for CY 2018." Customary updates for utilization data, as well as PBP and formulary data used for CY 2019 bid submissions, are also included in the 2019 model.

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 not evaluate TBC for EGWPs, D-SNPs, and MSA plans. EGWP benefit packages are negotiated arrangements between employer groups and MA organizations so we believe that the employer would have taken these costs into account in making such plans available. D-SNP benefits entered into the plan benefit package do not include state benefits and cost sharing relief, which means that a TBC evaluation would not be based on the full benefit and cost sharing package available to enrollees. Finally, MSAs have unique benefit designs that includes a medical savings account for purposes of paying costs below the deductible. Beginning in CY 2019, Special Needs Plans for End Stage Renal Disease (ESRD) Requiring Dialysis will not be subject to the TBC evaluation for reasons discussed below.

We received comments concerned about the TBC evaluation for Special Needs Plans for End Stage Renal Disease (ESRD) Requiring Dialysis, 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 either adjust the current model, create a new model, or not apply the TBC requirement to ESRD plans. The OOPC model generates estimated beneficiary out-of-pocket costs, which represents a significant portion of the TBC calculation. We understand the concerns expressed by the commenters related to these challenges and agree that the volatility of beneficiary out-of-pocket costs and year-to-year payment for these plans supports a different approach. Similar to D-SNPs, Special Needs Plans for ESRD Requiring Dialysis will not be subject to the TBC evaluation for CY 2019. The OOPC model used for the

TBC evaluation does not effectively address ESRD SNP enrollees and these plans potentially experience larger increases and/or decreases in payment amounts. ESRD SNPs are subject to all other MA standards and CMS will contact plans if CMS identifies large benefit or premium changes (while taking into consideration payment changes) during bid review. MA plans offering Part C uniformity flexibility (discussed later in this section) and/or participating in the Value-Based Insurance Design (VBID) model test will be subject to the TBC evaluation for CY 2019. However, benefits and cost sharing reductions (entered in Section B-19 of the PBP) that are offered as part of Part C uniformity flexibility or the VBID model test will be excluded from the TBC calculation. This approach allows CMS to readily evaluate changes in cost sharing and benefits that are provided to all enrollees in a plan. We remind MAOs to carefully develop and accurately reflect these parameters and cost-sharing designs in the PBP.

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.

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

In mid-April 2018, as in past years, CMS will provide plan specific CY 2019 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 ($22.00 for CY 2019).

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

CMS solicited feedback and received supportive comments about an increase in the TBC change threshold, for most plans, from $34.00 PMPM to $36.00 PMPM in CY 2019 to provide flexibility in addressing medical and pharmacy inflation and benefit design and formulary changes. Therefore, a plan experiencing a net increase in adjustments must have an effective TBC change amount below the $36.00 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 $36.00 PMPM threshold. In an effort to support plans

that received increased 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 2019, the TBC change evaluation will be different 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 $36.00 PMPM will have a TBC change threshold of $0.00 PMPM (i.e., −1 times the TBC change limit of $36.00 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 -$36.00 PMPM will have a TBC change threshold of $72.00 PMPM (i.e., 2 times TBC change limit of $36.00 PMPM) plus applicable technical adjustments. That is, plans are not allowed to make changes that result in greater than $72.00 worth of decreased benefits or increased premiums.
- Plans with a star rating below 3.0 and an overall payment adjustment amount less than −$36.00 PMPM will have a TBC change threshold of $72.00 PMPM (i.e., 2 times TBC change limit of $36.00) plus applicable technical adjustments.
- Plans not accounted for in the three specific situations above are evaluated at the $36.00 PMPM limit, similar to CY 2018.

If CMS provides an opportunity to correct CY 2019 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 formulary review process has multiple stages and making changes that are unrelated to CMS's formulary review 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 will necessitate additional CMS review, outside of the normal review stages, and may jeopardize the approval of a sponsor's formulary and could affect approval of its bid and contract. Detailed TBC information and examples will be provided in mid-April 2018 via the HPMS Memorandum titled "CY 2019 MA Bid Review and Operations Guidance."

CMS will maintain the TBC evaluation used during CY 2018 for consolidating or crosswalking plans. CMS will include the operational details of this process in the annual HPMS Memo titled "CY 2019 Medicare Advantage Bid Review and Operations Guidance," issued in mid-April.

As discussed in the draft Call Letter, CMS is considering the elimination of the current TBC evaluation in future years, subject to statutory and regulatory limitations or changes. CMS requested comments on this matter and suggestions on other approaches to determine whether plan bids propose too significant an increase in cost sharing or decrease in benefits from one plan year to the next. Several commenters supported eliminating the requirement because the out-of-pocket cost (OOPC) model, which is a primary driver of the TBC calculation, may not accurately

reflect innovative benefit designs, formulary changes, and important supplemental benefits. In addition, the TBC calculation does not account for the payment model and the health insurance providers' fee, which MA organizations are expected to address independently of the TBC requirement. Commenters indicated the TBC evaluation is an arbitrary control that limits organizations from making necessary changes to plan designs and restricts innovation to meet the diverse needs of beneficiaries.

Several commenters suggested alternatives to the TBC evaluation, such as allowing market forces and/or other MA requirements (e.g., cost sharing standards and medical loss ratio limits) to control year-over-year changes. Commenters suggested eliminating the TBC evaluation in highly competitive market areas. Another commenter proposed that plans with significant increases should be required to send a letter to beneficiaries summarizing the changes (separate from the annual notice of change) and include other plan options in the service area. Other commenters suggested allowing beneficiaries to choose the plan that meets their individual needs and that CMS work with organizations to discuss alternatives. Several commenters opposed eliminating the TBC evaluation because the requirement protects beneficiaries from unexpected changes in benefits and/or premiums. We appreciate the thoughtful comments and suggested alternatives and will conduct additional research and evaluate potential changes for future years, and determine if potential changes would require rulemaking.

Maximum Out-of-Pocket (MOOP) Limits

As codified at 42 CFR §422.100(f)(4) and (5) and §422.101(d)(2) and (3),[27] 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 that are subject to the MOOP. MA plans may establish as their MOOP limit any amount within the ranges shown in the table.

Table 23 below displays the CY 2019 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 previous Call Letters, the in-network MOOP amount

[27] The proposed rule, Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (CMS-4182-P), which was published in the Federal Register on November 28, 2017 (82 FR 56336), included proposals for changing these regulations and the standard for adopting MOOPs. Those proposed amendments do not affect the bid parameters or cost sharing required for CY 2019 so we are providing guidance on the MOOP and standards for evaluating cost sharing in this final Call Letter.

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 23: CY 2019 Voluntary and Mandatory MOOP Range Amounts by Plan Type

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

As explained in the CY 2012 Call Letter, MOOP limits are currently based on a beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Original Medicare. Actual data for Parts A and B services are based on claims from the National Claims History files. The Office of the Actuary conducts an annual analysis to help CMS determine the proposed MOOP amounts by projecting cost sharing using trend factors, such as enrollment changes and enrollment shifts between MA and Original Medicare. The mandatory MOOP amount represents 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.

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.

Although most dual-eligible enrollees are not responsible for paying cost sharing, certain D-SNPs (Medicare Non-Zero Dollar Cost Sharing Plans) enroll dual-eligible enrollees who do pay cost sharing. Also, any dual-eligible enrollee exempted from cost sharing who loses his/her Medicaid eligibility may be responsible for cost sharing for the period they have lost Medicaid coverage, and remain enrolled in the D-SNP. This also applies to Zero Dollar Cost Sharing Plans that apply cost sharing in their Medicare Part A and B benefit package but enroll only dual-eligible individuals who are exempt from cost sharing.

D-SNPs have the flexibility to establish $0 as the MOOP limit, 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 apply cost sharing for Medicare Part A and B covered benefits, then 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 related to the CY 2019 draft Call Letter suggesting changes to encourage MAOs to offer voluntary MOOP limits as part of their plan designs. For example, some suggestions included increasing the amount of the voluntary MOOP limit; creating a sliding scale MOOP with higher cost sharing limits for lower MOOP limits, increasing the number of service categories that provide cost sharing flexibility, and increasing the differential between the voluntary and mandatory MOOP limits for certain highly utilized cost sharing standards. One commenter requested that CMS require supplemental benefits be included in the MOOP limit rather than allowing plans' to have discretion. We also received comments requesting the inclusion of Part D services in the MOOP for MA-PD plans. CMS appreciates the comments and will consider them for future contract years. A commenter also requested clarification if the MOOP limit could vary by segment based on the reinterpretation of section 1854(h) of the Social Security Act (the Act) and MA regulations governing plan segments (see Medicare Advantage (MA) Segmented Service Area Options in this Call Letter). Consistent with past years, MA plans may vary the MOOP limit by segment.

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

Total MA cost sharing for Part 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) and (f)(6),[28] CMS will evaluate actuarial equivalent cost sharing limits separately in the

[28] The proposed rule, Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (CMS-4182-P), which was published in the Federal Register on November 28, 2017 (82 FR 56336), included a proposal to amend §422.100(f)(6). That proposed amendments does not affect the bid parameters or cost sharing required for CY 2019 so we are providing guidance on cost sharing requirements in this final Call Letter.

following service categories for CY 2019: Inpatient, Skilled Nursing Facility (SNF), Durable Medical Equipment (DME), and Part B drugs.

Whether in the aggregate, or on a service-specific basis, excess cost sharing is identified by comparing two values found in Worksheet 4 of the BPT. Specifically, a plan's PMPM cost sharing for Medicare covered services (BPT Worksheet 4, Section IIA, column l) is compared to Original Medicare Actuarially Equivalent Cost Sharing (BPT Worksheet 4, Section IIA, column n). For Inpatient services, the AE Original Medicare cost sharing values, unlike plan cost sharing values, do not include Part B cost sharing; therefore, an adjustment factor is applied to these AE Original Medicare values to incorporate Part B cost sharing and to make the comparison valid. Please note that factors for Inpatient in Column 4 of the table below (Part B Adjustment Factor to Incorporate Part B Cost Sharing) have been updated for CY 2019.

Once the comparison amounts have been determined, excess cost sharing (which is potentially discriminatory) 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 24: 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	1.395	$35.30	$0.00	Pass
SNF	$10.83	$58.19	$9.89	1.066	$10.54	$0.29	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: Beginning 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 continue to be subject to all unwaived

MA regulatory requirements regardless of whether they are affirmatively evaluated as part of bid review or in connection with other oversight.

Part C Cost Sharing Standards

For CY 2019, 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.[29] Table 25 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 2019 bids must reflect enrollee cost sharing for in-network services no greater than the amounts displayed below. These standards will be applied 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 and Skilled Nursing Facility (Days 21 through 100) standards have been updated to reflect estimated changes in Original Medicare cost for CY 2019. 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 2019 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 cost sharing threshold for these services that we consider compliant and non-discriminatory has increased: (1) for plans with a voluntary MOOP, the amount increased from $100 to $120, and (2) for plans with a mandatory MOOP, the amount increased from $80 to $90. We received several comments in support of this increase, although a commenter suggested the amount should be $120 regardless of whether the plan has a MOOP at the higher mandatory amount. Some commenters did not support the cost sharing increase, stating emergency room departments are not routinely utilized as a replacement for primary care, concerns the cost sharing burden will be too high and potentially deter some enrollees from going to the emergency room when needed, and concerns about hospitals experiencing unpaid bills. CMS appreciates the comments and believes that the changes to have different cost sharing 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. CMS also notes that plans may waive emergency room cost sharing for enrollees who are admitted to the hospital from the emergency room to limit financial deterrents for enrollees to seek care.

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[29] The proposed rule, Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (CMS-4182-P), which was published in the Federal Register on November 28, 2017 (82 FR 56336), included a proposal to amend § 422.100(f)(6). That proposed amendments does not affect the bid parameters or cost sharing required for CY 2019 so we are providing guidance on cost sharing requirements in this final Call Letter.

We also received a comment that emergency care and post-stabilization care should not be included together. The PBP description for 4a: Emergency/Post-Stabilization was updated to reflect CMS guidance in the Medicare Managed Care Manual, Chapter 4, Section 20.5 to 20.5.3. Although post-stabilization may encompass a wide variety of services, CMS includes post-stabilization with the emergency category to reflect the services the enrollee receives immediately following stabilization in the emergency department. We appreciate the comments and suggestions we received. We are issuing this final guidance regarding these thresholds consistent with the CY 2019 draft Call Letter.

Table 25: CY 2019 In-Network Service Category Cost Sharing Requirements

Cost Sharing Limits			
PBP Service Category Description	**PBP Section B data entry field**	**Voluntary MOOP**	**Mandatory MOOP**
Inpatient Hospital – Acute - 60 days	1a	N/A	$4,314
Inpatient Hospital – Acute - 10 days	1a	$2,552	$2,042
Inpatient Hospital – Acute - 6 days	1a	$2,325	$1,860
Inpatient Hospital Psychiatric - 60 days	1b	$2,737	$2,190
Inpatient Hospital Psychiatric - 15 days	1b	$2,075	$1,660
Skilled Nursing Facility – First 20 Days[1,2]	2	$20/day	$0/day
Skilled Nursing Facility – Days 21 through 100[1,2]	2	$172/day	$172/day
Emergency Care/Post Stabilization Care[3]	4a	$120	$90
Urgently Needed Services[3]	4b	$65	$65
Partial Hospitalization	5	$55/day	$55/day
Home Health Services	6a	20% or $35	$0
Primary Care Physician Services	7a	$35	$35
Chiropractic Services	7b	$20	$20
Occupational Therapy Services	7c	$40	$40
Physician Specialist Services	7d	$50	$50
Psychiatric and Mental Health Specialty Services	7e and 7h	$40	$40
Physical Therapy and Speech-language Pathology Services	7i	$40	$40
Therapeutic Radiological Services	8b	20% or $60	20% or $60
DME-Equipment	11a	N/A	20%
DME-Prosthetics	11b	N/A	20%
DME-Medical Supplies	11b	N/A	20%
DME-Diabetic Supplies and Services	11c	N/A	20% or $10
DME-Diabetic Therapeutic 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 including chemotherapy drugs and radiation therapy integral to the treatment regimen, 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/Post Stabilization Care and Urgently Needed Service 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 including chemotherapy drugs and radiation therapy integral to the treatment regimen, 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, CMS has a longstanding interpretation of the anti-discrimination provisions that payment of less than 50% of the contracted (or Medicare allowable) rate and use of cost sharing for services that exceeds 50% of the total MA plan financial liability for the benefit discriminates against enrollees who need those services. 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). For example, cardiac and pulmonary rehabilitation services are areas of concern that CMS continues to monitor and requires MA organizations provide justification for cost sharing above the following amounts for CY 2019: cardiac rehabilitation services ($50), intensive cardiac rehabilitation services ($100), and pulmonary rehabilitation and supervised exercise therapy (SET) for peripheral artery disease (PAD) services ($30). CMS has determined that the cited amounts are non-discriminatory so higher cost sharing amounts require additional scrutiny and explanation to ensure that they are not discriminatory. Additional information about SET for PAD services is located in the Call Letter section: "Coverage of Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD)."

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 threshold for non-discriminatory cost-sharing (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 the regulatory requirements, as interpreted and implemented here, 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 link for uploading cost sharing justification files will be located at Plan Bids > Bid Submission > CY 2019 > Upload > Cost-Sharing Justification.

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

As stated in the draft Call Letter, CMS is considering changes to its policies related to service category cost sharing limits in future years. For example, inpatient limits are based on Original Medicare cost data and other limits are based on at least 50% of the total MA plan financial liability for the benefit. CMS solicited comments on whether CMS's interpretation of the cost sharing limits affects plans' ability to offer more flexible benefit designs that would provide beneficiaries with valuable plan options, while remaining compliant with the law governing the Part C program.

Several commenters oppose changing the current policies, while others indicated they need additional information or the opportunity to discuss with CMS. Commenters were generally supportive of CMS providing cost sharing standards for important services to avoid discrimination. Some comments indicated support for adding more cost sharing standards and providing cost sharing flexibility in return for offering lower MOOP limits. Rather than using the 50% limit for other services, a commenter suggested using bid pricing tool data to evaluate whether cost sharing is discriminatory. The commenter indicated that CMS could establish either per member per month or percentage of "allowed cost" limits, which would place plans on a level playing field with regard to provider contracts, geographic variations in costs, and projected utilization patterns.

We also received comments encouraging CMS to maintain and increase the number of services with cost sharing limits that do not exceed Original Medicare under its authority in section 1852(a)(1)(B) and §422.100(j). In addition, commenters suggested that we allow cost sharing flexibility for therapy services requiring a series of repetitive visits to complete a course of treatment. Suggestions included varying copayment levels based on the number of visits, one copayment that includes several visits, and providing a "rebate" for completing a course of multiple visits. CMS currently allows one copayment for several visits, but does not permit copayments to increase based on the number of visits, which would potentially discriminate against sicker individuals. We appreciate these comments and suggestions and will consider them for future years. We note that some of the suggestions may require extensive research and potential rulemaking.

Part C Optional Supplemental Benefits

Consistent with past years, 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.

A commenter had questions about how this optional supplemental benefit evaluation interacts with the CMS announcement regarding benefit flexibilities in the proposed Medicare Advantage and Part D rule, as well as the expansion of supplemental benefits in the recent Bipartisan Budget Act of 2018. CMS designs and applies this evaluation to include all Part C optional supplemental benefits offered by non-employer plans within the same contract and has not changed from past years. Additional information about supplemental benefit flexibilities is in the following sections below: "Health Related Supplemental Benefits" and "Medicare Advantage Uniformity Flexibility."

We also received a comment requesting CMS to expand permissible optional supplemental benefits beyond those allowed for mandatory supplemental benefits (to permit services like cosmetic services and funeral expenses) because the enrollee, not Medicare, funds the premium. Section 1852(a)(3) provides that supplemental benefits, whether mandatory or optional, must be health care benefits so CMS does not believe that there is authority to provide flexibility for the benefits requested by the commenter. We note that the Bipartisan Budget Act of 2018 amended

section 1852(a)(3) to provide additional fleixbilty for benefits for chronically ill enrollees so we will take the comment into consideration when developing guidance for that new provision..

Employer Group Waiver Plans

Beginning 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 2019 member months for each plan and place the amount in Section A-2 of the PBP. All MA and 1876 Cost Plan organizations must complete the following question: "Indicate CY 2019 total projected member months for this plan."

Tiered Cost Sharing of Medical Benefits

MAOs may choose to tier cost sharing of medical benefits to encourage enrollees to seek care from providers the plan has identified based on efficiency and quality data as described in Chapter 4, Section 50.1 of the MMCM. The tiered cost sharing of medical benefits must be applied so all plan enrollees are charged the same cost sharing amount for any specific provider and all providers are available and accessible to all enrollees in the plan. CMS reminds MAOs that they may not exclude any members from being eligible to access tiered providers.

For CY 2019, CMS does not expect MAOs to submit a proposal summarizing their intent to tier cost sharing of medical benefits prior to bid submission. MAOs must to indicate they are tiering medical benefits and the applicable service categories in Section A-6 of the PBP. MAOs must use minimum/maximum data entry and notes fields to describe tiering in each applicable section of the PBP.

Tiered cost sharing of medical benefits must satisfy the following standards:

- The plan fully discloses tiered cost sharing amounts and requirements to enrollees and plan providers;
- The services at each tier of cost sharing are available to all enrollees;
- Enrollees may not be limited to obtaining services from providers/suppliers assigned to a particular tier;
- All enrollees are charged the same amount for the same service provided by the same provider; and
- Deductibles, MOOP, and out-of-network benefits are not to be tiered.

The following examples of "differential cost sharing" are allowable, and not considered to be tiering of medical benefits:

- Facility settings for furnishing some services, such as diagnostic imaging services; and
- In-network versus out-of-network services.

We received several comments supporting the tiering of medical benefits, while others expressed concerns about beneficiary confusion. Plan communication materials must describe benefits in a clear manner to support beneficiaries in making informed health care decisions and to meet the disclosure requirements in the MA statute and regulations. Other commenters asked about the number of organizations that are tiering medical benefits, and more specific questions regarding plan requirements. Further information and guidance about tiering of medical benefits is available in the Medicare Managed Care Manual, Chapter 4, Section 50.1.

Outpatient Observation Services

The outpatient hospital services category in the PBP (B9a) includes a variety of services such as observation, outpatient palliative care, and outpatient surgical services (i.e., outpatient surgical services not provided in an Ambulatory Surgical Center as defined by Original Medicare). Observation care is a highly utilized, well-defined set of specific, clinically appropriate services, which include ongoing short-term treatment, assessment, and reassessment to support plan of care decisions such as, whether a patient needs to be admitted as inpatient or may be discharged from the hospital. In an effort to make the cost sharing for observation services more transparent, CMS will distinguish the cost sharing for observation services from other outpatient hospital services by modifying PBP category B9a to include separate cost sharing data entries.

CMS received several comments supporting the guidance in the draft Call Letter. A commenter requested clarification about accounting for cost sharing differences between observation services and other outpatient services (e.g., emergency room and outpatient surgery) to avoid potential beneficiary confusion. CMS expects plans to enter the cost sharing for each service separately in the appropriate PBP category (e.g., observation-B9a and emergency room-B4a). MA plans that bundle observation with other services (e.g., emergency room visit and outpatient surgery) may include a cost sharing range, enter the appropriate minimum and maximum cost sharing amounts for these services in observation-B9a, and describe the cost sharing arrangement. Another commenter requested that CMS require the Original Medicare two-midnight policy be applied by MA organizations. CMS disagrees with the commenter; MA plans must furnish medically necessary covered services at the medically appropriate level of care, and may adopt the Original Medicare two-midnight policy for in-network hospital services when classifying a stay as inpatient or observation. However, 42 CFR 422.214 requires MA PPOs to pay for services consistent with Original Medicare coverage and payment rules on an out-of-network basis (i.e., the two midnight-rule).

Coverage of Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD)

For CY 2018, CMS determined that the National Coverage Determination (NCD) requiring coverage of supervised exercise therapy (SET) for symptomatic peripheral artery disease (PAD) was a significant cost under 42 C.F.R. § 422.109(a)(2). As a result, for CY 2018 only, original fee-for-service Medicare will pay for reasonable and necessary items and services obtained by beneficiaries enrolled in MA plans. (See HPMS email, Subject titled "MAO Coverage of Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD)" sent on August 12, 2017). For CY 2019, MAOs should account for these items and services in their bids as a basic benefit, and should not include these Medicare-covered items and services as supplemental benefits.

Some commenters requested clarification about where these services fit within the PBP. For CY 2019, MA plans should include Medicare-covered SET for PAD in the cardiac and pulmonary rehabilitation services PBP service category B3, under "Medicare-covered Pulmonary Rehabilitation Services" and include the appropriate range of cost sharing. Although SET for PAD services are distinctly different from pulmonary rehabilitation services, cost sharing for the two services are similar. CMS will consider creating a separate PBP data entry field for SET for PAD in CY 2020.

Health Related Supplemental Benefits

CMS currently defines a supplemental health care benefit in the Medicare Managed Care Manual (section 30.1) as an item or service (1) not covered by Original Medicare, (2) that is primarily health related, and (3) for which the MA plan must incur a non-zero direct medical cost. This definition derives from section 1852(a)(3) of the Act, which permits MA plans to offer only "supplemental health care benefits" in addition to the benefits covered by original Medicare. An item or service that meets all three conditions may be proposed as a supplemental benefit in an MA plan's bid and submitted plan benefit package. The final determination of benefit status is made by CMS during the annual benefit package review.

An item or service is primarily health related if the primary purpose of the item or service is to prevent, cure, or diminish an illness or injury. CMS has not previously allowed an item or service to be eligible as a supplemental benefit if the primary purpose is daily maintenance. However, medical and health care research has demonstrated the value of certain items and services that can diminish the impact of injuries or health conditions and reduce avoidable emergency and health care utilization. For example, fall prevention devices can be an effective means to assist enrollees at high risk of fall and protect against the likelihood of additional injury resulting from a fall; CMS believes provision of a fall prevention device – and similar items and services that diminish the impact of injuries/health conditions and reduce avoidable utilization -

could be provided as a supplemental benefit for a defined period of time and in certain situations, even if a significant purpose of the item or service is daily maintenance.

CMS is expanding the scope of the primarily health related supplemental benefit standard. Section 1852(a)(3) permits the offering of "healthcare benefits" as supplemental benefits but does not define the term. We therefore have authority to interpret the term more broadly than we have in the past, to permit MA plans to offer additional benefits as "supplemental benefits" so long as they are healthcare benefits. Under our new interpretation, in order for a service or item to be "primarily health related" under our three-part test for supplemental health care benefits, it must diagnose, prevent, or treat an illness or injury, compensate for physical impairments, act to ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization. Any supplemental health benefit proposed by an MA organization must be reasonably and rationally encompassed by this standard and may not have a primary purpose that is outside of this standard. This will allow MA plans more flexibility in designing and offering supplemental benefits that can enhance beneficiaries' quality of life and improve health outcomes.

The primary purpose of an item or service will be determined by national typical usages of most people using the item or service and by community patterns of care. To be considered healthcare benefits, supplemental benefits must focus directly on an enrollee's healthcare needs. Supplemental benefits under this broader interpretation must be medically appropriate and recommended by a licensed provider[30] as part of a care plan if not directly provided by one; supplemental benefits do not include items or services solely to induce enrollment. Prior to CY 2019 bid submissions, CMS will issue detailed guidance for MAOs on this issue as they consider upcoming plan offerings.

We note that the Bipartisan Budget Act of 2018 (Public Law No. 115-123) further expands supplemental benefits for chronically ill enrollees beginning CY 2020. The new legislation permits supplemental benefits that are not primarily health related but only for the chronically ill. It adds new supplemental benefit options for the chronically ill that are in addition to the existing supplemental benefit options available to all MA enrollees; the statutory language is clear that these new supplemental benefits for chronically ill enrollees are in addition to the supplemental heatlh care benefits that MA plans may make available for all enrollees. The expansion of supplemental benefits for chronically ill enrollees does not affect our newly expanded scope of the primarily health related supplemental benefit standard because our supplemental benefit

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[30] Enrollees are not currently required to get physician orders for supplemental benefits (e.g., OTC items) and requiring it now would impose new restrictions on MA plans and potentially cause large administrative burden and interruptions in care. Therefore, CMS will use the "recommended" standard. We note that supplemental benefits must also be medically appropriate.

standard requires more than just a reasonable expectation of improving overall health and instead requires supplemental benefits to address specific illnesses and/or injuries. CMS will continue to consider the scope of the additional flexibilities authorized by the Bipartisan Budget Act of 2018 and will provide guidance prior to the CY 2020 bid deadline. Additionally, the forthcoming detailed guidance will further differentiate newly allowable supplemental benefits under our reinterpretation and those new supplemental benefits that will be allowed for the chronically ill beginning CY 2020.

Enhanced Disease Management (EDM) for Dual Eligible Special Needs Plans (D-SNPs) and Institutional Special Needs Plans (I-SNPs)

Over the past several years, CMS has sought to improve care coordination and enhance the experience of care for beneficiaries, particularly those that are a part of the SNP population. We believe that specialized, targeted care through enhanced disease management programs is one way to achieve this goal. Beginning CY 2019, D-SNPs and I-SNPs may offer the EDM supplemental benefit that is currently available to Non-SNP MA plans.

As discussed in section 30.1 of the Medicare Managed Care Manual, services in a supplemental EDM benefit would include qualified case managers with specialized knowledge about the target disease(s)/condition(s), educational activities that are focused on the target disease(s)/condition(s), and routine monitoring applicable to the target disease(s)/condition(s). The benefit may be proposed as a supplemental benefit in an MA plan's bid and submitted plan benefit package.

The EDM supplemental benefit will not be made available to Chronic Condition SNPs (C-SNPs) as it is not necessary. C-SNPs must already have comprehensive targeted disease management elements (beyond the EDM supplemental benefit requirements) in order to receive the special C-SNP designation and marketing and enrollment accommodations.

Medicare Advantage (MA) Uniformity Flexibility

We discussed a reinterpretation of the uniformity requirement for MA plans in the proposed rule CMS-4182-P (82 FR 56336, 56360). We will further address that policy in the final rule when published. Under the reinterpretation, MA plans providing access to services (or specific cost sharing and/or deductibles for services or items) that is tied to disease state in a manner that ensures that similarly situated individuals are treated uniformly will be considered consistent with the uniformity requirement in the MA regulations at §422.100(d). The statutory provisions at sections 1852(d)(1) and 1854(c) and the regulation at § 422.100(d) will be interpreted and implemented to permit MA organizations the ability to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria, provided that similarly situated enrollees (that is, all enrollees who meet the identified criteria) are treated the same and enjoy the same access to these targeted benefits. This flexibility will apply only to Part C benefits and not to prescription drug benefits

under Part D. Under our reinterpretation, these Part C supplemental benefits can be offered through a benefit package that ensures equal treatment of enrollees with the same clinical conditions for whom such services and benefits are useful consistent with section 1852's equal access and anti-discrimination provisions, and is priced at a uniform premium consistent with the requirement for uniform bids and premiums in section 1854(c) of the Act. CMS believes this flexibility will help MA plans better manage healthcare services for particularly vulnerable enrollees. Prior to CY 2019 bid submissions, CMS will issue detailed guidance for MAOs on this issue as they consider upcoming plan offerings. Additionally, CMS will include language in the preamble of the rule, including a discussion regarding the Bipartisan Budget Act of 2018 and how it relates to CMS' authority to waive uniformity requirements for the chronically ill, effective CY 2020.

Medicare Advantage (MA) Segmented Service Area Options

CMS reviewed section 1854(h) of the Social Security Act (the Act) and MA regulations governing plan segments and has determined that it has the authority to allow MA plans to vary supplemental benefits, in addition to premium and cost sharing, by segment, as long as the benefits, premium, and cost sharing are uniform within each segment of an MA plan's service area. CMS is revising its interpretation of the regulations to allow MA plan segments to vary by supplemental benefits, premium, and cost sharing, consistent with the MA regulatory requirements defining segments at §422.262(c)(2). Segments are defined in the MA regulations at §422.262(c)(2). MA plans can segment Part C benefits; however, if an MA plan offers Part D, it must offer the Part D benefit uniformly within the plans service area, including any segments the MA plan may have.

Medicare Diabetes Prevention Program (MDPP) Services Clarification

In the CY 2017 Physician Fee Schedule (PFS), we finalized the nationwide expansion of the MDPP model and defined the parameters of MDPP services. The expansion was further defined in the CY 2018 PFS final rule[31]. The MDPP expanded model is effective April 1, 2018. The services provided under this expanded model are Medicare Part B covered services.

MDPP services consist of structured health behavior change sessions that are furnished under the MDPP expanded model with the goal of preventing diabetes among Medicare beneficiaries with prediabetes, and that follow a CDC-approved curriculum. The goal of the MDPP expanded model is to prevent the onset of type 2 diabetes in individuals with an indication of prediabetes. Under §422.100(k), and as with coverage of preventive benefits covered under original Medicare without cost sharing, in-network coverage of MDPP expanded model services must be covered for eligible Medicare beneficiaries at zero cost sharing. We want to ensure that MA plans are aware that while they must cover MDPP services in accordance with the MDPP regulations, they

[31] 82 FR 53234 through 53339

may also offer additional MDPP-like services as a supplemental benefit. For example, although MDPP services cannot be provided only remotely or in a 100% virtual format under current regulations to satisfy the Part B coverage requirement (and thus to be a basic benefit when covered by an MA plan), an MA plan may offer similar services in a virtual format as a supplemental benefit through the Remote Access Technology supplemental benefit. The similar supplemental benefit does not count as the Part B covered service for purposes of the basic benefit bid, but may still be offered by the plan.

Special Needs Plan (SNP)-Specific Networks Research and Development

In the final CY 2018 Call Letter (pp. 138-139), CMS announced plans to move forward on developing SNP-specific network adequacy evaluations. However, CMS believes that the current network adequacy criteria and exception request process account for the unique health care needs and delivery patterns for Medicare Advantage (MA) beneficiaries enrolled in SNPs, including chronic condition SNPs (C-SNPs), dual eligible SNPs (D-SNPs), and institutional SNPs (I-SNPs). For CY 2018, CMS has made substantial improvements to the guidance and evaluation of compliance with network adequacy requirements, as detailed in the Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance. CMS updated this guidance on February 20, 2018. We continue to examine the need for SNP-specific network adequacy evaluations, welcome continued stakeholder feedback, and solicited comment on this topic in the draft CY 2019 Call Letter as summarized below.

The majority of commenters believed that the current network adequacy criteria and exception request process do not adequately account for the unique health care needs and delivery patterns for SNP enrollees. Many of these commenters recommended that CMS reconsider and resume its work to develop SNP-specific network adequacy evaluations. Some commenters suggested that CMS accommodate innovative care delivery models by allowing telehealth and mobile providers to count towards network adequacy, especially for rural areas. Several commenters recommended that CMS consider lessons learned from both Medicaid managed care network adequacy standards as well as Medicare-Medicaid Plan (MMP) standards and apply this knowledge to D-SNPs.

Some commenters agreed with CMS that the current network adequacy criteria and exception request process account for the unique health care needs and delivery patterns for SNP enrollees. Commenters stated that the development of SNP-specific network adequacy evaluations was not necessary. Two commenters mentioned D-SNPs specifically, stating that the current MA network adequacy criteria is acceptable for D-SNPs, and CMS already has sufficient oversight of SNP networks through the Model of Care. One commenter expressed appreciation for CMS's ongoing development of the general MA network adequacy criteria, for example, releasing the provider supply file, monitoring population distributions, and updating county access standards.

CMS appreciates the feedback from all commenters. CMS may re-examine this issue once we gain experience with the improved network adequacy processes described in our February 2018 guidance on network adequacy.

Rewards and Incentives for Completion of a Health Risk Assessment (HRA)

Regulations at §422.134 allow MA plans to create Rewards and Incentives (RI) Programs that provide rewards and incentives to enrollees for participation in activities that focus on promoting improved health, preventing injuries and illness, and promoting efficient use of healthcare resources. Under §422.112(b)(4)(i), all MA plans musts make a best effort to conduct an initial assessment of each enrollee's healthcare needs within 90 days of the effective date of enrollment. Finally, regulations at §422.101(f)(1)(i) require all SNPs to perform a comprehensive initial HRA within the first 90 days of enrollment and conduct reassessments annually thereafter.

Completion of a federally mandated survey, though arguably a health-related activity, may not be included in an RI Program because of the potential for biased responses due to the influence of rewards and incentives. CMS has previously included HRAs in this exclusion because of §§422.112 and 422.101. However, CMS also believes a completed HRA is vital to proper care management, improved health, and promotes the efficient use of healthcare resources – so much so that, beginning in CY 2014, CMS included SNPs' HRA timeliness and completion rates as factors in the Star Ratings methodology. CMS now also recognizes that HRA tools must be designed to objectively assess and analyze the medical, functional, cognitive, psychosocial and mental health needs of each beneficiary, and therefore do not consist of material that is susceptible to bias like other enrollee satisfaction and outcome surveys.

Therefore, beginning CY 2019, MA plans may include the completion of an HRA as a permitted health-related activity in an RI Program. An RI Program is not a benefit but it must be included in the bid as a non-benefit expense. See section 100 of Chapter 4 of the Medicare Managed Care Manual for more information about rewards and incentives.

Cost Plan Transition to MA under MACRA

CMS wants to remind cost plan entities that they must complete the transition to MA by contract year 2019 in order to deem their cost enrollees into an affiliated MA plan offered by the organization under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) cost transition requirements. In connection with the transition of cost to MA, MACRA also delayed the implementation of the cost plan competition requirements through contract year 2018.

MACRA specifies notification, enrollment, and benefit requirements that transitioning cost plans must follow in order to be eligible for deeming enrollees, which are generally codified as amendments to section 1876(h) of the Act. In addition, the transitioning cost plan (if it is to receive the deemed enrollment instead of an existing affiliated MA plan) must meet all contracting requirements necessary to become an MA plan.

Any plan wishing to deem enrollees from its cost plan to one of its MA plans under the MACRA provisions must notify CMS of that intention via the HPMS crosswalk process. This may be completed as early as May of 2018 for enrollments in 2019, the final contract year for deeming enrollment from a non-renewing cost plan to an affiliated MA plan, but must be completed by June 4, 2018. All crosswalks must be completed by the time the bid is due, unless a plan qualifies to submit a crosswalk during the exceptions window. Plans are responsible for following all contracting, enrollment, and other transition guidance released by CMS.

In order to ensure beneficiaries have the information they need to make informed choices about their healthcare options, enrollees of discontinuing cost plans will receive early notice that the cost plan is terminating, a special election period to elect enrollment in a different MA plan or original Medicare, and other protections.

CMS has released guidance on the requirements of the cost plan transition, which is available at the following link: https://www.cms.gov/Medicare/Health-Plans/MedicareCostPlans/index.html

Cost Plan Competition Requirements

CMS wants to remind MAOs that the cost plan competition requirements will first be effective in 2019, that is, cost plans affected by these requirements will first be unable to offer a cost plan in a service area or portion of a service area in contract year 2019. Under amendments to section 1876(h)(5)(C) of the Act, implementation of the cost plan competition requirements was delayed until the end of contract year 2018 by MACRA.

CMS will non-renew any portion of a cost plan's service area if there are at least two competing MA local or two MA regional coordinated care plans with a minimum of 5,000 enrollees (urban areas) or 1,500 enrollees (non-urban areas) for the entire year prior to the non-renewal. We used 2017 enrollment data to determine the cost plans subject to non-renewal pursuant to section 1876(h)(5)(C). CMS provided the results of the competition analysis to each cost contract in December, 2017.

Improving Beneficiary Communications and Reducing Burden for Integrated D-SNPs

We received broad support from commenters, including D-SNP sponsors, states, and beneficiary advocates, for CMS' continued efforts to maximize the potential for D-SNPs to align benefits and improve coordination for individuals dually eligible for Medicare and Medicaid and to collaborate with additional states in which there are integrated D-SNP products available to dually eligible individuals. In the draft Call Letter, we identified four specific areas for further integration in which administrative alignment for integrated D-SNPs is currently feasible within existing statutory, regulatory, and operational constraints: (1) oversight; (2) integrated model materials; (3) non-renewals; and (4) the Model of Care. In addition to the comments on the specific areas we identified, we received comments suggesting that CMS use its administrative

flexibility in two additional areas – appeals and grievances and joint CMS-state review of member material. We are considering those comments as we move forward.

In addition, we received a number of comments encouraging CMS to expand the current Financial Alignment Initiative capitated model demonstrations and to explore models allowing states, D-SNPs, and Medicaid managed care plans to test the delivery of services to dually eligible individuals under certain regulatory flexibility. While these comments are outside the scope of this Final Call Letter, we appreciate the support for current and new models for delivery and financing of integrated care for dually eligible individuals.

We remind states that we are happy to discuss these and other opportunities to promote integration and improve beneficiary experiences. We are also available to work with states on issues related to the required contracting between states and D-SNPs. Interested state Medicaid officials should contact the Medicare-Medicaid Coordination Office at: mmcocapsmodel@cms.hhs.gov.

D-SNP Oversight

CMS will continue to engage interested states in efforts to improve CMS-state communication and information sharing, as permitted by applicable law, to improve oversight and administration of D-SNP contracts. Commenters generally supported these efforts.

D-SNP Integrated Model Materials

In the draft Call Letter, we described our ongoing efforts to collaborate with states to develop a set of model materials with integrated benefit information for use by integrated D-SNPs. In response to previous stakeholder comments on this topic, we have prioritized the following materials: (1) Summary of Benefits; (2) Annual Notice of Change (ANOC)/Evidence of Coverage (EOC); (3) provider and pharmacy directory; and (4) formulary. A number of commenters supported CMS' efforts to create better and more integrated model materials for MMPs and D-SNPs.

Some commenters recommended that, in designing model materials, CMS use plain language and a reading level no higher than sixth grade; consumer test all documents; apply more stringent translation standards similar to those applicable to MMPs; and tailor notices to the individuals' circumstances and only include information that is directly relevant to the purpose of the notice. We appreciate these comments and note that CMS has engaged in a number of efforts to simplify and consumer test MMP and integrated D-SNP materials to ensure they are as focused and tailored as possible. CMS will continue to prioritize such efforts. Under the Financial Alignment Initiative capitated model demonstrations, we used waiver authority to apply the more stringent of the Medicaid or Medicare translation standard to MMPs; however, we do not have the same discretion to apply the Medicaid translation standards to D-SNPs absent demonstration authority. We note that states can impose additional requirements regarding translation of member

materials via their contracting with D-SNPs. In addition, as outlined in 42 CFR § 422.111(h)(1)(iii) and § 423.128(d)(1)(iii), Medicare Advantage organizations and Part D sponsors must provide interpreter service to all non-English speaking and limited English proficient beneficiaries regardless of the percentage of non-English speaking beneficiaries in the service area.

One commenter recommended that CMS allow D-SNPs to develop an EOC document based on the MMP Member Handbook models rather than the existing standardized D-SNP EOC model. We appreciate the support for the MMP Member Handbook model. We note that we have used waiver authority to exempt MMPs from the requirements to use the standardized EOC approved under the Paperwork Reduction Act process but do not have the same authority to exempt D-SNPs from those requirements. However, starting with the CY 2018 cycle, the standardized ANOC and EOC models for D-SNPs include new opportunities for integrating Medicare and Medicaid benefit descriptions similar to those available in the Summary of Benefits guidance. We will continue to work to streamline and simplify model materials and consider additional flexibility for integrated D-SNPs.

One commenter expressed concern about the difficulty of fully leveraging integrated materials for D-SNPs who serve members whose D-SNP and Medicaid managed care plan benefits are delivered by different organizations. We appreciate this concern and agree that aligned enrollment offers the best platform for Medicare-Medicaid integration. We will continue to provide technical assistance to states and plans on options to align enrollment for dually eligible individuals enrolled in D-SNPs and Medicaid managed care plans.

D-SNP Non-Renewals

Commenters supported better coordination of state and CMS communications and processes for D-SNP non-renewals, including working with states and plans to develop state-specific integrated non-renewal notices that include information about changes in the delivery of Medicaid benefits that will accompany the non-renewal of an integrated D-SNP.

One commenter recommended that CMS develop a truly integrated notice in which plans would be able to include optional, customizable language outlining steps that members should take if they also receive Medicaid services from the non-renewing or terminating plan. Over the last few years, non-renewing integrated D-SNPs have had the option to use a model non-renewal notice that allows inclusion of information regarding the non-renewal's impact on how D-SNP enrollees receive their Medicaid benefits. We will take this comment into consideration as we consider options to make this notice more customizable. Another commenter recommended that CMS release the annual non-renewal guidance and model documents earlier in the year and provide alternative plan information for non-renewal notices, as well as information about Medigap notices, by the end of August. These recommendations are applicable to non-renewal notices from both D-SNPs and other MA plans and will inform our work in the coming year.

D-SNP Model of Care

Commenters supported a more robust Model of Care (MOC) review process that allows: (1) the D-SNP to incorporate information about the integration of Medicare and Medicaid Managed Long Term Services and Supports (MLTSS); and (2) the state to review the integrated MOC submissions concurrent with the National Committee for Quality Assurance (NCQA) MOC review pursuant to 42 CFR §422.152(g). This approach is consistent with the process CMS has implemented with MMPs under the Financial Alignment Initiative, as well as with certain D-SNPs in Minnesota since 2014 and, more recently, the Commonwealth of Massachusetts.

Some commenters noted that, as part of a joint review process, it will be important to ensure that D-SNPs receive timely and consistent feedback and approval from both CMS and states, and that the state and NCQA MOC reviews recognize that D-SNPs may serve a variety of subpopulations, including members who do not need MLTSS services, under a single MOC. We agree with commenters about the importance of timely and consistent feedback and note that we have been able to implement joint MOC requirements and reviews in a variety of states, both within and outside the Financial Alignment Initiative, in a way that allows for integration of state-specific requirements while maintaining the integrity of the CMS MOC requirements and of NCQA's review of MOCs under 42 CFR § 422.152(g). In addition, we believe that the MOC requirements provide a sufficiently broad framework to allow D-SNPs to differentiate between subpopulations with respect to the provision of MLTSS services.

D-SNP Appeals and Grievances and Integration Standards

We received comments supportive of section 50311(b) of the Bipartisan Budget Act of 2018 (115–123), which directs CMS to: (1) develop unified grievance and appeals processes for D-SNPs; and (2) establish new standards for integration of Medicare and Medicaid benefits for D-SNPs. These commenters encouraged CMS to issue preliminary information to stakeholders as part of this process and requested that CMS provide additional guidance to advise D-SNPs working toward integration on how to better integrate without curtailing member rights. CMS appreciates these comments and looks forward to working with a variety of stakeholders to develop standards for unified grievance and appeals processes and integration of Medicare and Medicaid benefits by April 2020, as directed by the statute.

We invite stakeholders to submit comments to help inform CMS' next steps related to unified D-SNP grievance and appeals processes and new integration standards by April 12, 2018. More information is available at https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/DSNPBBA2018.html.

D-SNP Member Material Reviews

In addition to developing integrated member materials, some commenters supported an integrated CMS-state process for review and approval of member materials in order to streamline

and coordinate the multiple levels of reviews these materials undergo in some states. These commenters note that CMS and states have accomplished these efficiencies under the Financial Alignment Initiative capitated model and Minnesota demonstrations and recommend extending them to D-SNPs and states wishing to pursue this additional level of integration. We appreciate these commenters' support of the integrated marketing material review process under current demonstrations. We agree that extending current demonstration joint review processes could yield additional efficiencies, but note that, at this time, there remain both operational and statutory obstacles to extending these processes in the absence of demonstration waiver authority.

Parts A and B Cost-sharing for Individuals Enrolled in the Qualified Medicare Beneficiary (QMB) Program

In the 2016 Call Letter, CMS reminded plans of their obligations under 42 CFR §422.504(g)(1)(iii) to educate network providers about QMB billing rules and to maintain procedures that ensure network providers do not discriminate against enrollees based on their payment status, e.g., QMB.[32] During summer 2016, CMS engaged in strategic conversations with MA organizations to discover their technical assistance needs and learn about concrete strategies to promote compliance. During this process and in follow-up, MA organizations have asked CMS to help identify the QMB status of enrollees and to recommend promising practices regarding QMB billing.

The QMB Program is a Medicaid benefit that pays Medicare premiums and cost sharing for certain low-income Medicare beneficiaries. Federal law prohibits Medicare providers from collecting Medicare Part A and Part B coinsurance, copayments, and deductibles from those enrolled in the QMB Program, including those enrolled in Medicare Advantage and other Part C plans. Timely access to enrollees' QMB status is critical to inform, monitor, and promote provider compliance with these requirements. In June 2017, CMS informed plans about CMS sources of QMB information, including the Medicare Advantage Medicaid Status Data File, which provides the most current information about monthly dual status, including QMB, and corresponding dual status codes.[33] As a reminder, for Medicare-Medicaid Plans (MMPs) in the capitated model of the Financial Alignment Initiative and for Program of All-Inclusive Care for the Elderly (PACE) organizations, coinsurance, copays, and deductibles are zero for all Medicare Parts A/B services.

To reinforce billing requirements, simplify compliance, and prevent instances of improper billing, CMS encourages plans to affirmatively inform providers about enrollee QMB status and exemption from cost-sharing liability. Plans can provide real-time QMB status information and

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[32] See Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter; *and* Medicare Managed Care Manual, Ch. 4, Section 10.5.2.

[33] See HPMS memo, "Qualified Medicare Beneficiary Program Enrollee Status Resources" June 21, 2017.

indicators through online provider portals and phone query mechanisms and clearly indicate the QMB patient owes $0 directly on the Explanations of Payment document that they send to providers and on member identification cards. MMPs should make clear that all enrollees – regardless of whether they have QMB status or not – have zero Medicare Parts A and B coinsurance, copayments, and deductibles. In addition, plans can highlight that for any providers who are enrolled in Medicare, Medicare's HETS eligibility query system will identify those who are QMB.

CMS also encourages plans to educate providers about the QMB billing requirements for Medicare Parts A and B deductibles and coinsurance. Potential strategies include holding recurring trainings, conducting targeted education to providers that improperly bill members, and adding language to provider-focused websites, provider newsletters, and/or provider manuals.

Plans may want to leverage CMS information for providers and plans on CMS's QMB webpage at https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/QMB.html.

Moreover, starting in March 2017, the Complaints Tracking Module (CTM) began distinguishing QMB complaints from other complaints. When appropriate, CMS encourages plans to use this source of information, alongside grievance and plan call center data, to identify further opportunities to strengthen provider education activities, improve internal call center messaging, and reduce future CTM complaints regarding QMB billing.

We received several comments supportive of CMS' continued efforts to highlight plan requirements to protect enrollees from inappropriate billing and to advise plans to proactively notify providers of the QMB status of enrollees. Commenters stated that, while recent CMS efforts have helped improve awareness, billing problems persist and providers need further assistance in identifying the QMB status of enrollees.

We received a number of requests for additional CMS guidance and actions. In response to commenters' request for clarification, we note that plans' education and monitoring responsibilities extend to all providers of Parts A and B items and services, including pharmacies dispensing Part B drugs and suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). CMS encourages plans to tailor outreach and assistance to pharmacies and suppliers, which may have different needs and systems than physicians and institutional providers.

Some commenters asked CMS to require, instead of recommend, that plans convey QMB information to providers, work with stakeholders to develop uniform protocols to identify QMB status, and require plans to develop standard operating procedures for providers to check for QMB status. At this time, we decline to mandate that plans use specific methods to facilitate QMB verification by providers. CMS will instead focus on supporting plans in developing their own solutions. We note that, starting November 2017, all Medicare-enrolled providers (and their

authorized third party eligibility and billing vendors) can discern a beneficiary's QMB status through HETS.

One commenter stated it is an undue burden for plans to provide real-time QMB information to providers because confirmation of QMB status is a provider, not plan, responsibility. Since plans are responsible for protecting beneficiaries from inappropriate billing, and early identification of QMB status is a central way to prevent such problems in the first place, we believe real-time transmission of QMB information is a reasonable and effective use of plan resources.

A number of commenters requested that CMS use the CTM to focus our plan compliance and education efforts. We appreciate this suggestion and note that we continue to explore additional steps to address and track billing problems and to promote adherence to billing rules. Finally, one commenter asked that CMS work not just with plans but also with states, providers, and pharmacists to raise awareness of QMB billing requirements. We agree these other stakeholders have an important role and have included them in our outreach efforts.

Encounter Data Listening Forums, Monitoring and Compliance Activities

Under 42 C.F.R. § 422.310, MA organizations are required to submit encounter data records 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 3 billion encounter data records to date. PACE organizations are also required to submit encounter data.

In order to assist organizations in meeting requirements for submitting complete and accurate data, CMS conducts a range of activities aimed at providing feedback and technical assistance to, and soliciting input from, stakeholders. These efforts include distribution of quarterly report cards, site visits with submitters, one-to-one communication with plans, and monthly user group calls which provide updates, training, and an open-mic question and answer period.

Listening Forums. CMS has also initiated a series of listening forums with MA organizations, and MA organizations have expressed appreciation for the opportunity to participate in these forums. CMS has viewed them as successful and has gained important insight into submitters' experiences with the submission of encounter data. In light of the positive feedback received in response to these listening forums, CMS expects to continue holding listening forums in 2018 and will again be reaching out to plans to participate.

The listening forums have helped to highlight areas in the submission process where both plans and CMS can make improvements. A priority for CMS continues to be to ensure the completeness and accuracy of submissions and to seek feedback from stakeholders. CMS presented an approach to monitoring and compliance of encounter data in the 2018 Call Letter. CMS's framework for monitoring and compliance activity was categorized into three performance 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).

Stakeholder feedback indicated support of this activity to ensure the completeness and accuracy of encounter data, but also suggested that CMS adopt an incremental approach and continue to seek out stakeholder feedback on monitoring and compliance.

CMS issued an HPMS memo entitled "CMS Monitoring and Compliance of Encounter Data, Performance Metrics and Thresholds – For Comment" on November 1, 2017 and requested feedback from stakeholders. CMS will review comments and finalize the performance and monitoring metrics and thresholds in an HPMS memo that will be distributed in 2018.

CMS thanks those who submitted comments on encounter data listening forums and monitoring and compliance activities and appreciates stakeholders' general support for both the forums and performance standards for encounter data submissions.

Listening Forums. With regard to listening forums, CMS acknowledges commenters' concerns regarding the need for improved transparency of proceedings from previous and upcoming listening forums. CMS also received suggestions to invite a broader variety of participants to the forums in order to ensure that discussions are representative of the full spectrum of perspectives involved in encounter data submission. We will consider this as we plan for forums in the future.

CMS solicits feedback on and provides technical assistance related to encounter data submissions through various means, such as 1-on-1 calls, site visits, mailbox inquiries, and most recently, listening forums. Information gathered through these channels feeds outreach activities, such as user group calls, technical assistance communications, new guidance, and email communications. Typically, these outreach communications are not attributed to the specific feedback channel that spurred CMS's outreach. For example, information gathered through site visits, mailbox inquiries, and listening forums resulted in the release of several HPMS submission guidance memos last fall. Thus, although CMS has not explicitly attributed information shared to listening forums, we have addressed certain issues raised during the forums and shared the outcome with all MAOs.

CMS continues to work on issues raised during the first round of listening forums and going forward, CMS will consider ways of more directly sharing information gathered during listening forums.

Monitoring and Compliance Activities. Commenters' primary suggestion about monitoring and compliance activities was to delay implementation (of some or all metrics) to allow time for MAOs to understand the metrics and thresholds and for CMS and MAOs to collaborate and address deficiencies. In response to stakeholder concerns about the need to adopt an incremental approach to monitoring and compliance, CMS continues to take a phased-in approach that targets entities experiencing the most difficulty in submitting encounter data. CMS will consider comments related to timing of its compliance actions as we finalize metrics and thresholds and will provide updated communications to keep MAOs informed.

Transparency & Timeliness with Prior Authorization Processes

CMS is aware of stakeholder concerns about the burdens imposed by coverage restrictions such as prior authorizations (PA) in the Part C program.

MAOs receive a capitated payment from CMS and are accountable for furnishing all medically necessary Part A and B services through a network of contracted providers. They are permitted to manage the delivery of benefits within their provider networks using utilization management tools such as prior authorization (PA).

CMS reminds MAOs that they should be transparent and provide adequate notice of any coverage restrictions, such as PA requirements, to providers and enrollees. Plans should specify the existence of any coverage restrictions, including what information is needed when submitting a PA request, in the plan's Evidence of Coverage (EOC), their contracts with providers and additional provider communications/materials (e.g., provider manuals). Where an enrollee or provider is attempting to satisfy a PA requirement and the plan requires or has a PA request form, the plan should make PA request forms available and easily accessible.

MAOs should ensure they are delivering timely decisions on PA requests. CMS reminds MAOs that requests for PA for a service (whether by an enrollee directly or by a provider on behalf of an enrollee) are requests for a pre-service organization determination. Therefore, these requests are subject to applicable pre-service organization determination adjudication timeframes and notice requirements under the MA regulations. See 42 CFR §§422.568 and 422.572.

Section III – Part D

Formulary Submissions

CY 2019 Formulary Submission Window

The CY 2019 HPMS formulary submission window will open this year on May 14, 2018 and close at 11:59 PM PDT on June 4, 2018. CMS must be in receipt of a successfully submitted and validated formulary submission by the deadline of June 4, 2018 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 4 deadline will result in denial of that bid submission.

CY 2019 Formulary Reference File

CMS publishes the Formulary Reference File (FRF), which is utilized by Part D sponsors for submitting Part D formulary files into HPMS. The FRF is not intended to be a comprehensive list of Part D drugs – the presence on or absence from the FRF does not indicate whether a particular drug is eligible for Part D coverage. However, we do recognize that the FRF has expanded and now includes several drugs for which utilization under Part D would be extremely rare. We also understand that the inclusion of some of these drugs within the Medicare Plan Finder may lead to beneficiary confusion when the drug is more commonly covered under Medicare Part B, for example. To that end, CMS analyzed the Part D utilization of FRF drugs, as well as their usual route of administration, and proposed removing drugs from the FRF based on these results. The proposed deletion of drugs was based on very infrequent utilization under Part D, their indication, dosage and administration, and usual administration setting. An example proposed for deletion was an intravenous antihypertensive with very little Part D utilization, indicated for the short-term treatment of hypertension when the oral route is not feasible.

CMS released a draft CY 2019 FRF reflecting these changes on February 28, 2018. An HPMS email was sent to stakeholders announcing the availability of the draft file, along with comment instructions. A total of 376 RXCUIs were proposed for deletion due to this analysis. The largest category of drugs deleted belonged to the antineoplastic category. Injectable drugs within the antineoplastic category that are not usually self-administered were the most commonly removed drugs. We received responses from a total of 15 organizations (6 pharmaceutical manufacturers and 9 Part D sponsors/PBMs) concerning the draft FRF. The comment that was most commonly submitted for proposed FRF deletions was that plan sponsors are currently utilizing prior authorization to manage appropriate utilization for many of these drugs and were concerned that they could not continue to use their utilization management edits. In response to comments we received on the FRF deletions, we believe additional clarification with respect to coverage of drugs not on the CMS FRF is warranted. Specifically, and as noted above, the FRF is not a comprehensive Part D coverage determination tool. Part D sponsors are able to cover drugs that are not on the FRF provided that they meet the definition of a Part D drug. In contrast to non-

formulary drugs, which are not subject to utilization management (UM) restrictions because they are not included on the formulary, formulary drugs that are not on the FRF can be subject to UM, just like other formulary drugs. To the extent that a sponsor included a drug on its CY 2018 formulary that has been removed from the CY 2019 FRF, the sponsor may continue to maintain the drug on its CY 2019 formulary.

A subsequent CY 2019 FRF was published on March 27, 2018. This version of the CY 2019 FRF reflects comments received on the February version, new drugs that have become available since February, and deletion of drugs due to standard annual processes. 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 2018, in order to assist plan sponsors in preparing their bid submissions. Sponsors should note that the OOPC model released in April will not be modified to incorporate any subsequent FRF updates, as described below.

CMS will update the CY 2019 FRF again in mid to late May, prior to the June 4 formulary submission deadline. Since the OOPC model incorporates Medicare Current Beneficiary Survey (MCBS) data from 2012 and 2013, 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 CY 2019 FRF and the June 4 deadline, CMS is unable to accommodate an updated version of the 2019 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 CY 2019 FRF will not be included in the 2019 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 UM than what was applied to the existing brand. In the draft CY 2019 Call Letter, we sought feedback regarding the optimal timeframe for this formulary update window. Based on responses, we will maintain a late-July or early-August window in order to provide Part D sponsors with enough time to finalize formulary documents for printing. Given that we do not anticipate the availability of the necessary data files to begin the FRF update process until August 6, the subsequent production and corresponding formulary submission and review times would be problematic for some Part D sponsors.

We remind Part D sponsors that they may enhance their formularies at any time, including prior to the start of the plan year, regardless of whether the drugs are on the FRF. Such enhancements may entail adding Part D drugs (with or without UM restrictions), reducing beneficiary cost-sharing, or removing UM edits. These enhancements must be included in the beneficiary communication materials (i.e. comprehensive formulary) and must be submitted during the next available HPMS formulary submission window. Under the current formulary submission

process, HPMS formulary files are not updated between the aforementioned summer update window and the first HPMS submission window during the plan year. Since the HPMS formulary files feed into the Medicare Plan Finder (MPF), MPF formulary information will not reflect any enhancements Part D sponsors have made to their formulary files after the summer update. In an effort to provide more up-to-date information within the MPF, CMS will add an optional formulary submission window that will occur in late fall. Likewise, a January formulary update window will be added.

Changes for CY 2019 Formulary Submissions

For the CY 2019 plan year, CMS is implementing changes to the following formulary-related files:

Additional Demonstration Drug (ADD) File

The Additional Demonstration Drug (ADD) file is a supplemental formulary file submitted by Medicare-Medicaid Plans, which contains all non-Part D drugs required by the State. In an effort to streamline the submission process for Part D sponsors offering a Medicare-Medicaid Plan, CMS will make the ADD Validation File available via HPMS in advance of the ADD File submission deadline.

Non-Extended Day Supply (NDS) File

The Non-Extended Day Supply (NDS) file is a supplemental file for formularies that offer partial extended day supply coverage for at least one tier. We have concluded the burden of maintaining this supplemental file outweighs the benefit, and thus CMS is eliminating this supplemental file for CY 2019. Part D Sponsors will continue to identify in the plan benefit package (PBP) if there are any drugs for which the plan imposes a limit of a one month supply, if the drugs are included on a tier that is otherwise available at an extended day supply.

Over-the-Counter (OTC) Validation File

Part D sponsors wishing to offer over-the-counter drug products (OTCs) as part of step therapy or as a UM strategy are required to submit an OTC supplemental file. The current file format is National Drug Codes (NDCs) submitted by Part D sponsors. The submitted files are validated against an internal CMS file that contains a universe of OTC NDCs that CMS believes could be offered as part of the sponsor's step therapy or UM strategy, consistent with the Chapter 7 of the Medicare Prescription Drug Benefit Manual. NDCs not contained within the CMS validation file are rejected, which necessitates a subsequent submission of a revised file by the Part D sponsor. In an effort to reduce the burden on Part D sponsors to create and submit these files, and to streamline the CMS review of the OTC submissions, CMS will provide plans with an OTC reference file for CY 2019 that uses a proxy code (e.g., RXCUI) to represent each unique drug ingredient, strength, route, and dosage form, but the file will not contain every possible branded

OTC. Providing the file of acceptable OTCs, via proxy code, in advance to plan sponsors will enable them to prepare their files based on known CMS acceptable OTCs, significantly reduce the size of the OTC files, and simplify the submission and review process. For example, the current OTC validation file contains nearly 100 rows representing various products for ranitidine 75 mg oral tablets. These are condensed to one row for CY 2019. We will provide Part D sponsors an opportunity to review a draft OTC reference file well in advance of the supplemental file submission deadline.

Expanding the Part D OTC Program

The definition of a Part D drug does not include over-the-counter drug products (OTCs). Therefore, Part D sponsors cannot cover OTCs under their basic prescription drug benefit or as a supplemental benefit under enhanced alternative coverage. However, given that OTCs may offer a significantly less expensive alternative to prescription medications, CMS allows Part D sponsors the option to provide OTCs as a UM strategy within their administrative cost structure, with the expectation that the use of the OTC medication will offset the use of a more costly Part D drug.

For those sponsors who elect to do so, OTCs offered through a Part D UM strategy are a component of the Part D plan premium and result in OTCs provided to the enrollee without any direct cost-sharing at the point-of-sale. The OTCs must be available for the full duration of the contract year and cannot be limited to certain benefit phases. Under this policy, OTCs do not have the same beneficiary protections, such as coverage determinations or temporary fills, required to ensure appropriate access to Part D drugs.

Currently, no standalone PDPs and only a very few MA-PDs offer OTCs under existing Part D policies, but there has been plan interest to broaden what could be provided. Consequently, CMS indicated in the draft CY 2019 Call Letter that we were contemplating additional flexibilities for Part D plan sponsors to offer access to OTCs. For example, CMS could consider allowing sponsors to include additional OTC products such as dietary supplements and cough medicines, without the requirement that the OTC product offset the use of a Part D drug.

We noted that any such expansion of the current policy could potentially increase program costs and reminded plan sponsors that beneficiary inducement laws would still apply. In the draft CY 2019 Call Letter, we solicited feedback from stakeholders on Part D OTC enhancements that could be considered for future policy. Of the feedback we received, most was in opposition to any expansion of the current OTC program. Concerns cited included: likely increases to program costs, additional UM controls creating access barriers to prescription drugs, and the potential inclusion of dietary supplements under such a program. Several commented that this proposal runs counter to the congressional intent of the program and statutory definition of a Part D drug, which intends to provide access to a prescription drug benefit program. We received feedback from a few plan sponsors expressing general support for the expansion of the Part D

OTC program. However, few offered any specifics to modify the program nor provided comment on potential impacts. Given the opposition to expanding the program and the limited input received from the few sponsors that expressed support, we do not intend to pursue expansion of the program at this time, but may revisit OTC program expansion in the future.

Medication Therapy Management (MTM) Annual Cost Threshold

Targeted beneficiaries for a Part D plan's MTM program, in general, are enrollees who meet all of the following criteria: have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur annual Part D drug costs that meet or exceed a certain threshold. Per 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 increase (API) in Part D drug expenditures, specified in 42 C.F.R. § 423.104(d)(5)(iv). The 2018 MTM program annual cost threshold is $3,967. The 2019 MTM program annual cost threshold is updated for 2019 using the annual percentage increase of 1.94% as specified in the Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies. Therefore, the 2019 MTM program annual cost threshold is $4,044.

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 2019 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 2019 will be released approximately one month before the 2019 MTM program submission deadline. The CY 2019 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.

Part D Benefit – Change in the Coverage Gap Discount Program

The Bipartisan Budget Act of 2018 (BBA) (Public Law No. 115-123), enacted on February 9, 2018, made the following two modifications to the Medicare Part D Coverage Gap Discount Program (CGDP).

Manufacturer Discounts. For applicable drugs, (see definition below), the BBA increases the manufacturer discount for beneficiaries in the gap from 50 to 70 percent[34] and reduces beneficiary cost sharing to 25 percent in 2019. Manufacturer discount amounts will continue to count towards a beneficiary's true out-of-pocket cost (TrOOP).

For non-applicable drugs, the law does not change the existing schedule that finishes closing the coverage gap in 2020.

The cost sharing values for current and future years are as follows:

Year	**Applicable Drugs**			**Non Applicable Drugs**		
	Manufacturer Discount	*Beneficiary Cost Sharing*	*Plan Cost Sharing*	*Manufacturer Discount*	*Beneficiary Cost Sharing*	*Plan Cost Sharing*
2018	50%	35%	15%	N/A	44%	56%
2019	70%	25%	5%		37%	63%
2020 and Beyond	70%	25%	5%		25%	75%

Applicable Drug Definition. Currently, biosimilars are excluded from the definition of applicable drugs under the Coverage Gap Discount Program. Section 53113 of the Bipartisan Budget Act sunsets that exclusion as of January 1, 2019.[35] As a result, for CY 2019 biosimilars will be subject to a 70 percent manufacturer discount and must be covered under a CMS CGDP agreement in order to be covered by Medicare Part D.

These changes will become effective on January 1, 2019. CMS will update our regulations, the CGDP manufacturer agreement, and subregulatory guidance as necessary to comply with these statutory requirements.

We remain concerned about the impact these changes will have on drug costs under Part D in 2019 and future years, particularly as plan liability in the gap significantly decreases for brand name drugs beginning in 2019. We remain committed to addressing the rising cost of prescription drugs for seniors and will closely monitor the effects of the changes enacted in the BBA of 2018 on drug utilization and the pace of progression of beneficiaries into the catastrophic phase of the benefit. This may include, but is not limited to, changes in generic drug

[34] Public Law No. 115.-123, Section 53116

[35] See Public Law No. 115-123, Section 53113 amends section 1860D-14A(g)(2)(A) of the Act so that it now defines applicable drugs to mean drugs that are approved under a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) or, in the case of a biological product, licensed under section 351 of the Public Health Service Act (PHSA) (other than with respect to a plan year before 2019, a product licensed under subsection (k) of such section 351).

uptake, formulary inclusion, tier composition, and substitutions. As we gain experience under this new benefit structure, we will consider additional changes necessary to protect beneficiary out-of-pocket costs and federal spending. We are interested in stakeholder recommendations on how, such as through changes to the Part D risk corridors, Part D sponsors might be incented to promote the use of high value drugs in the Part D program given the modified benefit parameters structure. We are also interested in recommendations on additional measures we could monitor to ensure the integrity of the competitive marketplace which has been the cornerstone of the Part D program's success.

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, as provided under §423.265(b)(2), by the sponsor in the service area with respect to key characteristics such as cost-sharing, formulary structure, or benefits offered. 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 2019 are set forth in Table 26 below.

As part of the Medicare Program Contract Year 2019 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs NPRM, published November 28, 2017, CMS proposed to eliminate the PDP enhanced alternative (EA) to EA meaningful difference requirement, while maintaining the requirement that enhanced plans be meaningfully different from the basic plan offered by a plan sponsor in a service area. Guidance related to EA to EA plan offering requirements will be provided in the final rule. As part of the NPRM, we also sought stakeholder input on how to best define the meaningful difference between basic and enhanced plans. Although the feedback submitted was limited, we appreciate the comments that we did receive and will continue to evaluate ways to refine this requirement, including efforts to improve upon the Out-of-Pocket Cost (OOPC) model. Until this work is completed, we will continue to use the same methodology that was utilized to determine the CY 2017 and CY 2018 basic to enhanced meaningful difference threshold. The minimum monthly cost-sharing OOPC difference between basic to enhanced PDP offerings for CY 2019 is $22. This value is based on the 50th percentile of the November CY 2018 Bid data run through the updated CY 2018 OOPC MPF model that incorporates CY 2018 Formulary Data, 2012/13 MCBS Data, and FDA Application Type for applicable/non-applicable determinations related to coverage gap cost-sharing estimates.

For purposes of determining whether coverage gap cost-sharing thresholds specified in Table 26 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 50% 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 17% 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. Please refer to the section titled "Part D Benefit – Change in the Coverage Gap Discount Program" for additional information related to the coverage gap discount modifications, made as a result of the Bipartisan Budget Act of 2018.

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 26 below, to determine whether the coinsurance values are discriminatory. Similarly, we will evaluate the drug composition of copay tiers in order to assess whether the formulary and benefit structure is providing a meaningful benefit.

Tier Composition

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 a non-preferred drug tier, but not both. As such, the inclusion of a significant number of generic drugs on a tier that is labeled as brand is misleading and may lead to beneficiary confusion. CMS will continue to evaluate the brand/generic composition of the non-preferred brand tier as part of the bid review process. In recent years, we have communicated concerns based on an outlier analysis; however, in the draft CY 2019 Call Letter, we proposed a maximum threshold of 25% generic composition for the non-preferred brand tier for CY 2019. The majority of comments received were in support of this threshold; therefore, we will finalize the maximum generic composition threshold at 25% for the non-preferred brand tier. We would like to remind Part D sponsors that they have the option to choose a tier model that incorporates a non-preferred drug tier label if a larger proportion of generics will be included on that 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. We expect the justification to include detailed information about the generic drugs on the non-preferred drug tier, such as expected utilization, the formulary alternatives represented on lower tiers, and any tier placement strategy with respect to UM. Sponsors may be asked to make modifications to their benefit structure or formulary tiering if the submitted justification is not accepted.

Improving Access to Part D Vaccines

According to the Center for Disease Control and Prevention's (CDC) Surveillance of Vaccination Coverage among Adult Populations — United States, 2015, vaccination rates remain low for tetanus and diphtheria with acellular pertussis (Tdap)[36]. While the Healthy People 2020 herpes zoster target vaccination rate has been achieved, approximately 70% of adults for whom the vaccine is recommended remain unprotected. In an effort to improve access to these and other Part D vaccines, we encourage Part D sponsors to either offer a $0 vaccine tier, or to place vaccines on a formulary tier with low cost-sharing.

[36] Williams WW, Lu P, O'Halloran A, et al. Surveillance of Vaccination Coverage among Adult Populations — United States, 2015. MMWR Surveill Summ 2017;66(No. SS-11):1–28. DOI: https://www.cdc.gov/mmwr/volumes/66/ss/ss6611a1.htm

Table 26: Benefit Parameters for CY 2019 Threshold Values

	CY 2019 Threshold Values
Minimum Meaningful Differences (PDP Cost-Sharing OOPC)[1]	
Enhanced Alternative Plan vs. Basic Plan	$22
Maximum Copay: Pre-ICL and Additional Cost-Sharing Reductions in the Gap (3 or more tiers)	S[2,3]
Preferred Generic Tier	<$20[4]
Generic Tier	$20
Preferred Brand/Brand Tier	$47
Non-Preferred Drug Tier	$100
Non-Preferred Brand Tier	$100
Injectable Tier	$100
Select Care/Diabetic Tiers[5]	$11
Vaccine Tier	$0
Maximum Coinsurance: Pre-ICL (3 or more tiers)	S[2,3]
Preferred Generic Tier	25%
Generic Tier	25%
Preferred Brand/Brand Tier	25%
Non-Preferred Drug Tier	50%
Non-Preferred Brand Tier	50%
Injectable Tier	33%
Select Care/Diabetic Tiers[5]	15%
Vaccine Tier	0%

	CY 2019 Threshold Values
Maximum Coinsurance: Additional Cost-Sharing Reductions in the Gap for Applicable Beneficiaries (all tier designs)	S[6]
Preferred Generic Tier	17%
Generic Tier	17%
Preferred Brand/Brand Tier	50%
Non-Preferred Drug Tier	50%
Non-Preferred Brand Tier	50%
Injectable Tier	50%
Select Care/Diabetic Tiers[5]	50%
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 2018 Bid Data run through the CY 2018 OOPC MPF model which incorporates CY 2018 Formulary Data, 2012/13 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.

[2] These thresholds are based on the 95th percentile of the CY 2018 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). 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 17% 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 70% manufacturer discount for applicable drugs.

Specialty Tiers

Per 42 C.F.R. §423.578 (a)(7), a Part D sponsor may exempt a formulary tier in which it places very high cost and unique items from its tiering exception process. In order for a Part D drug to be placed on this specialty tier, the sponsor-negotiated price must exceed an established dollar-per-month threshold. Similar to past years, an analysis was performed utilizing CY 2017 prescription drug event (PDE) data to identify monthly fills that exceed the current specialty tier threshold of $670. This analysis showed that just around 1% of 30 day-equivalent fills exceeded $670 and as a result, CMS will maintain the $670 threshold for CY 2019. We will continue to monitor this trend in future years to determine if specialty tier threshold increases are necessary.

Low Enrollment Plans (Stand-alone PDPs only)

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 a sufficient number of enrollees to establish that they are viable plan options. CMS evaluates plan enrollment at the PDP region level. Plans are deemed low enrollment plans if both of the following are true: 1) the plan enrollment is below 1,000 and 2) the plan is in the lowest quintile of enrollment within the specific PDP region. Prior to taking additional action on a low enrollment plan, CMS considers relevant factors such as: (1) whether the plan is a basic plan that is satisfying requirements set forth at 42 CFR § 423.104(f)(2), and the organization's enhanced plan does not have low enrollment in the same region; (2) whether the plan has been in existence for three years or less; (3) whether the plan is offered nationally; (4) the total number of plan offerings in the applicable region; and (5) if the plan's premium currently falls at or below the low income benchmark premium amount. We will notify affected low enrollment plans that do not meet at least one of the five criteria above by late March/early April 2018. In these circumstances, the Part D sponsor will have the option to consolidate or non-renew the plan, or they may alternatively submit a strategic plan that describes how enrollment will be increased for the upcoming plan year. We intend to non-renew a plan if it continues to be low enrollment for a second consecutive year despite a strategic plan aimed at increasing enrollment. For CY 2019, CMS will begin also notifying Part D sponsors that meet low enrollment criteria (< 1,000 members and within the lowest quintile for a given PDP region)

but possess one of the five relevant factors for informational purposes only. No action will be required for those sponsors.

Improving Drug Utilization Review Controls in Medicare Part D

Part D Opioid Overutilization Policy

Opioid medications ("opioids") have serious risks such as addiction, overdose, and death. CMS is deeply concerned about the magnitude of the opioid misuse epidemic and its impact on our communities, and is committed to a comprehensive and multi-pronged strategy to combat this public health emergency. It is a top priority of this Administration to address the opioid epidemic.

We value stakeholder input as we undertake multiple efforts to reduce the negative impacts of the opioid epidemic on our communities. While most beneficiaries utilize and clinicians prescribe opioids in ways that are medically appropriate, opioid overutilization is nonetheless a significant concern for the Medicare Part D program, and CMS is helping plans identify individuals potentially at risk for opioid abuse.

In the 2019 draft Call Letter, CMS announced a number of new strategies to further help Medicare plan sponsors prevent and combat opioid overuse. We received a significant number of comments in response to the draft guidance from patients, clinicians, plan sponsors, advocates, and associations, which we carefully considered before finalizing the policies in this Call Letter. The policies give health plans additional tools to employ more effective drug utilization review (DUR) programs to reduce overutilization of opioids and maintain access to needed medications for beneficiaries.

Furthermore, we recognize that a "one size fits all" approach does not take into account different circumstances related to opioid use. Therefore, while the strategies collectively work towards the same goal, an overall reduction in opioid overuse and overdoses, we have tailored each approach to address the distinct populations of Medicare Part D prescription opioid users (e.g., new opioid users; chronic users; those with uncoordinated care; those that concurrently use opioids with benzodiazepines, etc.). We also recommend that beneficiaries who are residents of a long-term care facility, in hospice care[37] or receiving palliative or end-of-life care, or being treated for active cancer-related pain be excluded from these interventions. In addition, it is also very

[37] We remind Part D sponsors that drugs and biologicals covered under the Medicare Part A per-diem payments to a Medicare hospice program are excluded from coverage under Part D. For a prescription drug to be covered under Part D for a beneficiary who has elected hospice, the drug must be for treatment unrelated to the terminal illness or related conditions. This is because drugs and biologicals covered under the Medicare Part A per-diem payments to a Medicare hospice program are excluded from coverage under Part D. Therefore, in 2014, we strongly encouraged sponsors to place beneficiary-level PA requirements on only four categories of prescription drugs including analgesics. Please see the most recent CMS guidance, "Update on Part D Payment Responsibility for Drugs for Beneficiaries Enrolled in Medicare Hospice", issued on November 15, 2016.

important that beneficiaries' access to medication-assisted treatment (MAT), such as buprenorphine, is not impacted.

Discussed in greater detail in the following pages, a summary of the 2019 opioid overutilization policies is as follows:

1. Opioid naïve patients: To reduce the potential for chronic opioid use or misuse, we expect all Part D sponsors to implement a hard[38] safety edit to limit initial opioid prescription fills for the treatment of acute pain to no more than a 7 days supply.

2. High risk opioid users: We are building upon and expanding the Overutilization Monitoring System (OMS), which has already significantly reduced the number of high risk beneficiaries. The OMS retrospectively identifies those beneficiaries we consider at significant risk (using high levels of opioids from multiple prescribers and pharmacies). Sponsors review these cases and perform case management with the beneficiaries' prescribers.

   We proposed to implement the Comprehensive Addiction and Recovery Act of 2016 (CARA) drug management program in 2019 and integrating those policies with the OMS process. Part D sponsors will be able to limit at-risk beneficiaries' coverage for frequently abused drugs to certain prescribers and pharmacies ("lock-in") and apply beneficiary-specific point-of-sale (POS) claim edits. The OMS will also be enhanced to include revised metrics to track high opioid overuse and to provide additional information to sponsors about high risk beneficiaries who take opioids and "potentiator" drugs (which when taken with an opioid increase the risk of an adverse event).

3. Chronic opioid users: We expect all sponsors to implement real-time safety edits at the time of dispensing as a proactive step to engage both patients and prescribers about overdose risk and prevention. We recognize that a tailored approach is needed to better address chronic opioid overuse at the POS. Some patients are using opioids where prescribers are considering increasing the opioid dosage above 90 morphine milligram equivalent (MME) per day or where prescribers may be unaware their patients are receiving high levels of opioids from additional prescribers. Other patients are already receiving higher opioid dosages long-term where the benefits and risks of maintaining or the decreasing opioid dosage should be carefully considered. Opioid withdrawal,

[38] See Chapter 6 of the Prescription Drug Benefit Manual: Hard reject: stops the pharmacy from processing a claim unless or until an override is entered or authorized by a plan representative; soft reject: stops the pharmacy from processing a claim unless or until a pharmacist-submitted drug utilization review (DUR)/prospective payment system (PPS) code is entered.

disruptions in care, obtaining opioids from other sources, and suicide risk affect clinical decisions.

4. We expect all sponsors to implement an opioid care coordination edit at 90 MME per day. This formulary-level safety edit would trigger when a beneficiary's cumulative MME per day across their opioid prescriptions reaches or exceeds 90 MME. In implementing this edit, sponsors should instruct the pharmacist to consult with the prescriber, document the discussion, and if the prescriber confirms intent, use an override code that specifically states that the prescriber has been consulted. Sponsors will have the flexibility to include a prescriber and/or pharmacy count in the opioid care coordination edit. Sponsors will also have the flexibility to implement hard safety edits and set the threshold at 200 MME or more and may include prescriber/pharmacy counts.

5. Opioid users also taking duplicate or key potentiator drugs: Lastly, we expect sponsors to implement additional soft safety edits to alert the pharmacist about duplicative opioid therapy and concurrent use of opioids and benzodiazepines.

6. Overall: CMS also uses quality measures to track trends in opioid overuse across the Medicare Part D program. To drive performance improvement among plan sponsors, CMS will implement technical revisions to the Pharmacy Quality Alliance (PQA) opioid overuse measures and add a new PQA measure, Concurrent Use of Opioids and Benzodiazepines.

Each of these policies is described in detail below. We are contemplating pilot testing the opioid naïve 7 days supply limit and care coordination safety edits in 2018 with Part D sponsors to further develop best practices and technical guidance for implementation in 2019.

Furthermore, CMS has significantly expanded its oversight of Medicare Part D plans to ensure compliance with requirements that protect beneficiaries, and can help prevent and address opioid overutilization. All Part D sponsors are expected to have a documented, written strategy for addressing overutilization of prescription opioids given the public health crisis.

Days Supply Limits for Opioid Naïve Patients

Recommendation 6 of the CDC Guideline for Prescribing Opioids for Chronic Pain[39] states that opioids prescribed for acute pain should be limited to 3 days or fewer, and that more than a 7 days supply is rarely necessary. Clinical evidence cited by the CDC review found that opioid use for acute pain is associated with long-term opioid use, and that a greater amount of early opioid exposure is associated with greater risk for long-term use.

[39] See https://www.cdc.gov/drugoverdose/prescribing/guideline.html.

Because the amount of opioid prescribed can often be in excess of the amount needed to treat an acute event, leftover supplies of opioids can become the source for misuse and diversion.[40] Limiting the initial amount of prescription opioids dispensed may reduce the risk that patients develop an affinity for these drugs and transition to chronic use or misuse.[41] At least sixteen states currently have, or plan to add by statute or agency rule, limits on the initial days supply (e.g. 5 or 7 days) and/or daily dose of opioids clinicians can prescribe for acute pain.[42] Several large prescription benefit plans are also implementing similar restrictions within their commercial lines, employer health plans, and Medicaid clients.[43,44]

To reduce the potential for chronic opioid use or misuse, CMS is establishing a days supply limitation policy for opioid-naïve patients. In the draft 2019 Call Letter, we solicited comment on guidance that all sponsors should implement a hard safety edit for initial opioid prescription fills that exceed 7 days for the treatment of acute pain. We also solicited comment on whether a days supply limit with or without a daily dose maximum (e.g., 50 MME per day) would be more effective.

In response to the draft 2019 Call Letter, most commenters supported a 7 days supply limitation policy, but there was no consensus on adding a daily dose (MME) maximum. Some commented that adding an MME threshold would cause confusion and add complexity. Beginning in 2019, we expect all Part D sponsors to implement a hard safety edit to limit initial opioid prescription fills for the treatment of acute pain to no more than a 7 days supply. After sponsors gain experience in implementing this policy in Medicare Part D, we will reassess if an MME edit for opioid naïve patients would be feasible or effective. Several commenters also raised technical questions.

Therefore, we recommend the following in implementing these edits:

- Sponsors should exclude beneficiaries who are residents of a long-term care facility, in hospice care or receiving palliative or end-of-life care, or being treated for active cancer-related pain.

- Some commenters recommended that an opioid naïve patient be defined as a patient with an opioid prescription who has not received an opioid fill over the past 30 days or longer.

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[40] Centers for Disease Control and Prevention (CDC). Adult use of prescription opioid pain medications—Utah, 2008. MMWR Morb Mortal Wkly Rep. 2010;59(6):153-157.

[41] Bateman, BT, Choudhry, NK. Limiting the Duration of Opioid Prescriptions: Balancing Excessive Prescribing and the Effective Treatment of Pain. JAMA Intern Med. 2016;176(5):583-584. doi:10.1001/jamainternmed.2016.0544

[42] http://www.astho.org/StatePublicHealth/A-Look-at-State-Legislation-Limiting-Opioid-Prescriptions/2-23-17/

[43] https://cvshealth.com/thought-leadership/fighting-opioid-abuse-our-pbms-approach

[44] http://drugtopics.modernmedicine.com/drug-topics/news/express-scripts-limits-opioid-prescriptions

In analyzing 2017 PDE data, we found that 95% of opioid Part D fills were for 30 days supply or less. Based on stakeholder feedback and data analysis, we recommend that sponsors use a look-back period of at least 60 days. Other commenters suggested a look-back period of 108 days[45].

- Sponsors should include both short-acting and long-acting opioids, except buprenorphine for MAT.

Furthermore, we clarify:

- Since the 7 days supply limit for opioid naïve patients is a safety edit, it can be applied during transition. See Section 30.4.8, "Edits for Transition Fills", Chapter 6, Part D Drugs and Formulary Requirements, Medicare Prescription Drug Benefit Manual.

- If the claim is rejected by the plan due to a days supply greater than 7 days, and the patient does not receive a covered fill of the full days supply as written, then consistent with 42 CFR § 423.128(b)(7)(iii), the sponsor is required to notify its network pharmacy to distribute a written copy of the standardized CMS pharmacy notice to the enrollee ("Medicare Prescription Drug Coverage and Your Rights", CMS-10147, OMB Approval No. 0938-0975; see also Section 40.3.1 of Chapter 18 of the Medicare Prescription Drug Benefit Manual).

- An enrollee, the enrollee's representative, or the enrollee's prescriber has the right to request a coverage determination from the plan for a drug or drugs subject to the days supply limit, including the right to request an expedited coverage determination.

- In the absence of other submitted and approved utilization management requirements, the sponsor should approve coverage for the full days supply once the prescriber attests that the days supply is the intended and medically necessary amount for the beneficiary.

A hard edit is not generally resolvable at POS without the Part D sponsor's explicit authorization of the claim. We recognize that plans may not always be able to automatically apply all of the exemptions to this edit through claims data or identify initial versus continuing use for new enrollees at the beginning of the plan year. Pharmacists may be able to provide this information to the plan sponsor to avoid the beneficiary or their prescriber from having to request a coverage determination on this particular fill. We expect sponsors to allow pharmacists to communicate this information through the plan's help desk or through override codes for plan authorization. CMS expects sponsors' network pharmacies and customer service representatives to be adequately trained with regard to these edits.

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[45] For consistency with the look-back period described in Chapter 6, Section 30.4.3, of the Prescription Drug Benefit Manual Chapter 6 regarding transition.

High Risk Opioid Use and the Overutilization Monitoring System (OMS)

Background on the OMS

In the CY 2013 Call Letter and supplemental guidance, CMS described the enhanced retrospective DUR policy that focuses on cases that have the highest risk of adverse events.[46] Part D sponsors should identify potential opioid overutilizers, conduct retrospective reviews, and perform case management with beneficiaries' prescribers aimed at coordinated care. These efforts do not include beneficiaries with cancer or in hospice. Under our current policy, if sponsors cannot establish medical necessity due to unresponsive prescriber(s), or if misuse is verified with prescribers, with the prescribers' agreement, sponsors may implement a beneficiary-specific point-of-sale (POS) claim edit at all network pharmacies that will result in the rejection of claims or quantities in excess of the opioid dosing deemed medically necessary.

To facilitate compliance with this policy, CMS developed the OMS in July 2013. This system identifies those beneficiaries we consider at significant risk (using high levels of opioids with potential coordination-of-care issues due to obtaining opioids from multiple prescribers and pharmacies). CMS expects plans to report back to us their results of implementing the review and case management policies through the OMS. In 2018, CMS modified the OMS opioid overutilization criteria based on stakeholder feedback and on the CDC Guideline for Prescribing Opioids for Chronic Pain. With regard to the latter, the OMS criteria incorporate a 90 MME threshold[47], cited in the CDC Guideline as the level that prescribers should generally avoid reaching with their patients, to establish a threshold to identify potentially high risk beneficiaries who may benefit from closer monitoring and case management.

To date, CMS's oversight through OMS has reduced very high-risk overutilization of prescription opioids in the Part D program. Despite increasing Medicare enrollment from 2011 to 2017, 31.5 to 45.2 million beneficiaries, the percent of opioid users has steadily decreased from about 32% to 28% (Table 27.). In addition, we concurrently observed a 76% decrease (almost 22,500 beneficiaries) in the number of Part D beneficiaries identified as potential very high risk opioid users (outliers) with the greatest decrease observed from 2016 to 2017 (40%). Likewise,

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[46] 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).

[47] During the most recent 6 months, beneficiaries with an average daily MME greater than or equal to 90 mg 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 Tax Identification Number (TIN) are counted as a single prescriber.

the percentage of opioid users identified as outliers has steadily decreased from 0.29% to 0.05%, a decrease of 81%.

Table 27: OMS Part D Potential Opioid Overutilization Rates, 2011 – 2017*

Year	Total Part D Enrollees	Total Part D Enrollees Utilizing Opioids	% Part D Enrollees Utilizing Opioids	Total Beneficiaries Meeting OMS Criteria**	Year-to-Year % Change	Share of Opioid Utilizers Flagged as Outliers	Year-to-Year Share % Change
2011 (Pre-policy /pilots)	31,483,841	10,049,914	32%	29,404	***76% decrease***	0.29%	***81% decrease***
2013	37,842,632	11,794,908	31%	25,347	−14%	0.21%	−28%
2014	39,982,962	12,308,735	31%	21,838	−14%	0.18%	−14%
2015	41,835,016	12,510,448	30%	15,651	−28%	0.13%	−28%
2016	43,569,035	12,885,620	30%	11,594	−26%	0.09%	−31%
2017	45,218,211	12,619,655	28%	6,931	−40%	0.05%	−39%

*Table 27 includes partial year inactive contracts. Hospice and cancer patients are excluded from the opioid utilizer and OMS criteria counts. For these opioid utilization comparisons, CMS used OMS methodology as of 2013 and prescription drug event (PDE) TAP Data processed with cut-off dates in the early January of the following year.
**2013 – 2017 OMS criteria: During the previous 12 months, beneficiaries with at least 90 consecutive days with greater than 120 mg morphine milligram equivalent (MME) dose daily with more than 3 prescribers and more than 3 pharmacies contributing to their opioid claims excluding beneficiaries with cancer and in hospice.

Comprehensive Addiction and Recovery Act of 2016 and the OMS

Through the parallel rule-making process (82 FR 56336), CMS proposed to implement requirements under Section 704 of the Comprehensive Addiction and Recovery Act of 2016 (CARA) (Pub. L. 114-198) to permit Part D sponsors to establish drug management programs for beneficiaries who are at-risk of overuse and limit beneficiaries' coverage for frequently abused drugs to certain prescribers and pharmacies ("lock-in"). We also proposed to codify the Medicare Part D OMS and current enhanced retrospective DUR policy by integrating both with the drug management program provisions required by CARA.

This proposed integration would mean that Part D plan sponsors implementing a drug management program could limit an at-risk beneficiary's access to coverage of frequently abused drugs beginning 2019 through a beneficiary-specific POS claim edit and/or by requiring the beneficiary to obtain frequently abused drugs from a selected pharmacy(ies) and/or prescriber(s) after case management and notice to the beneficiary. To do so, the beneficiary will have to meet clinical guidelines based on the level of opioids they are taking and the fact that they are obtaining them from multiple pharmacies and prescribers. We will consider the comments we received that were submitted in response to the notice of proposed rule-making. We plan to publish a final rule with sufficient time for Part D sponsors to consider it in preparing their 2019 bid proposals.

OMS Metrics

Since January 2016, the OMS reports to Part D sponsors have included an Opioid Daily Dose metric for informational purposes:

- 120 MME Opioid Daily Dose rate: # opioid days > 120 MME/1000 Opioid utilization days during the last 12 months.

Since the January 2016 OMS report, we have observed a 10% decrease in the Opioid Daily Dose rate across all Part D contracts, from 122.4 to 109.7 per 1,000 opioid utilization days[48].

Beginning with the April 2018 OMS reports, we will report two Opioid Daily Dose metrics. A 90 MME Opioid Daily Dose metric will be added with a 90 MME threshold and a 6-month measurement period to align with the revised OMS criteria implemented in 2018. The original 120 MME Opioid Daily Dose metric will be revised to use a 6-month measurement period.

- 90 MME Opioid Daily Dose rate: # opioid days > 90 MME/1000 Opioid utilization days during the last 6 months.
- 120 MME Opioid Daily Dose rate: # opioid days > 120 MME/1000 Opioid utilization days during the last 6 months.

We plan to discontinue reporting the 120 MME Opioid Daily Dose rate (with 6-month measurement period) in the 2019 OMS reports.

Opioid Potentiator Drugs

As previously mentioned, the OMS identifies and reports to Part D sponsors beneficiaries we consider at significant risk and may need case management because they use high levels of opioids and obtain their opioids from multiple prescribers and pharmacies.

In October 2016, we began reporting the concurrent use of benzodiazepines among potential opioid overutilizers to Part D sponsors through the OMS. Sponsors may use this information in the case management process. We found that 64% of potential opioid overutilizers had a claim(s) for a benzodiazepine. A year later, the percent dropped to 62%. Although the trend is going in the right direction, we find that the continued high use of benzodiazepines within this high-risk population to be of concern and will continue to identify this use for Part D sponsors' review.

[48] Compares 122.4 rate from the January 2016 OMS reported (measurement period: January 1, 2015 – December 31, 2015) to 109.7 rate from the October 2017 OMS report (measurement period: October 1, 2016 – September 30, 2017).

We have been working with the Office of the Inspector General (OIG) to identify other potentiator[49] drugs that may pose safety risks when misused with opioids. Gabapentin, a gapapentinoid, has been identified as an independent risk factor for opioid-related deaths and is reportedly misused due to the euphoria associated with use at high doses.[50,51] The increasing use of gabapentin for off-label indications, despite the lack of evidence from clinical trials, has been documented in the literature.[52,53] One such off-label indication is non-specific chronic lower back pain, which is on the rise.[54] As the focus on opioid use is intensifying, clinicians and patients may be looking for alternatives for their pain treatment.[55] Currently, gabapentin is FDA-approved for the treatment of postherpetic neuralgia in adults and the treatment of partial onset seizures.

From 2015 to 2017, the rate of gabapentin users increased by 14% from 93 to 108 users per 1,000 Medicare Part enrollees based on 6-month measurement periods. Higher gabapentin use was observed among opioid users. From January to June 2017, there were 308 gabapentin users per 1,000 Part D chronic opioid users[56], and 452 gabapentin users per 1,000 OMS potential opioid overutilizers.[57] From January - June 2015 to January - June 2017, we observed a change in the percent of gabapentin users receiving very high (> 2,400 mg) doses among opioid users and chronic opioid users of 7.5% and 8.5%, respectively. CMS is concerned that the increase in gabapentin use and higher doses among opioid users may place beneficiaries at a higher risk for adverse events. These safety concerns extend to pregabalin, which is also a gapapentinoid.

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[49] A drug potentiator is defined as a chemical, herb, or other drug that is used to increase the effects of a substance and consequently, increasing both the substance and the potentiators abuse potential.

[50] Gomes T, Juurlink DN, Antoniou T, Mamdani MM, Paterson JM, van den Brink W. "Gabapentin, opioids, and the risk of opioid-related death: A population-based nested case–control study." PLoS Med 14(10): e1002396.

[51] Evoy KE, Morrison MD, Saklad SR. Abuse and misuse of pregabalin and gabapentin. Drugs 2017;77:403-26.

[52] Mack, A. "Examination of the Evidence for Off-Label Use of Gabapentin" J Manag Care Spec Pharm, 2003 Nov;9(6):559-568.

[53] Fukada, Christine et al. "Prescribing Gabapentin off Label: Perspectives from Psychiatry, Pain and Neurology Specialists." Canadian Pharmacists Journal : CPJ 145.6 (2012): 280–284.e1. PMC. Web. 17 Nov. 2017.

[54] Shanthanna, Harsha et al. "Benefits and Safety of Gabapentinoids in Chronic Low Back Pain: A Systematic Review and Meta-Analysis of Randomized Controlled Trials." Ed. Alexander C. Tsai. PLoS Medicine 14.8 (2017): e1002369. PMC. Web. 3 Nov. 2017.

[55] Goodman, CW, Brett, AS. "Gabapentin and Pregabalin for Pain — Is Increased Prescribing a Cause for Concern?" DOI: 10.1056/NEJMp1704633.

[56] Opioid users are beneficiaries with at least one opioid claim; chronic opioid users are beneficiaries with an opioid episode of 90 days or more.

[57] Based on analysis using the revised 2018 OMS criteria (e.g., beneficiaries with average MME > = 90 mg, 4 or more prescribers and pharmacies, or 6 or more prescribers).

We will add a concurrent opioid-gabapentin/pregabalin flag to the OMS reports to Part D sponsors for informational purposes. However, based on feedback received in response to the draft 2019 Call Letter, we will only identify OMS at-risk beneficiaries who receive high dose gabapentin (> 2400mg). Part D sponsors commented that this information would be useful since these beneficiaries may have coordination-of-care issues due to receiving opioids from multiple providers along with other drugs that can potentiate the risk of overdose. We expect that when sponsors perform case management they would consider the use of other drugs (e.g., benzodiazepines, gabapentin and pregabalin) in their review process.

Sponsors also commented that information on OMS potential opioid overutilizers who concurrently use other potentiator drugs would be useful, such as muscle relaxants (e.g., carisoprodol) or sedative hypnotics (e.g., zolpidem, zalepron and eszopiclone). We will perform additional analyses and consider enhancements to OMS in the future.

Real-Time Care Coordination Safety Edits to Address Chronic Opioid Use

Part D sponsors commonly implement safety edits to prevent the unsafe dosing of drugs at the time of dispensing as part of their concurrent DUR requirements for all Part D drugs, such as drug-drug interactions, therapeutic duplication, or an incorrect drug dosage (e.g., doses above the maximum dosing in the FDA-approved labeling).

We will strengthen this aspect of the current Part D opioid overutilization policy as follows. We note that PACE organizations are expected to comply with these policies unless they do not adjudicate claims at POS.

Background on Current Cumulative MME Safety Edit Policy

Sponsors are currently expected to implement either soft and/or hard formulary-level safety edits for opioids based on a cumulative MME at POS to prevent potentially unsafe opioid dosing, as outlined and finalized in the 2017 and 2018 Call Letters. Plans may set any soft cumulative opioid claim edit MME threshold at or above 90 mg per day and any hard cumulative opioid claim edit at or above 200 mg per day.

These POS edits provide real-time information to help ensure providers are aware that potentially high-risk levels of opioids will be dispensed to their patients. Specifically, the POS edits are triggered at the pharmacy when a patient's total opioid dose across all of their adjudicated prescriptions reaches or exceeds a certain MME level per day. The pharmacist receives an alert and then action must be taken before the prescription can be covered.

As shown in Table 28, in 2017, the first year that sponsors were expected to have either a soft and/or hard edit, 51% of contracts (320 contracts) utilized a hard edit. In 2018, 50% of contracts (341 contracts) implemented a hard edit.

Table 28: Counts of Part D contracts with soft and/or hard MME edits

Contract	Contracts with Hard Edit only		Contracts with Soft Edit only		Contracts with both Hard and Soft edits		Total contracts
Year	Number	Percent	Number	Percent	Number	Percent	Number
2018	160	23.5%	340	49.9%	181	26.6%	681
2017	172	27.3%	310	49.2%	148	23.5%	630

Most contracts have implemented soft edits at 90 MME and hard edits at 200 MME, which are the "floor" of CMS's guidance. Of those contracts with hard edits, 76% in 2017 and 67% in 2018 set a threshold at the minimum recommended MME of 200 mg. Furthermore, 95% of contracts with a soft edit set an MME threshold from 90 – 120 MME in 2017 and 2018. In 2018, the proportion of contracts with 90 MME thresholds increased from 3% in 2017 to 40% in 2018.

Table 29: Counts of Part D contracts with soft edits by MME level

Contract Year	90	100	120	200-300	>300	Total contracts with soft edits
2018	209 (40%)	119 (23%)	166 (32%)	26 (5%)	1 (0%)	521
2017	16 (3%)	92 (20%)	326 (71%)	2 (0%)	22 (5%)	458

Table 30: Counts of Part D contracts with hard edits by MME level

Contract Year	200	>200-300	360	>360	Total contracts with hard edits
2018	227 (67%)	49 (14%)	61 (18%)	4 (1%)	341
2017	244 (76%)	10 (3%)	50 (16%)	16 (5%)	320

In the July 7, 2017 HPMS memo, Additional Guidance on CY 2017 Formulary-Level Cumulative Morphine Equivalent Dose (MED) Opioid Point-of-Sale (POS) Edit, we provided additional guidance to sponsors regarding appropriate use of these edits. As we stated in the

guidance memo, through review of complaints received via the CMS Complaint Tracking Module (CTM) during the first months of 2017, discussions with Part D sponsors, and receipt of questions from other stakeholders, we believed that some sponsors implemented these edits beyond their intended use as a safety edit. For example, the edits are not intended as a means to implement a prescribing limit or apply additional clinical criteria for the use of opioids, but instead to give physicians important additional information about their patients' opioid use. Since that time, we have observed few complaints per month in the CTM related to these edits.

Draft 2019 Call Letter Cumulative MME Safety Edit Policy Guidance Comments

Given the public health emergency and the fact that half of sponsors are already implementing hard MME edits, sponsors can and should do more to address chronic, high prescription opioid overuse. Therefore, in the draft 2019 Call Letter, we solicited comment on guidance that all sponsors should implement a hard edit in 2019 that is triggered when a beneficiary's cumulative daily MME reaches or exceeds 90 mg (meaning the MME threshold should only be set at 90 MME) without multiple prescriber or multiple pharmacy criteria, and to allow beneficiaries to receive a 7 days supply of the prescription that triggered the hard edit as written. Based on an analysis of 2016 PDE data across all Part D sponsors, we estimated that almost 1.6 million beneficiaries (3.6% of Part D enrollees) met or exceeded 90 MME for at least one day[58], excluding those with cancer, in hospice care, or with overlapping dispensing dates for timely continued fills for the same opioid (e.g., false positives).

We received more than 1000 comments, and the 90 MME hard edit guidance was strongly opposed by nearly all stakeholder groups for a variety of reasons. Physician groups opposed the forcible/non-consensual dose reductions due to the risks for patients of abrupt discontinuation and rapid taper of high dose opioid use. Similarly, we received hundreds of letters from patients who have taken opioids for long periods of time and are afraid of being forced to abruptly reduce or discontinue their medication regimens with sometimes extremely adverse outcomes, including depression, loss of function, quality of life, and suicide. Plan sponsors and other organizations expressed support for CMS's goal to aggressively address opioid overuse. However, the overall consensus was that a 90 MME-per-day hard edit threshold would have little clinical impact against opioid overuse (evidenced by high appeal approval rates, as data from one sponsor that implemented hard edits in 2018 showed that 93% of beneficiaries who hit their hard edit at 200 MED requested a coverage determination, and the vast majority were approved). Sponsors requested flexibility to set their own MME thresholds and the ability to include provider counts in the hard edit specifications. There was also much opposition for the 7 days supply allowance guidance as this may be very confusing for beneficiaries, and the systems capabilities do not

[58] The estimate is based on the MME daily dose calculated per opioid prescription. The daily dose is assigned to the prescription's covered days and calculated from the dispensing date and the days supply, and summed per day across all overlapping opioid fills. Methodology differs from the OMS average MME calculated from all opioid prescriptions dispensed during the measurement period.

currently exist today. Numerous operational challenges would need to be addressed to reduce disruption and potential beneficiary harm. Therefore, we are not implementing guidance for sponsors to implement hard 90 MME safety edits with a 7 days supply allowance.

New Opioid Care Coordination Safety Edit for 2019

The CDC Guideline states that tapering opioids for patients already taking high dosages of opioids after years on high dosages can be very challenging because of physical and psychological dependence. Furthermore, experts noted that "patients tapering opioids after taking them for years might require very slow opioid tapers as well as pauses in the taper to allow gradual accommodation to lower opioid dosages." Therefore, we are implementing a policy that aims to strike a better balance between addressing opioid overuse without a negative impact on the patient-doctor relationship, preserving access to medically necessary drug regimens, and reducing the potential for unintended consequences.

We recognize that a tailored approach is needed to better address chronic opioid overuse at POS and to support the recommendations described in the CDC Guideline. For example, in some cases, prescribers may be unaware their patients are receiving high levels of opioids from additional prescribers. In addition, some patients are using opioids where prescribers are considering increasing the opioid dosage. The CDC Guideline recommended against increasing opioid dosages above 90 MME per day in most cases in patients not yet receiving higher opioid dosages. Given that there may be some circumstances when the benefits of increasing opioids to higher dosages might outweigh the risks, the recommendation statement includes the option to "carefully justify a decision to titrate dosage to ≥90 MME/day." The supporting text for this recommendation outlines some factors that might be considered in individualized decisions about benefits and risks of increasing opioid dosages above ≥90 MME/day, including "diagnosis, incremental benefits for pain and function relative to harms as dosages approach 90 MME/day, other treatments and effectiveness, and recommendations based on consultation with pain specialists."

Other patients are already receiving higher opioid dosages long-term where the benefits and risks of maintaining or the decreasing opioid dosage should be carefully considered. Routine monitoring is important to review periodically for efficacy and safety of the regimen. Opioid withdrawal, disruptions in care, adverse effects, obtaining opioids from other sources, and suicide risk affect clinical decisions. Because of these considerations and because of challenges clinicians and patients face when reducing opioid dosages, the supporting text for Recommendation 5 of the CDC Guideline advises a different approach for patients already receiving long-term high dosages of opioids:

"Established patients already taking high dosages of opioids, as well as patients transferring from other clinicians, might consider the possibility of opioid dosage reduction to be anxiety-provoking, and tapering opioids can be especially challenging after years on high dosages

because of physical and psychological dependence. However, these patients should be offered the opportunity to re-evaluate their continued use of opioids at high dosages in light of recent evidence regarding the association of opioid dosage and overdose risk. Clinicians should explain in a nonjudgmental manner to patients already taking high opioid dosages (≥90 MME/day) that there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages. Clinicians should empathically review benefits and risks of continued high-dosage opioid therapy and should offer to work with the patient to taper opioids to safer dosages. For patients who agree to taper opioids to lower dosages, clinicians should collaborate with the patient on a tapering plan (See Recommendation 7).”

Tapering is most likely to be effective when there is patient buy-in and collaboration, tapering is gradual, and clinicians provide support. All of these elements require time. To support clinicians in tapering opioids when appropriate, the CDC offers a tapering pocket guide, a mobile app mobile app and online training with motivational interviewing components, and information about non-opioid treatments for pain. These resources are available at https://www.cdc.gov/drugoverdose/prescribing/resources.html.

To support these efforts, in 2019, we expect all sponsors to implement a real-time opioid care coordination safety edit at the time of dispensing as a proactive step to engage both patients and prescribers about overdose risk and prevention. This opioid care coordination safety edit should be based on a cumulative MME threshold of 90 MME per day. This formulary-level safety edit would trigger when a beneficiary’s cumulative MME per day across their opioid prescription(s) reaches or exceeds 90 MME.

In implementing this edit, sponsors should instruct the pharmacist (e.g., through messaging to the pharmacist through the claim billing transaction communications) to consult with the prescriber, document the discussion, and if the prescriber confirms intent, use an override code that indicates the prescriber has been consulted. These extra care coordination steps are what distinguish the new care coordination edit from a traditional soft edit. Use of a common process across all sponsors will improve sponsors’ ability to monitor and improve this type of drug utilization review in their pharmacy networks. The same clinical discussions can occur with patients and prescribers, without the fear of acute withdrawal or unintended consequences from a hard edit at 90 MME.

Pharmacies should be provided the override code without needing to contact the plan sponsor, or sponsors should allow the pharmacist to call the plan’s help desk for the plan to put in an override in real time if the plan sponsor does not have the capability to utilize automated codes. Plan sponsors should make it clear to pharmacies to only use the override code upon completion and documentation of the care coordination activities, and plan sponsors may consider auditing pharmacies’ documentation. Furthermore, even if the prescriber confirms intent, consultation with the prescriber does not supersede what is ultimately the pharmacist’s decision to fill the prescription or not based on professional judgment.

Sponsors will have the flexibility to include a prescriber and/or pharmacy count in the edit, in which case the edit would trigger if the cumulative MME threshold across the patient's opioid prescription(s) was met or exceeded, and the patient was receiving the opioid prescription(s) from a certain number of prescribers and/or pharmacies set by the plan sponsor. We are allowing this flexibility based on comments received in response to the draft 2019 Call Letter, in which we did not initially recommend provider counts. Many commenters noted that in the circumstance where a beneficiary at 90 MME per day or more hits an edit and only has one prescriber, the claim would virtually always be approved because the single prescriber would attest that the opioid dosage was medically necessary, thereby delaying beneficiary access. For this reason, we believe it would be appropriate for a plan sponsor to elect to have the edit not trigger in such a case. If sponsors decide to include a provider count criterion in the hard edit specifications, we recommend a minimum threshold of two prescribers of active opioid prescriptions.

Additionally, it is possible that the care coordination edit may trigger multiple times for a patient in a given month or calendar year if the conditions for the edit are still met. We expect sponsors to implement reasonable logic to remove the likelihood of redundant or duplicative coordination edits from triggering multiple times and necessitating repeated pharmacist-prescriber consultations (e.g., after they receive the prescriber attestation via a coverage determination request or confirmation from the pharmacy that the prescriber was consulted).

These edits would also serve to support the current pharmacist workflow by providing real-time information on risk complementing their review of the States Prescription Drug Monitoring Program (PDMP) systems to promote coordination and education with respect to opioid prescribing. We encourage pharmacists to review the patient's records in their State's PDMP (See Medicare Learning Network (MLN) Matters® Article SE1250: Prescription Drug Monitoring Programs: A Resource to Help Address Prescription Drug Abuse and Diversion: https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/se1250.pdf).

Sponsors will continue to have the flexibility to implement hard safety edits and set the threshold at 200 MME or more with or without prescriber/pharmacy counts. CMS expects sponsors' Pharmacy and Therapeutics (P&T) committees to develop the safety edit specifications based on the observed opioid overutilization in their Part D plans, to take into account other formulary and utilization management controls already in place by the plan, and to identify a reasonable number of enrollees that the sponsors can appropriately manage in a timely manner to avoid disruptions in access.

We recommend that sponsors exclude beneficiaries who are residents of a long-term care facility, in hospice care or receiving palliative or end-of-life care, or being treated for active cancer-related pain from the opioid care coordination edit or other hard edits. Sponsors should also apply specifications to account for known exceptions, such as reasonable overlapping

dispensing dates for prescription refills[59] or new prescription orders for continuing fills; and high-dose opioid usage previously determined to be medically necessary such as through coverage determinations, prior authorization, case management, or appeals processes. It is also very important that sponsors implement these edits in a way that beneficiaries' access to MAT, such as buprenorphine, is not impacted. Sponsors should not include buprenorphine products for MAT in this edit.

As stated above, CMS provided additional guidance to sponsors regarding appropriate use of hard edits. Any sponsors that cannot comply with these practices should immediately turn off their hard edit until they can implement the edit in a manner consistent with CMS's expectations.

When the coordination MME edit or the hard MME edit is triggered and cannot be resolved at the pharmacy (e.g., prescriber cannot be reached for care coordination edit consultation, prescriber consulted due to care coordination edit but does not verify the medical necessity of the prescription, pharmacist does not fill the prescription based on clinical judgment or other reasons, or due to hard edit reject), consistent with 42 CFR § 423.128(b)(7)(iii) the sponsor is required to notify their network pharmacy to distribute a written copy of the standardized CMS pharmacy notice to the enrollee ("Medicare Prescription Drug Coverage and Your Rights", CMS-10147, OMB Approval No. 0938-0975; see also Section 40.3.1 of Chapter 18 of the Medicare Prescription Drug Benefit Manual). This notice instructs enrollees on how to contact their plan and explains their right to obtain a coverage determination from the plan, including information about the exceptions process.

Sponsors are reminded that an enrollee, the enrollee's representative, or the enrollee's prescriber has the right to request a coverage determination for a drug or drugs subject to the MME edit, including the right to request an expedited coverage determination. 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 determination requests seeking exceptions to the MME edit to meet the criteria for expedited review, which means the plan sponsor must issue a decision no later than 24 hours from receipt of the prescriber's supporting statement (attestation). As with any other request for benefits, the Part D sponsor should determine the need for the expedited timeframe based on the facts and the circumstances of the case. See section 40 and 50 of Chapter 18 of the Prescription Drug Benefit Manual for more information.

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[59] Prescription opioids are controlled substances under the Controlled Substances Act (CSA) and are assigned to Schedule II through V. Schedules are assigned based on the abuse potential and the severity of the psychological or physical dependence of the prescription opioid. A complete list of the schedules is published annually in Title 21 Code of Federal Regulations (C.F.R.) §§ 1308.11 through 1308.15. Schedule II opioids require a new prescription for each fill while prescriptions for schedule III through V do not and therefore, can include refills.

Consistent with current guidance, if the only issue in dispute is the MME, CMS expects the Part D sponsor to rely on prescriber attestation that the higher MME is medically necessary to approve dosing that is higher than the edit when a coverage determination is requested. The authorization of the higher MME level should be considered an approved exception and be valid through the remainder of the plan year. The exception should apply to the cumulative MME level for the beneficiary, not just one specific drug, or one prescriber. In order to minimize unnecessary disruptions in therapy, Part D sponsors should consult with the prescriber(s) to determine whether dose escalation for the beneficiary is imminent, and authorize an increased MME accordingly. The sponsor should also remove the edit if it is determined that the beneficiary meets their established criteria for exclusions (i.e., cancer, hospice, etc.).

Since the MME edit is a safety edit, it can be applied during transition. See Section 30.4.8, "Edits for Transition Fills", Chapter 6, Part D Drugs and Formulary Requirements, Medicare Prescription Drug Benefit Manual. As outlined in 42 CFR § 423.120(b)(7), a Part D sponsor that uses a formulary under its qualified prescription drug coverage must establish policies and procedures to educate and inform health care providers and enrollees concerning its formulary. Accordingly, CMS expects sponsors' network pharmacies and customer service representatives to be adequately trained with regard to these edits to ensure affected beneficiaries are given timely and appropriate information and instruction. It is important that these edits be implemented in a manner that minimizes disruption to beneficiaries. It is integral that sponsors have the ability to process associated exceptions and appeals, including expedited requests, within the required timeframes. Plans are not permitted to instruct an enrollee who is requesting coverage that only their prescriber can initiate the request. CMS expects sponsors to ensure that their staff are trained to appropriately identify enrollee requests for a coverage determination, including verbal requests made by enrollees affected by hard MME edits.

The CDC Guideline for Prescribing Opioids for Chronic Pain and accompanying recommendations are intended to "improve communication between clinicians and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death." The care coordination edit and other opioid-related strategies implemented for Part D beneficiaries discussed in this Call Letter support adoption of the Guideline. MA-PDs are in a unique position and CMS believes it is important that MA-PDs set expectations for prescribers to implement the CDC's recommendations as a best practice through their provider contracts. As the CDC points out, periodic reassessment by prescribers of patient opioid use is important to assess patient goals, to look for opportunities for opioid discontinuation or alternative nonopioid treatment options, and to develop patient-specific care plans. PDPs should also reinforce these messages through DUR interactions with prescribers such as OMS/case management and care coordination edits. We expect these interactions to be an integral component of sponsors' drug utilization management programs.

Furthermore, we believe it is important Part D sponsors offer Medication Therapy Management (MTM) services to beneficiaries who are at risk of adverse events due to opioid overutilization or opioid users who are also taking key potentiator drugs. These beneficiaries may benefit from MTM services including a Comprehensive Medication Review, targeted medication reviews, and interventions with their prescribers. We will monitor progress in reducing prescription opioid overuse through data analysis and quality metrics. We are particularly concerned with protracted, high risk use without routine reassessment, care coordination, and tapering opioids to a lower dosage or to taper and discontinue opioids where appropriate. If the strategies finalized in this Call Letter do not result in an overall reduction in prescription opioid overuse in Medicare Part D, or if we do not see improvement in the management and treatment of pain through uptake of the CDC's recommendations, CMS will evaluate the need for alternative approaches again in the future.

Part D sponsors will continue to submit information on their cumulative MME safety edits using a template through HPMS. We will monitor implementation of these edits including complaints data and the effectiveness of the care coordination edits. In addition, Part D sponsors report implementation outcomes of their MME POS edits, such as number of claims rejected due to edits, number of beneficiaries impacted, and number of rejected claims overridden or processed through the Part D reporting requirements. CMS will analyze these data once reported and validated. The first data collection will be in February 2018 for 2017 reporting requirements data and validated data by September 2018.[60]

Additional Opioid Safety Edits

Concurrent Use of Opioids and Benzodiazepines Soft Edits

In 2016, the FDA added a boxed warning to prescription opioid analgesics, opioid-containing cough products, and benzodiazepines with information about the serious risks associated with using these medications concurrently.[61] Sponsors can reduce the concurrent use of opioids and benzodiazepines, as well as other potentially problematic concurrent medication use at POS. Prospective drug use review can identify and evaluate the appropriateness of concurrent use prior to dispensing. We expect that Part D sponsors implement a concurrent opioid and benzodiazepine soft POS safety edit (which can be overridden by the pharmacist) to prompt additional safety review at the time of dispensing beginning in 2019, which commenters largely supported. Sponsors have the flexibility to factor different prescribers, dose or days supply in the edit specifications.

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[60] See Part D reporting requirements: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ReportingOversight.html

[61] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm

Duplicative Therapy Soft Edits

Both the use of long-acting (LA) opioids and the number of opioid prescriptions are associated with a higher risk of mortality.[62,63] Clinically, there is little support for maintaining a patient on multiple different opioids and such use creates other health care issues. First, the use of multiple opioids that compete for similar pain receptors may provide little improvement in analgesia while increasing the risk of adverse events. In addition, prescriptions for multiple opioids (whether LA or short-acting (SA)) and/or multiple strengths increases the supply of opioids available for diversion and abuse, as well as the opportunity for self-medication and dose escalation.[64] Commenters agreed that additional DUR controls at the POS like a soft edit might help reduce excess opioid supplies and reduce adverse events. Beneficiaries who receive multiple LA opioids may lack coordinated care and be at higher risk of opioid overdose. Therefore, we expect all Part D plan sponsors to implement a soft POS safety edit (which can be overridden by the pharmacist) for duplicative LA opioid therapy beginning in 2019, with or without a multiple prescriber criterion. Plans have the flexibility to define duplicative therapy at the drug or class level and should, when possible, consider situations when beneficiaries switch between doses.

When such an edit is triggered for concurrent use of opioids and buprenorphine, the soft edit should only reject the opioid prescription following the buprenorphine claim and should not impede access to buprenorphine for MAT. It is very important that a sponsor should only implement this edit if it has the technical ability to not reject buprenorphine claims.

We also recognize that multiple opioid POS edits could potentially generate a combination of messages and soft or hard rejects that may cause confusion. Therefore, we recommend that industry develop and adopt more specific reject codes, and sponsors' P&T committees determine a hierarchy to manage multiple opioid POS edits to reduce confusion.

Quality Measures

CMS also uses quality measures developed by the PQA to track trends in opioid overuse across the Medicare Part D program.

See the Enhancements to the 2019 Star Ratings and Future Measurement Concepts section of the 2019 Call Letter. We will implement changes to the PQA-endorsed opioid overutilization

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[62] Ray WA, Chung CP, Murray KT, Hall K, Stein CM. Prescription of Long-Acting Opioids and Mortality in Patients with Chronic Noncancer Pain. JAMA. 2016 Jun 14;315(22):2415-23.

[63] Baumlatt JA, Wiedeman C, Dunn JR, Schaffner W, et al. High-risk use by patients prescribed opioids for pain and its role in overdose deaths. JAMA Intern Med. 2014 May; 174(5):796-801.

[64] Manchikanti, L. Helm II, S, Fellows, B. Janata, J.W. Pampati,V., Grider, J.S. Boswell, M.V. Opioid Epidemic in the United States. Pain Physician 2012; 15:ES9-ES38

measures in the Patient Safety reports and on the display page, and add a new PQA measure, Concurrent Use of Opioids and Benzodiazepines to the reporting.

Since 2016, sponsors have received monthly Patient Safety reports based on the PQA opioid measures. We communicate with plans about their performance on these quality measures, including sharing information about specific beneficiaries identified, and plan sponsors with the lowest rating on each measure should report actions they will take to improve performance.

Sponsors may use the reports to supplement their DUR programs to address overutilization of opioids across a population broader than OMS. CMS expects sponsors to routinely monitor these data to compare their performance to overall averages and assess their progress in reducing the number of beneficiaries using high doses of opioids, with or without multiple providers and pharmacies.

Access to Medication-Assisted Treatment

While CMS continues to work closely with Part D sponsors and other stakeholders to help combat inappropriate opioid utilization, it is imperative to also ensure that Medicare beneficiaries have appropriate access to medication-assisted treatment (MAT). As noted in previous Call Letter guidance, CMS will closely scrutinize formulary and benefit submissions with respect to formulary inclusion, utilization management criteria, and cost-sharing of Part D drugs indicated for MAT. Benefit designs that would substantially discourage enrollment by beneficiaries who need these therapies will not be approved. We continue to expect Part D sponsors to include products in preferred formulary tiers, and to avoid placing generic drugs indicated for MAT in brand tiers. As noted in previous Call Letter guidance, PA criteria that duplicates those requirements already set forth in the FDA Risk Evaluation and Mitigation Strategies and Drug Addiction Treatment Act of 2000 for applicable MAT products will not be approved.

On September 20, 2017, FDA announced that they recently had strengthened labeling requirements for buprenorphine MAT products to emphasize that treatment may be required indefinitely, as long as the use contributes to the intended treatment goals (https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm576752.htm). Consistent with FDA's position, CMS will not approve PA criteria that requires a beneficiary to need an authorization any more frequently than once during a plan year for buprenorphine MAT products. Further, when a sponsor has authorized MAT for a beneficiary in the prior plan year, we expect that the sponsor would carry that authorization through to the next plan year.

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 2019 COB user fee will be collected at a monthly rate of $0.1166 for the first 9 months of the coverage year 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 2019 bids.

In contract year 2019, 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 (MARx) system management of COB data; and
- Review of Workers' Compensation settlement set-aside

LIS Enrollee Cost-sharing for Out-of-Network Part D Drugs

Current regulations require that Part D enrollees will be afforded adequate access to covered Part D drugs dispensed at out-of-network (OON) when those enrollees cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy, and when such access is not routine. This includes situations in which Part D enrollees are provided covered Part D drugs dispensed by an OON institution-based pharmacy while they are patients in an emergency department, provider-based clinic, outpatient surgery, or other outpatient setting, and as a result cannot get their prescriptions filled at a network pharmacy. Part D enrollees must pay (or be billed) the institution-based pharmacy's usual and customary price at the point-of-sale, submit a paper claim to the Part D sponsor, and wait for reimbursement from the sponsor.

Beneficiary advocates have raised concerns about the disproportionate financial impact of paper claim-based reimbursement for low income beneficiaries receiving outpatient services in hospitals. We remind Part D sponsors that they cannot bill enrollees receiving LIS for any differential between the plan's negotiated price for a drug and the pharmacy's U&C cost – that is, LIS enrollees must be reimbursed the entire amount of the claim minus their applicable LIS cost-sharing amount.

We also remind Part D sponsors of their obligation to process direct member reimbursements (DMRs) from all enrollees timely. Delays in DMRs can have serious adverse consequences on enrollees, especially for those with limited financial resources. DMRs are coverage determinations as provided under § 423.566(b). For reimbursement requests, Part D sponsors must issue a decision and reimbursement, if applicable, no later than 14 days from receipt of the request for the coverage determination (both the decision and the actual check, if applicable).

We received comments thanking us for the reminders and clarifications of this policy. Commenters also encouraged us to update section 60.1 of Chapter 5 and section 60.4.4 of Chapter 13 of the Prescription Drug Benefit Manual to further clarify this policy, as well as to consider providing scripts and training to 1-800-MEDICARE staff on the issue. We will consider these policy clarifications in future updates to this guidance, as well as additional steps to ensure dually eligible and other LIS-eligible enrollees are aware of the protections afforded to them with respect to Part D drugs dispensed at out-of-network (OON) pharmacies.

Timely Updates to LIS Status Based on Best Available Evidence

Part D sponsors are obligated to use best available evidence when determining the cost-sharing levels for Part-D covered prescriptions. When situations arise that result in incorrect LIS cost-sharing data at the point-of-sale, Part D sponsors must comply with the "Best Available Evidence" (BAE) policy (see 42 CFR 423.800(d), Section 70.5 of Chapter 13 of the Medicare Prescription Drug Benefit Manual). This policy requires sponsors to update their systems to reflect the appropriate cost-sharing subsidy for Part D eligible individuals who are full or partial benefit Medicare/Medicaid dual eligible individuals, or receiving SSI-only, when presented with evidence that cost-sharing levels in their systems are incorrect. Sponsors should also ensure that key staff have needed resources to apply the policy quickly, as well as transmit any updates to CMS so we can update the status in our records on a timely basis.

We received comments thanking us for reiterating the important and long-standing BAE requirements. Commenters encouraged us to continue to highlight to sponsors on an ongoing basis the requirement to designate BAE points of contact, and to have that information available to their call center representatives, as well as reiterate to sponsors their obligation for ongoing education of network pharmacies on BAE. Finally, one commenter requested we expand requirements for sponsors to update systems with BAE changes internally and make those data available more quickly to network pharmacies. However, we note that section 70.5.2 of Chapter 13 of the Medicare Prescription Drug Benefit Manual already describes our policy for sponsors to update their systems rapidly – within 48-72 hours – so updated LIS levels should be available quickly to pharmacists.

Using the Best Available Information when making B vs D Coverage Determinations for Immunosuppressants and Inhalation Durable Medical Equipment (DME) Supply Drugs

A) Immunosuppressants Used to Prevent Transplant Rejection

Part D sponsors are responsible for determining whether immunosuppressants that are being used to prevent transplant rejections are coverable under Part D because immunosuppressants that are used for Medicare-covered transplants are covered under Part B. To make these determinations, sponsors generally have relied on either information from the prescriber or, in the case of renal transplants, information in MARx that confirms that Medicare covered the transplant (i.e. paid for in whole or in part). However, as a result of CMS Program Integrity audits, we have learned

that information obtained directly from prescribers often times is not reliable or conflicts with CMS information that is provided later.

In response to the draft Call Letter several commenters requested that CMS provide information on all types of transplants since MARx data is limited to renal transplants only. We are now announcing the launch of a new web portal that will provide additional enrollee information to plans. The portal, called Additional Beneficiary Information Initiatives (ABII), will be part of the group of Acumen web portals to which all Part D contracts already have access. As part of this initiative CMS will begin populating ABII with Medicare-covered transplant data derived from Medicare fee-for-service claims. CMS is investigating other sources of transplant data as well to see if they will improve the accuracy of the information provided. A forthcoming memorandum will detail the functionality of the new web portal and provide user authorization instructions for obtaining access well in advance of the 2019 contract year.

The following guidance establishes CMS' expectations for how Part D plans should perform due diligence to ensure that Part D does not pay for drugs that should be paid under Part B. In all cases, Part D sponsors should document the basis for their determinations to cover immunosuppressants and make such documentation available upon audit.

1. <u>No Prior Part D Claims History for Immunosuppressants</u>

a) The plan has received information from CMS (e.g. via MARx or ABII) indicating that Medicare covered the enrollee's transplant or, in the case of a Medicare Advantage enrollee, the MA Plan has medical claims history of a covered transplant regardless of previously received information from a prescriber on whether or not the transplant was covered by Medicare.

> In this situation, plans are expected to rely on the CMS information (or in the case of an MA plan, its own medical claims history) and cannot cover immunosuppressants under Part D even if information is also provided by the prescriber that indicates that the transplant was not Medicare covered.

b) The plan has NOT received information from CMS (via MARx or ABII) indicating that Medicare covered the transplant for the enrollee; in the case of a Medicare Advantage enrollee, the MA Plan does not have medical claims showing a history of a covered transplant; and the plan has not previously received information from a prescriber that the transplant was covered by Medicare.

> In this situation, CMS expects plans to default to covering the immunosuppressants under Part D and no longer expects plans to reach out to prescribers to inquire about Medicare coverage of the transplant. Such outreach is burdensome for plans and prescribers, and has been shown to be unreliable for accurately determining if Medicare covered a transplant. Nevertheless, the plan should approach this coverage decision using the best available information; if the plan has previously reached out to the

prescriber and received information indicating that the that the transplant was covered by Medicare (in full or in part), the Part D plan may not cover immunosuprressants under D.

2. Prior Part D Claims History AND neither MARx nor ABII currently indicates that Medicare covered the transplant:

   A plan might have covered the drugs under Part D previously because either:

   - MARx information was updated after the Part D sponsor relied on prior information from the prescriber that the transplant was NOT covered/ paid by Medicare; or
   - The Part D sponsor had relied solely on information from the prescriber that the transplant was NOT covered/paid by Medicare without regard to MARx.

   Under either scenario, the Part D sponsor must now rely on the MARx information **going forward** and notify the enrollee that the plan can no longer cover the immunosuppressant(s) because it is covered under Medicare Part B. No changes need to be made to prior Part D claims.

3. Prior Part D Claims History, no MARx indicator or MA plan medical claims history of a covered transplant BUT the Part D sponsor receives information from CMS that the transplant was covered by Medicare (e.g. Part D sponsor receives the information from CMS as part of a CMS Program Integrity audit or through ABII).

   Under this scenario, the Part D sponsor must now rely on the CMS information **going forward** and provide notice to the enrollee that the plan will no longer cover the immunosuppressant(s) under Part D because it is covered under Medicare Part B. No changes need to be made to prior Part D claims.

B) Inhalation Durable Medical Equipment (DME) Supply Drugs

Previous guidance documents indicate that inhalation drugs administered in a long term care setting where the stay is not covered under Medicare Part A can be covered under Part D. Some commenters had requested that the Long-Term Institution (LTI) report be released monthly rather than quarterly so plans can better monitor their enrollees, an option which we will continue to explore. Nevertheless, we are now clarifying how Part D plans can determine that a beneficiary is residing in a long term care facility.

Medicare Part B covers certain inhalation drugs, such as Albuterol and Levalbuterol nebulizer solutions, as supplies under the DME benefit. The DME benefit, however, is not available to beneficiaries residing in long-term care facilities (i.e. Nursing Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities). Consequently, if the beneficiary is not on a Part A stay in one of these facilities, these inhalation drugs can be covered under Medicare Part D. While Part D sponsors generally

have relied on the prescriber's statement that the beneficiary resides in long-term care facility to authorize Part D coverage, since 2013 CMS has required sponsors to report the patient residence code on prescription drug events (PDEs). We expect that patient residence codes submitted to CMS are accurate and because they represent a recent dispensing event; the residence codes offer a more timely view of patient's location than previous information communicated by the prescriber. Therefore, CMS permits Part D sponsors to rely on a patient residence code of "3" or "9" on a pharmacy claim for determining when such inhalation drugs may be covered under Part D. Moreover, we expect that sponsors will only pay claims for these products when the pharmacy claim includes these specified patient residence codes regardless of any prior coverage determination based upon a prescriber statement indicating that the beneficiary resides in a long-term care facility (i.e. the prescriber statement and patient residence code must be aligned).

Part D Mail-Order Refill Consent Policy– Solicitation for Comments

In the 2014 Call Letter, we stated that Part D sponsors should require their network retail and mail-order pharmacies to obtain patient consent to deliver a new or refill prescription prior to each delivery in an attempt to decrease the waste and unnecessary costs associated with unneeded or unwanted prescriptions. Subsequently, we modified this policy to permit exceptions, subject to certain conditions, that allow Employer Group Waiver Plan (EGWP) mail-order auto-ship programs that do not obtain patient consent prior to delivery for both new prescriptions and refills. We also modified the policy for all Part D plans with respect to automatic shipments of new prescription orders received directly from the prescriber, regardless of whether prior patient consent was received.

Consequently, since January 1, 2014, Part D sponsors of non-EGWP plans have obtained consent from beneficiaries prior to shipping refills of mail-order prescriptions. We have received requests to further modify or eliminate this policy. Some stakeholders suggest that the current policy creates an unnecessary burden and interferes with improving medication adherence via automatic refill shipments. However, we remain concerned that auto shipments of refills not specifically requested by beneficiaries increase shipments of unnecessary or unwanted prescription refills, leading to increased waste and potentially inappropriate drug therapy when a discontinued medication is shipped.

In the draft Call Letter we requested information and data associated with mail-order auto-ship programs (other than those detailing on-time refills, medication possession ratio, or proportion of days covered) that indicate actual improved adherence by patients resulting from automatic (not patient-initiated) refills. We also were interested in any information or data that rebuts concerns that such programs increase waste (to include unwanted or unneeded medications that go unused, as well as additional cost to the beneficiary or Part D program).

Finally, we requested feedback on possible modifications to the current policy if we determine that a change is warranted. For example:

- Replacing affirmative prior consent for refills with a refill shipping reminder, prior to shipping, which provides sufficient time for a beneficiary to cancel an order.
- Eliminating affirmative prior consent for refills but expecting plans to implement a full refund policy for any refills auto shipped that a beneficiary reports or returns as unneeded or otherwise unwanted. We requested feedback on possible approaches to confirm medications reported as unwanted were partially or fully unused.
- Modifying the current condition of annual beneficiary confirmation to continue automatic deliveries to be more frequent, such as bi-annual.
- Modifying the current condition of annual beneficiary confirmation to continue automatic deliveries but with an opt-in on a per drug basis.

We received responses from a number of stakeholders, and we thank you for your input. We continue to review the suggestions received and studies submitted in response to this solicitation to fully inform next steps as we evaluate this policy.

Section IV – Medicare-Medicaid Plans

Medicare-Medicaid Plan Annual Requirements and Timeline for CY 2019

Contract Year (CY) 2019 will be the sixth 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 many 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 2019 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. We will also provide guidance shortly after the issuance of the CY 2019 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.
- The Additional Demonstration Drug (ADD) file to supplement the Part D formulary submission.

Table 31 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 31: Previously Released MMP Guidance

Topic	Link to document
MMP Enrollment and Disenrollment Guidance and Additional State-specific Enrollment Guidance	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPEnrollment.html
State-specific Marketing Guidance and Model Materials	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPMarketingInformationandResources.html
MMP Application and Annual Requirements	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPApplicationandAnnualRequirements.html
MMP Reporting Requirements	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPReportingRequirements.html

Topic	Link to document
MMP Audit Programs	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPAuditPrograms.html
MMP Encounter Data Reporting	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPEncounterDataReporting.html
MMP Quality Withhold Methodology and Technical Notes	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPQualityWithholdMethodologyandTechnicalNotes.html
MMP Chronic Care Improvement Programs and Quality Improvement Projects	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPChronicCareImprovementProgramsandQualityImprovementProjects.html

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 2018 (i.e., September 18, 2018). 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/MMPInformationandGuidance/MMPApplicationandAnnualRequirements.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 2018.

We received feedback from several commenters strongly supporting annual MMP network reviews and urging CMS to enforce existing requirements for MMPs to update their provider directories. Commenters reported working with MMP enrollees who have received dated

network information, resulting in delayed access to care. Commenters urge CMS to consider, when reviewing the network information, whether the listed providers who speak additional languages can accommodate persons with disabilities and are currently accepting new MMP 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. As noted in the draft Call Letter, CMS has conducted monitoring studies of CY 2016 – CY 2018 MMP provider and pharmacy directories, interviewed a sample of Medicare-Medicaid enrollees, hosted capacity-building webinars (see https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/MMPPPDWebinar062117.pdf), and released an FAQ document that includes best practices and lessons learned (see https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/MMPPPDMonitoringFAQCY201707-18-2017.pdf).

One commenter recommends that in addition to the annual Medicare MMP network submission, CMS monitor network adequacy during the plan year, looking particularly at whether providers have left the network and why. CMS will continue to remind MMPs that they must, per the requirements specified in the respective three-way contracts, notify the contract management team when there is a significant change in the provider network during the plan year. Another commenter acknowledges that MMPs must also submit network adequacy information to states for Medicaid service providers, including long-term support and service (LTSS) providers. The commenter recommends that CMS develop a national set of standards for LTSS providers that focuses on time to placement, missed visits/appointments, and late appointments and recognizes the uniqueness of urban and rural areas. CMS appreciates the commenter's recommendation and, as CMS continues to work on the implementation of the 2016 Medicaid and CHIP Final Rule (CMS-2390-F), we will take into account the points raised by the commenter.

One commenter encourages CMS to continue working with states to implement network adequacy standards that align Medicare and Medicaid and that are appropriate for the targeted population. The commenter further encourages CMS to explore extending this process for FIDE SNPs. CMS continues to assess ways to improve the Medicare network adequacy standards for SNPs (see Part C section of the Call Letter titled Special Needs Plan Specific Networks Research and Development).

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 2019 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 4, 2018. Supplemental formulary files are due in HPMS on June 8, 2018 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 2018. 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. One commenter expressed support for our goal of providing applicable ADD file guidance to states by May 2018.

As follow-up to feedback received on the CY 2018 draft Call Letter, CMS has been working on options to facilitate more direct access of the ADD validation file for MMPs starting for CY 2019. We received some comments in support of these efforts, and these commenters expressed appreciation for CMS' ongoing evaluation of possible additional efficiencies regarding the timing of the file's completion. In an effort to streamline the submission process for Part D sponsors offering a Medicare-Medicaid Plan, CMS will make the ADD Validation File available via HPMS in advance of the ADD File submission deadline/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.

Some commenters encouraged CMS to develop special procedures for prescription drugs that may be covered under Part D in some circumstances but, when they are not, are covered under the Medicaid program. These commenters urged CMS to ensure adequate coverage and coordination between the formulary and supplemental drug file for these prescriptions. We 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.

We clarify that mid-year ADD file change submissions – that is, changes to the ADD file after the contract year has begun – are at the discretion of each state. CMS will work with states to open HPMS gates for ad hoc and/or regular ADD file resubmissions as necessary. 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 6, 2018, and we expect to provide further guidance at that time on MMP-specific updates to the PBP software for CY 2019. In addition, CMS will release an online training module on the CY 2019 PBP software for plans on April 6, 2018.

MMPs must submit their integrated PBPs to CMS no later than June 4, 2018 (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 2019)
- 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 2018. 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 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 2018 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 2018 (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 2018 (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 2018 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 maybe subject to compliance action, regardless of whether they are positive or negative changes.

MMP Member Handbook Timelines

Beginning with CY 2019 materials, MMPs will be required to provide an Evidence of Coverage (Member Handbook) to current enrollees consistent with the timelines applicable to MA organizations. We will provide additional guidance to all plans, including MMPs, later this year.

Appendix 1: Methodology for Plan Finder (PF) Composite Price Accuracy Display Measure

CMS's drug pricing performance measure evaluates the accuracy of prices displayed on Medicare Plan Finder (PF) for beneficiaries' comparison of plan options. The accuracy score is calculated by comparing the PF price to the PDE price and determining the magnitude and frequency of differences found when the latter exceeds the former. This document summarizes the methods currently used to construct each contract's accuracy index.

Contract Selection

This measure relies in part on the submission of pricing data to PF. Therefore, only contracts with at least one plan meeting all of the following criteria are included in the analysis:

- Not a PACE plan
- Not an employer plan
- Part D plan
- Plan not terminated during the contract year

Only contracts with at least 30 claims throughout the year are included in the accuracy measure. This ensures that the sample size of PDEs is large enough to produce a reliable accuracy score.

PF Composite Price Accuracy Score

To calculate the PF Composite Price Accuracy Score, the point-of-sale cost (ingredient costs plus dispensing fee) reported on each PDE claim is compared to the cost resulting from using the unit price reported on Plan Finder.[65] This comparison includes only PDEs for which a PF cost can be assigned. In particular, a PDE must meet seven conditions to be included in the analysis:

1. The NPI number for the pharmacy on the PDE claim must appear in the pharmacy cost file as either a retail only pharmacy or a retail and limited access only pharmacy, regardless of pharmacy service type reported on PDE. Claims for pharmacies that are listed as retail in the pharmacy cost file and also have a pharmacy service type on the PDE of either Community/Retail or Managed Care Organization (MCO) are included as well. NCPDP numbers are mapped to their corresponding NPI numbers. The

[65] Plan Finder unit costs are reported by plan, drug, days of supply, and pharmacy. The plan, drug, days of supply, and pharmacy from the PDE are used to assign the corresponding Plan Finder unit cost posted on medicare.gov on the date of the PDE.

corcorresponding reference NDC must appear under the relevant price ID for the pharmacy in the pricing file.[66]

2. The reference NDC must be on the plan's formulary.
3. Because the retail unit cost reported on Plan Finder is intended to apply to a 1, 2, or 3-month supply of a drug, only claims with a Days Supply of 28-34, 60-62, or 90-93 are included.[67] Claims reporting a different day supply value are excluded.
4. PDEs for dates of service during which the plan was suppressed from Plan Finder or where the relevant pharmacy or drug was not reported in Plan Finder are not included since no Plan Finder cost can be assigned.[68]
5. PDEs for compound drugs or non-covered drugs are not included.
6. The PDE must occur in Quarter 1 through 3 of the year. Quarter 4 PDEs are not included because PF prices are not updated during this last quarter.

The PF Composite Price Accuracy Measure factors in both how much and how often PDE prices exceeded the prices reflected on the PF. The contract's PF Composite Price Accuracy score is the average of the Price Accuracy Score, which measures the difference between PDE total cost and PF total cost[69], and the Claim Percentage Score, which measures the share of claims where PDE prices are less than or equal to PF prices.

Once PF unit ingredient costs are assigned, the PF ingredient cost is calculated by multiplying the unit costs reported on PF by the quantity listed on the PDE. The PDE cost (TC) is the sum of the PDE ingredient cost paid and the PDE dispensing fee. Likewise, the PF TC is the sum of the PF ingredient cost and the PF dispensing fee that corresponds to the same pharmacy, plan, and days of supply as that observed in the PDE. Each claim is then given a score based on the difference between the PDE TC and the PF TC. If the PDE TC is lower than the PF TC, the claim receives a score equal to zero. In other words, contracts are not penalized when point-of-

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[66] Plan Finder prices are reported at the reference NDC level. A reference NDC is a representative NDC of drugs with the same brand name, generic name, strength, and dosage form. To map NDCs on PDEs to a reference NDC, we use First Data Bank (FDB) and Medi-Span to create an expanded list of NDCs for each reference NDC, consisting of NDCs with the same brand name, generic name, strength, and dosage form as the reference NDC. This expanded NDC list allows us to map PDE NDCs to PF reference NDCs.

[67] If a plan's bid indicates a 1, 2, or 3 month retail days supply amount outside of the 28-34, 60-62, or 90-93 windows, then additional days supply values may be included in the accuracy measure for the plan. For example, a plan that submits a 3 month retail supply of 100 days in their bid will have claims with a days supply of 90-100 included in their accuracy measure calculation.

[68] Because sanctioned plans typically are not suppressed on MPF and display data to the plan's current enrollees only, non-suppressed sanctioned plans will have their data during the sanction counted towards the measure.

[69] PF total costs are rounded to the nearest cent. For example, if the PF total cost is $10.237, then it is rounded to $10.24. PF unit costs are not rounded.

sale costs are lower than the advertised costs. However, if the PDE TC is higher than the PF TC, then the claim receives a score equal to the difference between the PDE TC and the PF TC.[70,71] The contract level PF Price Accuracy Index is the sum of the claim level scores and PDE TC across all PDEs that meet the inclusion criteria, divided by the PDE TC for those same claims.

The PF Claim Percentage Index is the percent of all PDEs that meet the inclusion criteria with a PDE TC higher than the PF TC. Note that the best possible PF Price Accuracy Index is 1, and the best possible PF Claim Percentage Index is 0. This occurs when the PF TC is never lower than the PDE TC. The formulas below illustrates the calculation of the contract level PF Price Accuracy Index and PF Claim Percentage Index:

$$\text{Price Accuracy Index} = \left(\frac{\sum_i \max(TC_{iPDE} - TC_{iPF}, 0) + \sum_i TC_{iPDE}}{\sum_i TC_{iPDE}} \right)$$

where

TC_{iPDE} is the ingredient cost plus dispensing fee reported in PDE_i, and
TC_{iPF} is the ingredient cost plus dispensing fee calculated from PF data, based on the PDE_i reported NDC, days of supply, and pharmacy, then rounded to the nearest cent.

$$\text{Claim Percentage Index} = \left(\frac{\sum_i Claims_{iPDE>PF}}{\sum_i Claims_{iTotal}} \right)$$

where

$Claims_{iPDE>PF}$ is the total number of claims where the PDE price is greater than the rounded PF price

$Claims_{iTotal}$ is the total number of claims

We use the following formulas to convert the Claim Percentage Index and Price Accuracy Index into the PF Composite Price Accuracy score:

$$\text{Claim Percentage Score} = (1 - \text{Claim Percentage Index}) \times 100$$
$$\text{Price Accuracy Score} = 100 - [(\text{Price Accuracy Index} - 1) \times 100]$$
$$\text{PF Composite Price Accuracy Score} = (0.5 \times \text{Claim Percentage Score}) + (0.5 \times \text{Price Accuracy Score})$$

[70] To account for potential rounding errors, this analysis requires that the PDE cost exceed the rounded PF cost by at least a cent ($0.01) in order to be counted towards the accuracy score. For example, if the PDE cost is $10.25 and the rounded PF cost is $10.24, the 1-cent difference would be counted towards plan's accuracy score. However, if the rounded PF cost is higher than $10.24, the difference would not be considered problematic, and it would not count towards the plan's accuracy score.

[71] The PF data includes floor pricing. For plan-pharmacy drugs with a floor price, if the PF price is lower than the floor price, the PDE price will be compared against the floor price.

The score is rounded to the nearest whole number.

Example of PF Composite Price Accuracy Score **Calculation**

Example of PF CTable M-1 shows an example of the PF Composite Price Accuracy Score calculation. This contract has 4 claims, for 4 different NDCs and 4 different pharmacies. This is an abbreviated example for illustrative purposes only; in the actual accuracy index, a contract must have 30 claims to be evaluated. From each of the 4 claims, the PDE ingredient cost, dispensing fee, and quantity dispensed are obtained. Additionally, the plan ID, days of supply, date of service, and pharmacy number are collected from each PDE to identify the PF data that had been submitted by the contract and posted on Medicare.gov on the PDE dates of service. The NDC on the claim is first assigned the appropriate reference NDC, based on the brand name, generic name, strength and dosage form. Using the reference NDC, the following PF data are obtained: brand/generic dispensing fee (as assigned by the pharmacy cost file) and unit cost (as assigned by the Price File corresponding to that pharmacy and days of supply on the date of service). The PDE cost is the sum of the PDE ingredient cost and dispensing fee. The PF cost is computed as the quantity dispensed from PDE multiplied by the PF unit cost plus the PF brand/generic dispensing fee (brand or generic status is assigned based on the NDC), and then rounded to the nearest cent. The last column shows the amount by which the PDE cost is higher than the rounded PF cost. When the PDE cost is less than the rounded PF cost, this value is zero. The Price Accuracy Index is the sum of the last column plus the sum of PDE costs divided by the sum of PDE cost. The Claim Percentage Index is the number of rows where the last column is greater than zero divided by the total number of rows.

Table M-1: Example of PF Composite Price Accuracy Score Calculation

NDC	Pharmacy Number	PDE Data					Plan Finder Data				Calculated Values			
		DOS	Ingredient Cost	Dispensing Fee	Quantity Dispensed	Days' Supply	Biweekly Posting Period	Unit Cost	Dispensing Fee		Brand or Generic Status	Total Cost		Amount that PDE > PF
									Brand	Generic		PDE	PF	
A	111	1/8/2016	3.82	2.00	60	60	1/4/16-1/17/16	0.014	2.25	2.75	B	5.82	3.09	2.73
B	222	1/24/2016	0.98	2.00	30	60	1/18/16-1/31/16	0.83	1.75	2.50	G	2.98	27.40	0
C	333	2/11/2016	10.48	1.50	24	28	2/1/16-2/14/16	0.483	2.50	2.50	B	11.98	14.09	0
D	444	2/21/2016	47.00	1.50	90	30	2/15/16-2/28/16	0.48	1.50	2.25	G	48.50	45.45	3.05
											Totals	69.28		5.78
											Price Accuracy Index			1.08343
											Claim Percentage Index			0.5
											PF Price Accuracy Score			71