April 6, 2020

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

Announcement of Calendar Year (CY) 2021 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies

In accordance with section 1853(b)(1) of the Social Security Act, we are notifying you of the annual capitation rate for each Medicare Advantage (MA) payment area for CY 2021 and the risk and other factors to be used in adjusting such rates.

CMS received many submissions in response to our request for comments on Part I of the Advance Notice of Methodological Changes for CY 2021 MA Capitation Rates and Part C and Part D Payment Policies (CY 2021 Advance Notice), published on January 6, 2020, and Part II of the CY 2021 Advance Notice, published on February 5, 2020. Commenters included professional organizations, MA and Part D sponsors, advocacy groups, state Medicaid agencies, pharmaceutical manufacturers, pharmacy benefit managers, pharmacies, and concerned citizens. After considering all comments received, we are finalizing a number of policies in the Announcement of CY 2021 MA Capitation Rates and Part C and Part D Payment Policies (CY 2021 Rate Announcement) that reflect CMS' continued commitment to providing MA organizations and Part D plan sponsors with the flexibility to develop and implement innovative approaches, as well as offer more affordable plan choices, to care for and empower 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.

The capitation rate tables for 2021 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 of the Rate Announcement shows the final estimates of the National Per Capita MA Growth Percentage for 2021 and the National Medicare Fee-for-Service (FFS) Growth Percentage for 2021, used to calculate the 2021 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 5.62 percent, and the final estimate of the FFS Growth Percentage is 3.64 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 Social Security 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 2018 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 CY 2021 Advance Notice.

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

Attachment V provides the final Part D benefit parameters and details how they are updated.

Attachment VI presents responses to comments on updates for MA and Part D Star Ratings.

Attachment VII contains economic information for significant provisions in the CY 2021 Rate Announcement.

COVID-19

The 2021 Rate Announcement does not catalog CMS' actions related to the 2019 Coronavirus Disease (COVID-19) outbreak. The health, safety, and welfare of America's patients and provider workforce in the face of the COVID-19 outbreak is the top priority of the Trump Administration and CMS. We are working around the clock to ensure that Americans can sleep soundly, knowing that their government is prepared and equipped to address any possible spread of this disease.

CMS is taking action to protect the health and safety of our nation's patients and providers in the wake of the COVID-19 outbreak. Following President Trump's declaration of a national emergency, CMS announced aggressive actions and regulatory flexibilities to help healthcare providers and states respond to and contain the spread of COVID-19. These actions are part of the ongoing White House Task Force efforts in response to the COVID-19 outbreak. To keep up with the important work the Task Force is doing in response to COVID-19, go to Coronavirus.gov. For information specific to CMS, please visit the Current Emergencies Website.

Key Updates 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, upon which the capitation rates are based, and information on deductibles for MSAs.

Location of Network Areas for Private Fee-for-Service (PFFS) Plans in Plan Year 2022: The list of network areas for plan year 2022 is available on the CMS website at https://www.cms.gov/Medicare/Health-Plans/PrivateFeeforServicePlans/NetworkRequirements.html.

Calculation of FFS Costs: The Secretary has directed the CMS Office of the Actuary to adjust the FFS experience for beneficiaries enrolled in Puerto Rico to reflect the propensity of "zero–dollar" beneficiaries nationwide.

The kidney acquisition cost carve-out factors for CY 2021, calculated using the methodology described in the Advance Notice, are published at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Ratebooks-and-Supporting-Data.html.

Policies Adopted as Described

As in past years, policies in the Advance Notice that are not modified or retracted in the Rate Announcement become effective for the upcoming payment year. Clarifications in the Rate Announcement supersede information in the Advance Notice and prior Rate Announcements as they apply for payment year 2021.

CMS-HCC Risk Adjustment Model: For CY 2021 CMS will continue to phase in the model implemented in 2020, which meets the statutory requirements of the 21st Century Cures Act (Pub. L. 114-255). The 2020 CMS-HCC model (previously known as the alternative payment condition count (APCC) model) will be used along with the 2017 CMS-HCC model for the blended risk score calculation. Therefore, for 2021, we will calculate risk scores as proposed in Part I of the CY 2021 Advance Notice. Specifically, we will sum 75% of the risk score calculated with the 2020 CMS-HCC model, using diagnoses from encounter data, RAPS inpatient records, and FFS, with 25% of the risk score using the 2017 CMS-HCC model, using diagnoses from RAPS and FFS, as discussed in Attachment III, Sections G and M.

Final 2021 Normalization Factors:

2020 CMS-HCC Model: 1.097

2017 CMS-HCC Model: 1.106

CMS-HCC 2019 ESRD dialysis model & 2020 ESRD dialysis model: 1.079

CMS-HCC 2019 ESRD functioning graft model & 2020 ESRD functioning graft model: 1.118

2020 RxHCC model: 1.063

Frailty Adjustment for PACE organizations and FIDE-SNPs: CMS will implement FIDE-SNP frailty factors consistent with the versions of the CMS-HCC models that will be used for 2021 for the applicable entity. Consistent with CMS' proposal to blend risk scores for MA organizations, a blended frailty score for FIDE SNPs will be compared with PACE frailty in the same manner as for 2020, to determine whether that FIDE SNP has a similar average level of frailty as PACE. For PACE organizations, CMS will calculate frailty scores using the frailty factors for the 2017 CMS-HCC model.

MA Benchmark, Quality Bonus Payments and Rebate: We will continue to implement the methodology, as described in the 2021 Advance Notice, used to derive the benchmark county rates, how the qualifying bonus counties are identified, and the applicability of the Star Ratings.

Indirect Medical Education (IME) Phase Out: We will continue phasing out IME amounts from the MA capitation rates.

End Stage Renal Disease (ESRD) State Rates: We will continue to determine the ESRD dialysis rates by state as specified in Part II of the CY 2021 Advance Notice.

MA Employer Group Waiver Plans (EGWPs): We will continue to use the payment methodology as described in the Advance Notice, continuing for 2021 the payment methodology for MA EGWPs finalized in the 2020 Rate Announcement, including the enhancement to permit MA EGWPs to buy down Part B premiums. The bid-to-benchmark ratios applied in calculating 2021 MA EGWP Payment Rates are:

Applicable Percentage	Bid to Benchmark Ratio
0.95	84.2%
1	85.1%
1.075	84.9%
1.15	85.1%

ESRD Risk Adjustment Models: We are finalizing use of the ESRD dialysis and ESRD functioning graft risk adjustment models as proposed in the CY 2021 Advance Notice. Therefore, for 2021, we will calculate risk scores as proposed in the Advance Notice. Specifically, we will sum 25% of the risk score calculated with the 2019 ESRD models, using diagnoses from RAPS and FFS with 75% of the risk score calculated with the 2020 ESRD models, using diagnoses from encounter data, RAPS inpatient records, and FFS. For PACE organizations, we will continue to calculate ESRD risk scores for CY 2021 using the 2019 ESRD dialysis and ESRD functioning graft models.

CMS-HCC Risk Adjustment Model Used for PACE Organizations: For 2021, we will use the 2017 CMS-HCC risk adjustment model and associated frailty factors to calculate risk scores for non-ESRD aged/disabled participants of PACE organizations as proposed in the Advance Notice.

Adjustment for MA Coding Pattern Differences: We will implement an MA coding pattern difference adjustment of 5.90 percent for 2021.

Medical Loss Ratio (MLR) Credibility Adjustment: The credibility adjustment factors published in the Medicare MLR final rule (CMS-4173-F), 78 FR 31284 (May 23, 2013) will apply to MLRs calculated for CY 2021 in the absence of a final rule establishing new credibility factors.

Encounter Data as a Diagnosis Source for 2021 (non-PACE): As proposed, CMS will calculate 2021 risk scores by adding: (1) 75% of the risk score calculated (using the 2020 CMS-HCC model) using diagnoses from encounter data (supplemented with diagnoses from RAPS inpatient data) and FFS data and (2) 25% of the risk score calculated (using the 2017 CMS-HCC model) using RAPS and FFS diagnoses.

Encounter Data as a Diagnosis Source for 2021 (PACE): As proposed, we will continue to calculate Part C, Part D, and ESRD risk scores for PACE organizations by pooling risk adjustment-eligible diagnoses from encounter data, RAPS data, and FFS claims (with no weighting) to calculate a single risk score.

RxHCC Risk Adjustment Model: We will continue to use the 2020 RxHCC risk adjustment model for 2021, as discussed in the CY 2021 Advance Notice.

Part D Risk Sharing: As part of this CY 2021 Rate Announcement, we are not making changes to the 2021 threshold risk percentages and payment adjustments for Part D risk sharing.

Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2021: Attachment V provides the 2021 Part D benefit parameters for the defined standard benefit, low-income subsidy, and retiree drug subsidy.

Part D Calendar Year Employer Group Waiver Plans: We are maintaining the Part D Calendar Year EGWP prospective reinsurance policy as discussed in the CY 2021 Advance Notice.

/ s /
Demetrios L. 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 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, 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 2021 described in Attachments IV and V.

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

Attachments

2021 RATE ANNOUNCEMENT
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Attachment I. Final Estimates of the National Per Capita Growth Percentage and the National Medicare Fee-for-Service Growth Percentage for Calendar Year 2021

Table I-1 below shows the National Per Capita MA Growth Percentage (NPCMAGP) for 2021. An adjustment of 1.12 percent for the combined aged and disabled cohort 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 (NPCMAGP) for 2021

	Prior increases	Current increases			NPCMAGP for 2021 with §1853(c)(6)(C) adjustment[1]
	2003 to 2020	2003 to 2020	2020 to 2021	2003 to 2021	
Aged + Disabled	77.909 %	79.910 %	4.447 %	87.910 %	5.62 %

[1] Current increases for 2003-2021 divided by the prior increases for 2003-2020.

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 benchmarks. The percentage change in the FFS USPCC is shown as the current projected FFS USPCC for 2021 divided by projected FFS USPCC for 2020 as estimated in the 2020 Rate Announcement released on April 1, 2019.

Table I-2. FFS USPCC Growth Percentage for CY 2021

	Aged + Disabled	*Dialysis–only ESRD*
Current projected 2021 FFS USPCC	$975.06	$8,110.21
Prior projected 2020 FFS USPCC	940.81	7,795.38
Percent change	3.64 %	4.04 %

Table I-3 below shows the monthly actuarial value of the Medicare deductible and coinsurance for 2020 and 2021. In addition, for 2021, the actuarial value of deductibles and coinsurance is being shown for non-ESRD only, since the plan bids will not include ESRD benefits in 2021. These data were furnished by the Office of the Actuary.

Table I-3. Monthly Actuarial Value of Medicare Deductible and Coinsurance for 2020 and 2021

	2020	2021	Change	2021 non-ESRD
Part A Benefits	$36.72	$36.31	-1.1 %	$34.61
Part B Benefits[1]	140.46	145.31	3.5	135.31
Total Medicare	177.18	181.62	2.5	169.92

[1] Includes the amounts for outpatient psychiatric charges.

Medical Savings Account (MSA) Plans. The maximum deductible for MSA plans for 2021 is $14,150.

Attachment II. Key Assumptions and Financial Information

The USPCCs are the basis for the National Per Capita MA Growth Percentage. Attached is a table that compares last year's estimates of USPCCs with current estimates for 2003 to 2022. In addition, this table shows the current projections of the USPCCs through 2023. 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 2023.

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 Part D prescription drug benefit.

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

Calendar year	Part A		Part B		Part A + Part B		
	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	367.30	367.93	751.21	751.84	0.999
2010	383.94	383.94	376.12	376.79	760.06	760.73	0.999
2011	387.73	388.15	385.19	386.41	772.92	774.56	0.998
2012	377.40	377.72	391.84	392.97	769.24	770.69	0.998
2013	380.06	380.30	398.63	399.64	778.69	779.94	0.998
2014	370.41	372.59	418.19	418.60	788.60	791.19	0.997
2015	373.92	376.08	434.76	435.61	808.68	811.69	0.996
2016	378.01	379.90	443.91	445.63	821.92	825.53	0.996
2017	383.38	385.90	458.83	460.41	842.21	846.31	0.995
2018	387.29	391.41	488.29	493.05	875.58	884.46	0.990
2019	398.66	405.04	521.72	522.40	920.38	927.44	0.992
2020	419.53	419.00	558.89	548.54	978.42	967.54	1.011
2021	433.78	434.24	588.15	580.16	1,021.93	1,014.40	1.007
2022	449.17	452.61	616.15	612.18	1,065.32	1,064.79	1.000
2023	466.70		651.30		1,118.00		

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

Calendar year	Part A		Part B		Part A + Part B		
	Current estimate	Last year's estimate	Current estimate	Last year's estimate	Current estimate	Last year's estimate	Ratio
2010	$371.20	$371.20	$373.99	$374.92	$745.19	$746.12	0.999
2011	371.15	371.70	383.01	384.70	754.16	756.40	0.997
2012	356.97	357.52	390.54	392.25	747.51	749.77	0.997
2013	363.75	364.32	394.32	396.04	758.07	760.36	0.997
2014	364.25	367.61	408.58	409.50	772.83	777.11	0.994
2015	369.16	372.34	427.33	428.66	796.49	801.00	0.994
2016	372.04	374.82	432.90	435.52	804.94	810.34	0.993
2017	374.27	378.52	447.62	450.74	821.89	829.26	0.991
2018	376.60	385.24	472.01	482.87	848.61	868.11	0.978
2019	385.10	395.52	501.41	507.69	886.51	903.21	0.982
2020	400.59	409.27	531.75	531.54	932.34	940.81	0.991
2021	415.36	424.78	559.70	563.03	975.06	987.81	0.987
2022	429.79	442.49	586.05	593.81	1,015.84	1,036.30	0.980
2023	446.16		618.89		1,065.05		

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

Calendar year	Part A		Part B		Part A+Part B		
	Current estimate	Last year's estimate	Current estimate	Last year's estimate	Current estimate	Last year's estimate	Ratio
2010	$2,952.75	$2,952.75	$3,881.39	$3,881.39	$6,834.14	$6,834.14	1.000
2011	2,862.38	2,862.38	3,908.01	3,908.01	6,770.39	6,770.39	1.000
2012	2,774.49	2,774.49	3,944.59	3,944.59	6,719.08	6,719.08	1.000
2013	2,794.19	2,794.19	4,088.66	4,088.66	6,882.85	6,882.85	1.000
2014	2,784.52	2,784.52	4,115.70	4,115.70	6,900.22	6,900.22	1.000
2015	2,775.84	2,775.84	4,060.87	4,060.87	6,836.71	6,836.71	1.000
2016	2,895.91	2,895.91	4,081.27	4,081.27	6,977.18	6,977.18	1.000
2017	2,883.27	2,883.27	4,102.66	4,102.66	6,985.93	6,985.93	1.000
2018	2,952.21	2,928.10	4,526.09	4,459.82	7,478.30	7,387.92	1.012
2019	3,034.25	2,993.78	4,661.83	4,569.75	7,696.08	7,563.53	1.018
2020	3,163.25	3,098.04	4,747.62	4,697.34	7,910.87	7,795.38	1.015
2021	3,232.31	3,205.96	4,877.90	4,899.79	8,110.21	8,105.75	1.001
2022	3,317.94	3,327.60	4,999.52	5,109.43	8,317.46	8,437.03	0.986
2023	3,431.07		5,168.08		8,599.15		

Basis for ESRD Dialysis-only FFS USPCC Trend

Calendar year	Part A			Part B			Part A & Part B		
	All ESRD cumulative FFS trend	Adjustment factor for dialysis-only	Adjusted dialysis-only cumulative trend	All ESRD cumulative FFS trend	Adjustment factor for dialysis-only	Adjusted dialysis-only cumulative trend	All ESRD cumulative FFS trend	Adjustment factor for dialysis-only	Adjusted dialysis-only cumulative trend
2019	1.02929	0.99855	1.02779	1.03191	0.99814	1.02999	1.03087	0.99830	1.02912
2020	1.07461	0.99709	1.07149	1.05286	0.99628	1.04895	1.06145	0.99661	1.05784
2021	1.09967	0.99564	1.09488	1.08377	0.99443	1.07773	1.09005	0.99491	1.08450
2022	1.13045	0.99419	1.12388	1.11286	0.99258	1.10460	1.11980	0.99322	1.11221
2023	1.17069	0.99275	1.16220	1.15253	0.99073	1.14184	1.15970	0.99153	1.14988

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	4.7
2014	1.5	0.9	0.6
2015	–0.4	1.4	3.2
2016	1.0	0.9	4.3
2017	2.1	0.2	3.9
2018	2.5	1.8	3.9
2019	1.7	1.9	4.7
2020	2.3	3.1	7.4
2021	2.4	3.1	6.3
2022	2.4	3.5	6.4
2023	2.4	3.3	6.4

Part B[2]

Calendar year	Physician fee schedule		Outpatient hospital	ESRD dialysis update factor[5]	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	8.2		4.3
2008	-0.3	4.0	6.3		4.8
2009	1.4	2.3	5.4		3.9
2010	2.3	2.1	6.6		2.4
2011	0.8	2.3	7.1	2.5%	2.3
2012	-1.2	0.8	7.2	2.1	1.7
2013	-0.1	0.2	7.0	2.3	0.7
2014	0.4	0.6	12.6	2.8	3.4
2015	-0.3	-0.3	7.4	0.0	2.6
2016	-0.4	-0.3	5.2	0.15	1.8
2017	0.1	1.2	7.4	0.55	2.8
2018	0.5	1.2	8.5	0.3	5.8
2019	1.2	2.1	5.7	1.3	5.6
2020	-0.1	2.8	10.1	1.7	5.8
2021	-0.2	1.5	8.8	1.8	4.8
2022	0.0	2.2	8.6	2.0	4.8
2023	0.0	2.3	8.3	1.8	5.7

[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.

[5] The ESRD Prospective Payment System was implemented in 2011.

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	44.533	8.776	41.064	7.894
2015	45.911	8.853	42.311	7.977
2016	47.371	8.862	43.624	7.990
2017	48.893	8.940	44.945	8.008
2018	50.464	8.809	46.308	7.985
2019	51.933	8.394	47.948	7.653
2020	53.536	8.188	49.341	7.447
2021	55.159	8.104	50.865	7.353
2022	56.836	8.087	52.447	7.320
2023	58.495	8.026	54.021	7.247

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	29.362	6.149	27.459	5.270
2007	28.838	6.225	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	30.603	6.618	27.060	5.732
2015	30.947	6.490	27.274	5.610
2016	31.630	6.379	27.815	5.504
2017	31.917	6.301	27.883	5.362
2018	32.175	5.981	27.925	5.152
2019	32.280	5.338	28.181	4.552
2020	32.055	4.910	27.721	4.158
2021	32.666	4.668	28.256	3.910
2022	33.515	4.519	29.008	3.744
2023	34.449	4.373	29.855	3.587

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	0.454	0.441	0.385	0.371
2014	0.469	0.456	0.390	0.377
2015	0.482	0.468	0.393	0.379
2016	0.496	0.481	0.400	0.384
2017	0.510	0.494	0.402	0.385
2018	0.522	0.505	0.402	0.385
2019	0.529	0.514	0.398	0.383
2020	0.539	0.524	0.399	0.382
2021	0.551	0.534	0.369	0.350
2022	0.563	0.546	0.350	0.331
2023	0.573	0.556	0.345	0.326

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	757.25	9,368
2007	2,707.49	504.24	143.72	905.74	10,518
2008	2,695.88	536.68	151.00	1,074.99	11,404
2009	2,651.47	551.67	153.86	1,246.02	12,274
2010	2,627.03	571.74	155.18	1,249.71	13,126
2011	2,585.95	623.31	138.31	1,299.29	13,897
2012	2,489.44	541.69	130.82	1,360.39	15,068
2013	2,485.37	540.47	128.47	1,400.05	15,263
2014	2,424.47	534.37	123.88	1,356.01	15,346
2015	2,407.27	531.01	126.08	1,417.07	16,158
2016	2,430.86	504.93	121.45	1,475.00	17,147
2017	2,408.73	484.86	117.38	1,585.70	18,271
2018	2,373.81	465.17	113.67	1,691.54	19,584
2019	2,329.31	450.00	115.13	1,886.12	21,237
2020	2,322.64	448.47	120.17	2,139.55	23,252
2021	2,368.70	460.75	124.94	2,247.38	25,138
2022	2,439.23	479.31	116.38	2,351.42	27,031
2023	2,507.21	499.58	131.91	2,457.83	29,003

*Average reimbursement per enrollee on an incurred basis.

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

Calendar year	Physician fee schedule	Outpatient hospital	Durable medical equipment
2003	1,226.51	364.77	196.96
2004	1,344.01	418.85	195.61
2005	1,397.43	477.65	196.83
2006	1,396.40	497.47	197.78
2007	1,368.35	526.92	195.68
2008	1,367.83	555.09	200.92
2009	1,386.03	587.64	183.61
2010	1,429.74	623.14	183.76
2011	1,459.65	663.06	175.84
2012	1,412.79	697.92	173.70
2013	1,369.73	735.35	152.53
2014	1,351.48	820.66	128.58
2015	1,336.37	872.93	132.77
2016	1,313.95	907.42	120.88
2017	1,294.34	948.92	112.03
2018	1,284.10	994.58	127.48
2019	1,297.48	1,022.32	127.59
2020	1,292.27	1,068.73	117.88
2021	1,292.22	1,145.80	120.72
2022	1301.03	1236.26	125.53
2023	1314.02	1333.88	130.45

Calendar year	Carrier lab	Physician administered drugs	Other carrier	Intermediary lab
2003	73.73	182.58	147.21	75.18
2004	78.48	195.20	158.78	80.47
2005	82.71	178.77	184.02	84.16
2006	85.59	185.41	175.66	84.51
2007	90.65	186.97	176.55	84.38
2008	94.50	184.43	182.19	85.78
2009	101.60	196.19	176.15	79.19
2010	103.81	196.41	176.03	80.23
2011	103.85	209.50	177.27	83.31
2012	111.73	209.34	183.09	84.64
2013	111.78	216.91	174.96	81.74
2014	117.60	224.56	171.34	55.45
2015	113.99	252.10	172.69	55.26
2016	100.91	271.46	170.71	56.22
2017	100.73	280.58	175.26	55.01
2018	107.12	304.05	173.65	52.76
2019	109.19	326.07	171.70	49.52
2020	96.99	342.67	168.30	45.93
2021	99.72	368.04	170.11	48.63
2022	109.32	397.87	174.15	48.95
2023	114.06	431.16	180.01	49.55

*Average reimbursement per enrollee on an incurred basis.

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	1,203.80
2010	193.08	283.25	1,221.30
2011	198.15	255.13	1,276.30
2012	205.08	240.01	1,368.43
2013	194.43	234.72	1,497.87
2014	200.41	227.96	1,705.94
2015	210.22	225.27	1,831.30
2016	214.22	219.63	1,939.06
2017	221.24	209.51	2,096.77
2018	229.21	206.32	2,370.65
2019	238.58	207.76	2,700.11
2020	240.31	216.67	3,105.92
2021	249.11	224.68	3,327.12
2022	260.39	208.93	3,519.29
2023	273.17	236.45	3,740.06

* Average reimbursement per enrollee on an incurred basis.

2021 Projections by Service Category for non-ESRD (Aged+Disabled)*

Service type	Current estimate	Last year's estimate	Ratio
Part A			
Inpatient hospital	$2,368.70	$2,512.37	0.943
SNF	460.75	509.72	0.904
Home health agency	124.94	134.10	0.932
Managed care	2,247.38	2,050.29	1.096
Part B			
Physician fee schedule	1,292.22	1,337.36	0.966
Outpatient hospital	1,145.80	1,221.90	0.938
Durable medical equipment	120.72	140.93	0.857
Carrier lab	99.72	109.26	0.913
Physician Administered Drugs	368.04	350.40	1.050
Other carrier	170.11	212.57	0.800
Intermediary lab	48.63	47.68	1.020
Other intermediary	249.11	260.28	0.957
Home health agency	224.68	235.88	0.953
Managed care	3,327.12	3,032.04	1.097

* Average reimbursement per enrollee on an incurred basis.

Claims Processing Costs as a Fraction of Benefits

Calendar year	Part A	Part B
2003	0.001849	0.011194
2004	0.001676	0.010542
2005	0.001515	0.009540
2006	0.001245	0.007126
2007	0.000968	0.006067
2008	0.000944	0.006414
2009	0.000844	0.005455
2010	0.000773	0.005055
2011	0.000749	0.004396
2012	0.001008	0.003288
2013	0.000994	0.002846
2014	0.001003	0.002884
2015	0.000952	0.002730
2016	0.000852	0.002348
2017	0.000833	0.002111
2018	0.000836	0.001953
2019	0.000699	0.001644
2020	0.000699	0.001644
2021	0.000699	0.001644
2022	0.000699	0.001644
2023	0.000699	0.001644

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 2021 (before adjustment for prior years' over/under estimates) is calculated by

adding the USPCCs for Part A and Part B for 2021 and then dividing by the sum of the current estimates of the USPCCs for Part A and Part B for 2020.

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 Parts 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. Estimates of the MA and FFS Growth Percentages for 2021

Comment: Three commenters expressed appreciation that CMS has made efforts over the last several years to provide plans with more information and earlier forecasts regarding the growth rates. One commenter appreciated the inclusion of the Dialysis-only ESRD USPCC in the 2021 Early Preview.

Response: We appreciate the support.

Comment: Many commenters expressed concerns regarding the change in growth rates between the 2021 Early Preview published in December 2019 and the CY 2021 Advance Notice Part II published in February 2020, and encouraged CMS to validate the accuracy of the growth rate estimates and requested more robust explanation and rationale for the changes in the growth rate estimates. Commenters suggested that CMS should release more data and be more transparent on how the growth rate estimates are determined and the assumptions used, particularly regarding prior year restatements, such as enrollment, pricing, and utilization data and other variables that impact the growth rate updates. Two commenters sought additional detail on the specific drivers of the growth rates and encouraged CMS to utilize more complete actuarial data and experience to improve accuracy, if applicable. One commenter cited Actuarial Standards of Practice as requiring additional disclosure from CMS.

One commenter urged CMS to take steps to minimize the impact of prior year restatements in the growth rate methodology. Two commenters questioned the updates to historical claims and enrollment since the 2021 Early Preview, and expressed concerns with CMS' practice of restating prior year spending as creating uncertainty for MA plans in developing business plans and forecasting trends.

One commenter encouraged CMS to release rate calculation adjustments, with verifiable support, at more frequent intervals throughout the year. Another commenter requested that trend information be released with the Early Preview and the Advance Notice, as is currently released with the Rate Announcement.

Two commenters requested identification and quantification of all factors contributing to the substantial restatement of the growth percentages between the 2021 Early Preview and Advance Notice. Additionally, they requested more specificity regarding the impact of each factor than was provided by CMS on a February 2020 actuarial user group call and clarity on why factors changed so significantly during such a short period of time.

One commenter questioned whether any factors related to timing and data completeness have a predictable impact on the growth rate estimates, such as the updating of enrollment projections and the timing of claims runout.

One commenter indicated that in order for the Early Preview to be of value to plans, the information must be accurate and the methodology and data sources must not be changed, and further questioned why CMS did not update the historical claims and enrollment data prior to the Early Preview. One commenter requested that the CMS Office of the Actuary (OACT) disclose its forecasting and estimation process for the various USPCC forecasts published throughout the calendar year. Three commenters requested explanation of how each published forecast is developed, including the types/sources of data and methodologies used for each baseline and differences among the forecasts, with impacts and explanations of any material change in forecast for specific service categories (e.g., inpatient hospital, physician services).

Response: The growth percentages, total USPCC, and FFS USPCCs are based on OACT's best estimate of historical program experience and projected trend at the time those values are announced. We continue to believe that the best practice is to base the growth rates on the most recent data and assumptions. Therefore, with each release, historical enrollment and claims, as well as projection factors, are updated as more recent data continues to emerge. CMS released additional information on the changes in the CY 2021 Advance Notice growth rates in the February 20, 2020 user group call Q&A document posted at https://www.cms.gov/files/document/cy-2021-actuarial-bid-questions.pdf-1. With the CY 2021 Advance Notice, CMS published information regarding the USPCC trend components at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Narrative-2020-Payment-Notice.pdf.

Each year, the Advance Notice provides the proposed methodological payment changes since the prior year's Rate Announcement. For the past several years, CMS has decided to provide the Early Preview growth rates to serve as preliminary estimates, based on the data available at that time, and has stated that these estimates are subject to change in the Advance Notice and Rate Announcement, as more data becomes available and is used to inform the estimates. Given that MA rates are based on FFS costs, we believe it is important to make updates using the most current FFS data available and apply repricing adjustments to reflect changes in FFS payment rules in order to best reflect program experience and develop appropriate projection factors. Some commenters characterized the growth rate updates as "misleading," "erratic," "inconsistent," having "discrepancy," and "contrast[ing] with" previous estimates. We note that the growth rates are developed based on actuarial assumptions that are also used in other modeling/projection baselines (including the timing of available enrollment and claims information). Given these concerns about the usefulness of the Early Preview, and given OACT's limited ability to address them in light of the timing of data availability, we will consider whether to discontinue the release of Early Preview growth rates in the future.

Annually with the final Rate Announcement, we publish additional detailed information regarding the growth percentages. Key economic assumptions underlying the USPCCs are also 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 believe that this useful information provides the additional support for USPCC levels and trends that commenters are requesting. The information provided with the annual Advance Notice and Rate Announcement is in compliance with the current standards of practice, as promulgated by the Actuarial Standards Board of the American Academy of Actuaries.

Comment: One commenter requested that enrollment information supporting the USPCC development be released with the Advance Notice, as currently done with the Rate Announcement. The commenter requested that CMS provide whether total enrollment increased and/or if there was movement of members between MA and FFS, the impact of revised historical enrollment for the years impacted, and additional rationale for such historical membership restatements (e.g., 2017 and 2018 membership restated in 2020). Another commenter also questioned the 2017 and 2018 enrollment updates since the Early Preview, and requested more detail on the 2018 enrollment update given the magnitude of the change. Further, the commenter compared the 2018 FFS enrollment data from the CY 2020 Rate Announcement with the 2018 FFS enrollment data published with the CY 2021 Advance Notice, and requested that CMS explain the changes in enrollment.

Another commenter requested clarification regarding why data pertaining to historical 2018 FFS enrollment increases were not available in time for the Early Preview announcement.

Response: The enrollment information supporting the USPCC development is based on OACT's best estimate of historical program experience at the time the USPCC estimate is announced. We note that the growth rates are developed based on actuarial assumptions that are also used in other modeling/projection baselines (including the timing of available enrollment information). Revisions to the pre-2019 enrollment supporting the USPCC tabulation, used for the Advance Notice growth rates, affected only the count of FFS beneficiaries. The updates resulted in an additional 216,000 average Part A beneficiaries in 2018 and an average of 270,000 additional Part B beneficiaries. The change in enrollment was due to a revision in the baseline supporting the USPCC tabulations.

Also, there is not a direct link between the enrollment projections supporting the USPCC tabulations and the historical county level experience used in the ratebook tabulation. The USPCC experience is updated periodically as new information is available. The historical county-level enrollment used in the ratebook development is tabulated directly from administrative records six months after the close of the calendar year and remains fixed.

Comment: One commenter questioned the updates to pre-2017 claims. Three commenters questioned the magnitude of the 2018 claim restatements, and requested the rationale for the magnitude, as well as greater detail on the changes due to emerging experience and the categories driving this change (inpatient, outpatient, physician, other).

One commenter noted that OACT had mentioned that "actual program experience" was a key component of the trends and the change in 2018 FFS spending, which the commenter was concerned meant that the change resulted from forecasting assumptions based on incomplete data. Another commenter requested clarification regarding why data pertaining to historical claims for Part A dating back to 2014 were not available in time for the Early Preview announcement.

One of the commenters sought information on how CMS is projecting Part B drug experience in the growth rate.

Response: The restatements of pre-2017 incurred claims are due to re-allocation of Part A home health spending from non-ESRD to ESRD, revisions to the tabulation of incurred bad debt expenditures, improvements in the modeling of incurred claims for Part A buy-in beneficiaries, and re-mapping of some Part B services to new benefit categories resulting in updated historical cash-to-incurred relationships. Collectively, these adjustments to claims experience affected the 2021 FFS non-ESRD growth rate reported in the CY 2021 Advance Notice by about -0.7 percent for Part A, -0.8 percent for Part B, and -0.8 percent for Parts A and B combined compared to the calculations supporting the final 2020 FFS non-ESRD growth rate in the Rate Announcement. Based on the USPCCs reported in this notice, collectively these adjustments to claims experience affected the 2021 FFS non-ESRD growth rate by about -0.7 percent for Part A, -0.6 percent for Part B, and -0.7 percent for Parts A and B combined compared to the calculations supporting the final 2020 FFS non-ESRD growth rate in the Rate Announcement.

These adjustments were not reflected in the baseline supporting the 2021 Early Preview announcement and were incorporated into the baseline supporting the 2021 Advance Notice. The claims information supporting the USPCC development are based on OACT's best estimate of historical program experience at the time the estimate is announced.

Finally, Part B physician-administered drugs are projected based on recent past trends which include growth in such factors as average sales price, volume and intensity.

Comment: Several commenters noted the difference between the FFS growth rate and the MA growth rate, and requested additional details on the drivers of this difference (such as demographics, case mix, price versus utilization). Since the MA growth percentage represents both MA and FFS trends, one commenter questioned how the MA growth rate could be so much higher than the FFS growth rate (and cited a study by another organization that implied a large MA-specific trend of over 8.4%).

Response: The MA growth rate has generally exceeded the Medicare FFS growth rate in recent years due primarily to higher trends in MA risk scores, an increase in MA enrollment in plans with 4 or more stars, and an increase in the share of dual eligible beneficiaries enrolled in MA.

Comment: One commenter noted that the CY 2021 Advance Notice did not mention either adjusting historical experience to include the costs of Chimeric Antigen Receptor T-Cell therapy or how CAR T-cell therapy costs have been accounted for in the development of the FFS USPCC, and recommended that CMS clarify whether the 2021 FFS USPCC incorporates the expected cost of CAR T-cell therapy for cancer.

As context for this issue, the commenter notes that on August 7, 2019, CMS issued a memo that stated, for CY 2019 and 2020, Medicare FFS will pay for CAR T-cell therapy for cancer obtained by beneficiaries enrolled in MA plans when the coverage criteria outlined in the decision memorandum is met. This policy was effective as of August 7, 2019.

Another commenter requested that CMS separately quantify the impact of CAR T-cell therapies on the MA growth rate. The commenter believes that CAR T-cell use will exceed 2020 FFS levels and therefore a separate adjustment is warranted, especially with the significant treatment costs and expansion of indications and patients covered. The commenter also requested the impacts from the fiscal analysis CMS performed to determine that the CAR T-cell therapies were classified as a significant cost. Further, the commenter requested CMS explicitly describe the percentage used in contributing to the FFS and USPCC growth rates.

Response: As explained on page 7 of Part II of the CY 2021 Advance Notice, the USPCCs included the cost impacts of program changes enacted through legislation, regulation, and national coverage decisions applicable for the contract year (2021). As the CAR T-cell therapy was added to Medicare coverage by a national coverage determination (NCD), we expected that explanation to sufficiently indicate that an adjustment was made to incorporate those costs. We also provide additional information here.

We have six quarters of experience with the CAR T-cell therapy benefit provided through hospital outpatient departments (2nd Quarter 2018 through 3rd Quarter 2019). In 2018, 14 patients received CAR T-cell therapy at an average cost of $464,000 per patient. In 2019, 24 patients received CAR T-cell therapy at an average cost of $427,000 per patient. Averaged across all Medicare FFS beneficiaries, the hospital outpatient per-member per-month cost of CAR T-therapy coverage in FFS is $0.02 in 2018 and $0.03 in 2019.

The USPCCs include the cost impacts of CAR T-cell therapy services provided through both inpatient and outpatient settings.

We anticipate that a summary of recent hospital inpatient experience for CAR T-cell services will be included in the fiscal year 2021 hospital inpatient prospective payment system (IPPS) proposed rule.

Further, we determined that the CY 2020 “significant cost” threshold per case limit was $224,000 and estimated that the average per-beneficiary cost of CAR T-cell therapy in 2020

would exceed $224,000. Accordingly, we determined that CAR T-cell therapy benefit exceeded the "significant cost" threshold in 2020.

Finally, given that the CAR T-cell spending represents a very small proportion of all spending for Part B drugs and biologics, we do not separately trend the CAR T-cell therapy benefit. Our latest estimate of the trend in per-capita spending for Part B drugs and biologics is 11.8 percent for CY 2020 and 11.0 percent for CY 2021. The projected expenditures for CAR T-cell therapy in CY 2021 are reflected in the FFS USPCC tabulation, along with expenditures for all other Part B drugs and biologics.

Comment: Two commenters contrasted the "lower" FFS growth percentage with the proposed normalization factors have been increasing at a faster rate in recent years due, in part, to higher FFS risk scores. The commenters believe that since FFS costs are increasing as indicated by the normalization factors, the FFS growth percentage should be higher.

Response: The increase in the FFS normalization factor is due primarily to changes in the volume and composition of diagnoses used in the CMS-HCC risk score computation. The normalization factor is a projection of the trend in risk scores and calculated independently from the estimation of per-capita spending. Therefore, there is not a direct relationship between the normalization factor and per-capita spending.

Comment: One commenter requested clarity around the how the elimination of the Health Insurance Tax (HIT) beginning in 2021 may have impacted actuarial assumptions for each of the growth percentages and to what magnitude. The commenter noted that CMS had indicated on a February 2020 actuarial user group call that the impact of the elimination of the HIT for 2021 was accounted for in the MA growth percentage, but it is not clear whether, or to what extent, CMS made any assumptions about the HIT in estimating the FFS or ESRD growth percentages.

Response: The Further Consolidated Appropriations Act, 2020, Division N, Subtitle E § 502 eliminated the Health Insurance Providers Fee (HIPF) (called the Health Insurance Tax by commenters) for calendar years beginning after December 31, 2020, which aligns with CY 2021 MA payments. We assumed that beginning with the CY 2021 submissions the MA bids would reflect the elimination of the HIPF, and that, based on prior bidding experience, 25 percent of the pre-elimination HIPF would implicitly be retained as bid margin for CY 2021 and 0 percent of the pre-elimination HIPF would implicitly be retained as bid margin for CY 2022 and later. That is, we assumed that the MA bids would reflect a phase-in of the HIPF reduction with 75 percent of the reduction of the HIPF reflected in the CY 2021 MA bids and 100 percent reduction of the HIPF in the MA bids for CY 2022 and later. The removal of the phased-in HIPF reduction reduces the Total USPCC growth rate in CY2021 by about 0.15 percent.

Also, given that the HIPF was never projected to affect Medicare FFS expenditures, the elimination of the HIPF had no impact on the 2021 FFS growth rate. Similarly, since payments

to MA plans for enrollees in ESRD status are based on administratively set capitation rates and not bids, the elimination of the HIPF had no impact on the 2021 ESRD dialysis growth rate.

Comment: One commenter noted ESRD FFS reimbursement changes and expressed concern that the data used to construct the ESRD USPCC may not capture and reflect ESRD-related costs in a timely manner. The commenter offered as an example the 2018 shift in Medicare coverage for calcimimetics from Part D to Part B, and noted that future ESRD-related drug development may result in additional coverage transitions. The commenter also mentioned potential forthcoming innovations and developments resulting from Executive Order 13879 on Advancing American Kidney Health (July 10, 2019). The commenter urged CMS to explore approaches to reimburse plans for these types of changes before the changes may be fully reflected in the FFS expenditures.

Response: The CY 2021 dialysis-only ESRD USPCC reflects our best estimate of the national per-capita cost, including changes to the ESRD PPS bundled payments made in final rules published before issuance of the CY 2021 Advance Notice. We note that the repricing adjustments to FFS costs support the average geographic adjustments (AGAs), and reflect changes in the wage index or GPCIs to update those figures from the experience year to, as applicable, CY 2020 or FY 2020. These county-level repricing adjustments do not reflect updates to the composition of the bundle, such as changes in the covered drugs, and reflect the actual cost of the bundle in the historical FFS experience.

Comment: Several commenters expressed concern regarding the volatility in the ESRD growth rates, compared to less volatility in the FFS growth rates. Two commenters requested that CMS provide detailed information, consistent with the types of information released for the MA and FFS growth percentages, regarding the specific data and trends, underlying methodology, and other variables impacting ESRD growth rate updates.

One commenter noted that the proposed ESRD growth rate was smaller than the non-ESRD growth rates, which they believe illustrates the impact of underfunding issues with ESRD Prospective Payment System (PPS) payments. The commenter also expressed concern regarding volatility in the ESRD growth rates in prior years between the Advance Notice and Rate Announcement, and urged CMS to explore methodological refinements to achieve greater year-to-year ESRD payment stability.

Several commenters recommended that CMS modify its methodology for the ESRD growth percentage to use five years of historical FFS claims data rather than one year, to better align with the methodologies for the non-ESRD growth percentages and to reduce volatility in ESRD payment rates. These commenters believe that the ESRD growth percentage is developed based on the most recent calendar year of data available trended to the upcoming year, while the FFS growth percentage is based on the most recently available five years of data.

Response: In response to commenters' request for more detailed information regarding the ESRD growth rate updates, in the "Summary of Key Projections" section of Attachment II we have added an additional column with the annual "ESRD dialysis update factor." Note that the Part B factors reflected in the "Summary of Key Projections" section of Attachment II apply to costs for both non-ESRD and ESRD beneficiaries.

We continue to refine and improve our data and methodology used in the projection of the ESRD dialysis growth percentage. However, often there are unforeseen changes in trends stemming from factors such as finalization of regulations, changes in statute, and aberrations in utilization.

Finally, both the non-ESRD and ESRD ratebook AGAs are based on five years of historical data. Further, the non-ESRD FFS USPCCs are tabulated directly from the baseline projection model. The ESRD dialysis USPCCs also are derived from the total USPCC baseline but are adjusted for recent trend differences between the total ESRD and dialysis ESRD populations. Thus, the ESRD dialysis USPCCs are projected using a base year USPCC, CY 2018 for the 2021 dialysis ESRD ratebook, trended from 2018 to 2021 using total ESRD growth with an "adjustment factor for dialysis only." The applicable trends are found in the Attachment II table, "Basis for ESRD Dialysis-only FFS USPCC Trend."

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

Comment: Several commenters expressed concern that the pre-ACA rate cap diminishes incentives for high performing plans to continuously improve quality. Commenters believed that the inclusion of the quality bonus in the rate cap calculation harms beneficiaries by undermining value-based care and reducing benefits to enrollees in high quality plans. Two commenters indicated that the benchmark cap makes it difficult for plans to expand supplemental benefits available to enrollees, and otherwise offer innovative plan designs that best serve beneficiaries' needs. One commenter expressed concern that the cap is inconsistent with the agency's 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. One commenter referred to legal analyses provided to CMS in previous years regarding this issue.

Response: While we appreciate the commenters' concerns, there is no 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.

Given this lack of discretion, we note that the Fiscal Year 2021 President's Budget included a legislative proposal to remove the cap on MA benchmarks and also to remove the doubling of quality bonus payments in qualifying counties.[1]

Comment: One commenter requested that we consider changing our regulations to mitigate or reduce the complete loss of the quality bonus payment for plans that decline from a 4-Star or higher rating in one year to a rating of fewer than 4 Stars in a subsequent year. The commenter suggested reducing the severity of the negative financial impact by phasing in the reduction (for example, by reducing the QBP by 50% in the first year) rather than a total loss of the QBP the first year a plan drops below a 4-Star rating.

Response: While we appreciate the commenter's suggestions, the specific suggestion to phase in the changes to the quality bonus payment associated in changes in the Star Ratings from year to year is not consistent with the statutory parameters for the quality bonus payments.

Comment: Two commenters expressed support for our determination that some of the counties in Puerto Rico will be eligible for the Qualifying County Bonus Payment in 2021. One of the commenters further requested that all counties in Puerto Rico be classified as qualifying counties, suggesting that the 2004 Urban Floor criteria should be based on the entire territory and that MSA delineations may be modified by the agency based on an OMB Bulletin dated February 28, 2013.

Response: As noted in Part II of the CY 2021 Advance Notice, section 1853(o)(3)(B) of the Act sets forth the criteria for determining a qualifying county. We do not have discretion to classify a county as a qualifying county if it does not meet the statutory criteria. The counties in Puerto Rico that are not classified as qualifying counties do not meet the criterion requiring that the county's MA capitation rate for 2004 was based on the amount specified in section 1853(c)(1)(B) for a Metropolitan Statistical Area with a population of more than 250,000.

Section C. Calculation of Fee-for-Service Costs

Comment: One commenter expressed appreciation for the detailed information released regarding the county-level FFS costs, including the publication of supporting files.

Response: We appreciate the support.

Comment: Several commenters requested that we calculate FFS spending using only claims and utilization data for beneficiaries enrolled in both Part A and Part B (rather than based on such data for beneficiaries in Part A and/or Part B, as is the practice today) because they believed that would be a more accurate, reasonable, appropriate, and/or equitable methodology. Two commenters pointed out that in order to enroll in an MA plan, beneficiaries are required to be

[1] https://www.whitehouse.gov/wp-content/uploads/2020/02/msar_fy21.pdf

enrolled in both Part A and Part B. The commenters expressed that the MA benchmark can only represent what an MA enrollee would cost in Medicare FFS, as required, if based on the Medicare FFS costs of only beneficiaries eligible for enrollment in MA. Several commenters cited MedPAC's support of benchmarks calculated based on FFS data for beneficiaries with both Part A and Part B.

Two commenters stated 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. One commenter expressed concern that increasing MA penetration leaves fewer, and a less representative population of, beneficiaries on which to calculate FFS spending. Two commenters noted that beneficiaries enrolled in Part A-only had utilization and cost patterns that differ from beneficiaries enrolled in both Part A and Part B, and requested excluding Part A-only beneficiaries from the methodology. Two commenters stated 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.

Three commenters expressed support for continuing our policy of basing benchmarks in Puerto Rico on Medicare costs for beneficiaries with both Part A and Part B coverage. Several commenters requested that we apply a uniform approach in all counties to calculate benchmarks, pointing to the methodology used by CMS for Puerto Rico rates. Two commenters noted that other counties beyond those in Puerto Rico, such as some in Hawaii, also have high MA penetration rates and low FFS Part B enrollment, contending that benchmarks in these areas should also be based on Medicare FFS costs for beneficiaries with both Part A and Part B coverage as a result. One commenter indicated that the adjustment to FFS rate calculations in Puerto Rico suggests the need to remedy disproportionately high penetration rates of MA and low FFS Part B enrollment.

One commenter noted that previous Rate Announcements have indicated that we would continue to analyze this issue and consider whether adjustment may be warranted, and that the 2021 Advance Notice did not provide any further analysis or discussion of this topic.

One commenter noted geographic differences that occur, based on the proportion of FFS beneficiaries enrolled in both Part A and B in certain areas, and urged CMS to analyze the differences in Parts A and B enrollment across the country and consider adjusting its methodology in areas found to be outliers.

One commenter recommended that we align our methodology with the approach under the new Direct Contracting Model, which bases model payments on the experience of beneficiaries enrolled in both Parts A and B. The commenter noted that in the Request for Applications for the Direct Contracting Model, the Innovation Center stated that it will make adjustments to payment rates to account for differences between the subset of Medicare FFS beneficiaries eligible to participate in the model and Medicare FFS beneficiaries generally, including an adjustment

because “aligned beneficiaries must be enrolled in both Medicare Parts A and B.” The commenter urged us to explain the distinction between the Direct Contracting Model and MA methodologies, including an impact analysis of applying this adjustment in the Direct Contracting Model compared to the MA benchmarks.

One commenter stated that we should explain why an adjustment is made to per capita costs for Medicare beneficiaries who are dually eligible for benefits through the Department of Veterans Affairs and the Department of Defense (i.e., the VA/DoD adjustment), but not for Medicare beneficiaries with Part A only or Part B only.

One commenter noted their belief that the detailed legal response that CMS provided to similar comments in the CY 2020 Rate Announcement, whereby CMS concluded that the methodology based on FFS beneficiaries in Part A and/or Part B is sound, has not substantively responded to actuarial concerns, failing to provide empirical evidence that the methodology appropriately addresses differences between the MA and FFS populations. Another commenter noted that previous Rate Announcements have indicated that CMS would continue to analyze this issue and consider whether adjustment may be warranted, but has not to date provided any further analysis of this topic.

Response: We refer commenters to the detailed response that we provided in the CY 2020 Rate Announcement regarding this issue, whereby CMS concluded that it finds the current ratebook methodology to be sound. As stated in the CY 2020 Rate Announcement, we continue to believe that it is not necessary or required to change the methodology at this time, as the statutory language clearly permits CMS to include Medicare beneficiaries who have Part A or Part B only. While we recognize that calculating rates based on data that excludes beneficiaries entitled only to Part A would yield different results than calculating rates based on our current methodology, that fact alone does not determine which methodology should be employed.

The statutory authority for the Direct Contracting Model is under section 1115A of the Act. Section 1115A provides for broad flexibilities in implementing models that do not exist in the MA ratebook statutes. Whether or not the experience and evaluation of the test of the Direct Contracting Model under section 1115A leads to information that may be relevant to CMS’ implementation of the MA statutory requirements for setting MA rates and benchmarks remains to be seen.

Further, the statute explicitly requires an adjustment for individuals dually eligible for benefits through the Department of Veterans Affairs and the Department of Defense. There is no statutory requirement for exclusion of beneficiaries with coverage for Part A only or Part B only.

We have discussed in past Advance Notices and Rate Announcements that 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 for Puerto Rico used to determine MA rates so that

it is based only on the Medicare costs for beneficiaries with both Part A and Part B. Our exercise in discretion for the data used to develop the estimate for one geographic area, based on circumstances unique to that area, illustrates how there is more than one way to develop a reasonable and reliable adjusted average per capita cost estimate for purposes of the MA statute.

We appreciate the suggestions submitted by commenters, and 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 2021, we will continue to calculate FFS spending for the purpose of establishing MA benchmarks using FFS claims and utilization data for beneficiaries in Part A and/or Part B.

Comment: One commenter requested that we implement methodological changes to the AGA calculation every three years, rather than annually, to promote stability in rates. Another commenter recommended that we solicit input from plans on other approaches (rather than annual rebasing) for implementing changes to the AGA calculation.

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 per capita cost estimates 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. We will consider these comments regarding the timing and frequency of rebasing for future years.

Comment: One commenter recommended that we develop a policy that limits the impact of rebasing relative to the growth rate. The commenter stated that in some cases, the effect of rebasing county FFS rates nearly offsets the effect of the estimated growth rate.

Response: While we appreciate the suggestion of the commenter, we do not find this specific suggestion, to artificially restrict the impact of rebasing to not exceed the impact of the growth rate, to be consistent with the statutory requirements for rebasing. As discussed on page 10 of Part II of the CY 2021 Advance Notice, section 1853(c)(1)(D)(ii) of the Act requires CMS to rebase the county FFS rates periodically; rebasing is updating the estimate of each county's FFS costs using more current FFS claims information. In addition, as discussed in Attachment I of the Advance Notice, the growth rates are used in the calculation of MA rates, per section 1853(k) and (n) of the Act.

Comment: One commenter requested information regarding the perceived disparate impact of rebasing on Florida relative to other states. The commenter stated that its projection of the impact of rebasing county FFS rates for 2021 found a much larger, negative impact in Florida than in most other states. The commenter requested additional detail on the drivers of this result and the magnitude of the impact of each driver.

Response: There are several factors that affect the impact of rebasing and repricing in each county, including the rolling forward of the experience period, repricing historical FFS claims, and changes in risk scores. It appears that the primary influence on rebasing in Florida counties is the rolling forward of the experience period. The CY 2020 rates included historical experience for 2013 through 2017, and the CY 2021 rates are based on experience for 2014 through 2018. For example, for Broward County FL (one of the largest counties in Florida in terms of the number of FFS beneficiaries), the 2013 standardized geographic adjustment used in the AGA calculation for rates in the 2020 non-ESRD ratebook was 1.2706, which was the county's highest standardized geographic adjustment for the experience period of 2013 through 2017. This was replaced with a 2018 standardized geographic adjustment of 1.2285 in the 2021 non-ESRD ratebook, which is within the range of the county's standardized geographic adjustments for the years 2014 through 2017. The standardized geographic adjustment reflects the relative costs for the county compared to the nationwide average; Broward County's relative costs compared to the nationwide average were higher in 2013 than in 2018. The 2020 Standardized Geographic Index is included in the "ffs_worksheet" tab of the published spreadsheet "Medicare FFS County 2020 Web.xlsx" and the 2021 Standardized Geographic Index is included in the published spreadsheet "Medicare FFS County 2021 Web.xlsx."

Comment: One commenter requested clarification on whether we were proposing to standardize county benchmarks using risk scores calculated using the proposed model blend for Part C risk adjustment—i.e., 25 percent of the risk score calculated with the 2017 CMS-HCC model blended with 75 percent of the risk score calculated with the 2020 CMS-HCC model.

Response: We clarify that the benchmarks will be standardized with risk scores calculated using the risk models being used for 2021 payment, accounting for the applicable blending of the risk scores calculated under each model.

Comment: One commenter expressed concern with our proposal to limit our adjustment of the AGAs for Innovation Center payment and service delivery models to the 16 listed in Table B1-1 of the Advance Notice, and with the proposed exclusion of certain payments under the 16 models (e.g., care management fees) that are funded through the Innovation Center rather than the Medicare Part A or B Trust Funds. The commenter stated that they were unaware of any statutory basis for excluding these payments from the MA benchmarks and that the exclusion of these funds means CMS is not determining the cost of providing a benefit to MA enrollees that is comparable to what it would be if the benefit were provided to such enrollees under the FFS program. The commenter recommended that we reconsider our policy of excluding model payments from our adjustment of the AGAs to the extent the model payments are funded through the Innovation Center. Instead, the commenter recommended that we apply the "actual spending impact" of any models and other initiatives in our adjustment of the AGAs, including care management fees and other payments not made from the Trust Funds.

Response: As explained on page 21 of Part II of the CY 2021 Advance Notice, we considered adjusting the FFS claims experience for care management fees, per-beneficiary-per-month fees, and/or advance payment of shared savings paid to providers for other Innovation Center models conducted in 2014-2018 period. However, in continuing prior policy, we will not take fees of this type into account in our adjustments to historical FFS experience when they were not funded under Medicare Parts A or B Trust Funds.

As we had discussed on page 20 of the CY 2018 Advance Notice, the fees paid from administrative accounts authorized by section 1115A of the Act are not from the Part A and Part B Trust Funds, from which Medicare claims are disbursed, so we do not consider those payments to be part of FFS costs. Section 1853(f) indicates that payments to MA organizations shall be made from the Trust Funds "in such proportion as the Secretary determines reflects the relative weight that benefits under Part A and under Part B represents of the actuarial value of the total benefits under this title." Section 1876(a)(4) indicates that FFS costs used for MA rates are based on the estimated amount that would be payable for services covered under Parts A and B, and types of expenses otherwise reimbursable under Parts A and B (including administrative costs incurred by organizations described in sections 1816 and 1842). As these costs described in section 1876(a)(4) of the Act are paid from the Trust Funds, excluding costs paid from another appropriation is appropriate to determine FFS costs. *See* sections 1817(h) and 1841(g) of the Act.

Accordingly, there will be not be any adjustment to historical FFS claims to account for payments made from the funds appropriated under section 1115A.

Comment: The CY 2021 Advance Notice sought public comment on the possibility of adjusting FFS experience in Puerto Rico to reflect the propensity of zero dollar beneficiaries nationwide. Many commenters supported the use of an adjustment to the Puerto Rico MA rates to reflect the prevalence of zero-dollar beneficiaries nationwide.

The commenters believed that such an adjustment is appropriate because the number of zero claimants in the Puerto Rico FFS population is a significantly greater proportion of the population relative to the rest of the United States. One commenter stated that beneficiaries in Puerto Rico with complicated and comprehensive health care needs enroll in MA, whereas beneficiaries in Puerto Rico who enroll in FFS Medicare have low levels of health care utilization and are not representative of the population as a whole.

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

The updated study analyzed experience for calendar years 2014 through 2018, using the cohort of FFS beneficiaries enrolled mid-year (i.e., enrolled in both Parts A and B as of the mid-year

dates used for the study) to approximate the average enrollment for the year. On average, 15.1 percent of Puerto Rico FFS beneficiaries with both Parts A and B were found to have no Medicare claim reimbursements per year. This compares to a nationwide, non-territory, proportion of 6.1 percent of FFS beneficiaries without Medicare spending. These results were applied to the Puerto Rico FFS experience by adjusting the weighting of the enrollment and risk scores for the zero-claim cohort to reflect the nationwide proportion of zero-claim beneficiaries. The resulting impact was an average increase in the standardized FFS costs in Puerto Rico of 4.7 percent for 2014 through 2018. Accordingly, a 4.7 percent adjustment was applied to the pre-standardized Puerto Rico FFS rates supporting the CY 2021 ratebook development.

Comment: Several commenters expressed concern regarding socio-economic conditions in Puerto Rico, citing beneficiary migration to the mainland and an exodus of health care providers. Commenters expressed concern regarding the disparity between payment rates in Puerto Rico and payment rates in the mainland. Commenters urged us to explore all potential options for reforms to stabilize the marketplace, improve the health care infrastructure, and achieve greater parity with FFS rates on the mainland.

One commenter expressed support for the proposed use of five years of FFS experience to mitigate any annual fluctuations and anomalies in the data. Three commenters requested that we consider additional rate adjustments for Puerto Rico, including establishing an AGA floor/proxy (e.g., applying an AGA of 0.70 or a nationwide average AGA) or applying a hold harmless minimum benchmark. One of the commenters cited actions we have taken in the Medicare FFS program in order to address disparities between high-cost and low-cost areas, including our use of a national average Geographic Practice Cost Index (GPCI) as a proxy to be used in calculating rates under the Physician Fee Schedule for the U.S. Virgin Islands and certain other territories and our use of a floor in the wage index payment adjustment made under the ESRD PPS under Medicare FFS. One commenter expressed concern that the FFS data used to set the MA rates for Puerto Rico are not representative of the population to which those rates are applied.

One commenter recommended that we adjust MA benchmarks in Puerto Rico to reflect the minimal representation of dual eligible beneficiaries in the FFS population in Puerto Rico. The commenter stated that the difference in the proportion of duals in the MA and FFS populations in Puerto Rico is so large that risk scores alone cannot correct the large discrepancy that exists between the two populations without an adjustment at the base rates.

Response: We appreciate the concerns and recommendations 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. As discussed in the 2017 Advance Notice, the law requires that MA benchmarks be based on a county's average Medicare FFS per-capita costs, and there is no evidence that FFS costs in Puerto Rico are higher than the costs observed in the FFS claims data and thus no basis for overhauling Puerto Rico's MA benchmarks. Note that the repricing adjustments reflect the applicable GPCI and wage indices used in Medicare FFS,

and therefore are reflected in the development of the MA rates. As we stated in the CY 2017 and 2018 Rate Announcements, we believe that the FFS data in Puerto Rico is sufficient for establishing accurate MA benchmarks.

Section D. Kidney Acquisition Costs

Comment: Two commenters appreciated the detailed information that CMS provided regarding the methodology used to calculate the kidney acquisition cost (KAC) carve-out in the CY 2021 Advance Notice, and the estimated impacts.

Response: We appreciate the support.

Comment: Several commenters requested additional transparency and data regarding the KAC carve-out methodology, such as county-level utilization and unit costs used to develop the KAC factors. Another commenter requested detailed information regarding organ acquisition costs and trends, such as the amounts that CMS has paid to each provider.

Two commenters requested that CMS release all data elements included in the carve-out methodology and underlying data, such as the specific donor, provider and hospital services included in the kidney acquisition costs obtained from the Cost Reports (e.g., donor surgery, the cost of the kidney itself, travel expenses, etc.), and how these can be identified consistently with CMS' identification in the carve-out calculation.

Response: In the MA ratebooks to date, organ acquisition costs have been included as a portion of the pass-through payments included on FFS claims in each county and ESRD state rate. To date, CMS has paid for organ acquisition costs through the county and ESRD state rates, by including these pass-through amounts, and no other payments are made to providers on behalf of MA beneficiaries.

As background, under Inpatient PPS, Medicare reimburses for organ transplants by making an MS-DRG (Medicare severity diagnosis related group) based payment for the hospitalization. On the Inpatient PPS claim records, the payment amount includes the base MS-DRG as well as some add-ons, such as IME. There are also some reimbursable claim costs which are referred to as "pass-through amounts." These "pass-through amounts" are not paid via the MS-DRG payment, and while they are not included in the claim payment amount, interim bi-weekly payments that include these amounts are paid throughout the year. These reimbursable claim costs include kidney acquisition costs and are later reconciled using data submitted on cost reports.

For MA rate calculations to date, these FFS pass-through amounts are estimated and specifically added to the inpatient claim records to account for the eventual payment in the FFS program on a reasonable cost basis. When the law specifies that such pass-through costs be excluded/carved out from the MA payment rate (as is the case for kidney acquisition costs in MA), we subtract from our claims tabulations an estimated amount that is commensurate with the previously

determined included pass-through amounts (in this case, the pass-through amounts that are for kidney acquisition costs).

Under the KAC methodology to calculate an estimate of the standardized costs for payments for organ acquisitions for kidney transplants covered under Medicare in order to exclude those costs from the MA rates, the share of the pass-through amounts that relate to FFS kidney acquisition costs was tabulated from the Medicare Cost Reports[2] as discussed on pages 24-26 of the CY 2021 Advance Notice. Data identifying specific donors is confidential protected health information and not releasable. We are including relevant Medicare Cost Report data pertaining to KACs and discharges, specifically the underlying cost and discharge data used to calculate the kidney acquisition cost carve-out factors for the years 2014-2018, at the following path: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/.

The allowable organ acquisition costs used to calculate the KAC carve out are organ donor and recipient costs before hospital admission for the transplant operation (i.e., pre-transplant evaluation services) and hospital inpatient costs associated with the donor. Post-operative care expenses for the kidney donor are also used to calculate the KAC carve out. Detailed donor, provider, and hospital services included in the kidney acquisition payments that Medicare makes are described in chapter 31 of the Medicare Provider Reimbursement manual available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R471PR1.pdf.

Comment: Two commenters suggested that CMS change the KAC carve-out methodology to use the number of acquisition cases by provider and county rather than allocations using the total patient cases by county. Another commenter expressed concern that there may be misalignment between the number of Medicare discharges as reported in the Cost Reports and the number of Medicare inpatient stays as reported in the claims data that is inflating the total estimated organ acquisition costs, which in turn leads to an inflated carve out from the MA payments.

Response: The pass-through amounts paid by the FFS program are allocated to all inpatient claims of a certified transplant center and are tabulated based on the enrollees' county of residence. As the pass-through amounts include the KAC payable by the FFS program, KACs should be carved out of the MA county rates consistent with this methodology (i.e., based on the enrollees' county of residence). The commenters' suggestion would be inconsistent with the way the pass-through costs are allocated to the county rates. Additionally, discharges in the Cost Reports and the number of Medicare discharge claims are consistent with each other – Medicare Administrative Contractors ensure consistency as part of the reporting and settlement process.

[2] Cost Reports show acquisition costs separately for each organ. The carve-out methodology specifically uses kidney acquisition costs.

We applied the per discharge KAC amounts from the Cost Reports to the discharge claims and found that they closely matched the total KAC on the Cost Reports.

Comment: Several commenters expressed concern with the magnitude of the KAC carve-out, contending that CMS may be overestimating the impact of excluding KACs. They note that MA organizations continue to be responsible for the costs associated with the transplant procedure and subsequent medical care.

A few commenters requested that we explain why the estimates in the CY 2021 Advance Notice appear to diverge from the estimates included in the separate Contract Year 2021 and 2022 Medicare Advantage and Part D Proposed Rule (CMS-4190-P) (whereby the commenter indicated that the FFS Medicare cost of kidney acquisition would be an estimated $2.82 per member-per month (PMPM) in 2021). One commenter suggested that the methodology used for the $2.82 average impact should be used for the KAC carve-out applied to the MA rates.

Two commenters cited a study performed by another organization that analyzed a five percent sample of Medicare FFS claims data from the Limited Data Set (LDS)[3] over the period 2014 to 2018, and estimated a total of 11,340 kidney transplants for FFS Medicare beneficiaries in 2017, which would be 26% lower than the estimate of 15,436 CMS provided in the Proposed Rule. Further, the study estimated that only 20 of the 82 counties with a kidney acquisition carve-out rate above one percent had any kidney transplants identifiable in the LDS claims data. The commenters requested that we release additional information to allow for validation of the underlying cost and discharge data used to calculate the kidney acquisition cost carve-out factors.

Two commenters indicated that MA organizations' estimates of KACs are substantially lower than our estimated average of $4 PMPM, which the commenter believes may be attributable to FFS data including a greater proportion of kidney transplant patients compared to MA organizations. One commenter estimated from their own analysis of Cost Report data that the CY 2021 KAC impact would be estimated as an average of $2.12 PMPM.

Response: The Medicare FFS cost of kidney acquisitions that is described in the CY 2021 and 2022 Proposed Rule (CMS-4190-P) is on a different basis than the impact for the MA ratebook. In the Proposed Rule, the impact that is being calculated is the impact on the Medicare Trust Funds and not the MA ratebook. The calculations for the KACs in the Proposed Rule make adjustments that are not appropriate for the ratebook calculations. Some of these adjustments include enrollee coinsurance, average government share of gross savings, and net of Part B premium. As discussed above, the KAC carve-out methodology yields our best estimate of the pass-through amounts that are for kidney acquisition costs. We have released additional KAC cost and discharge data with this Rate Announcement. The KAC impact was conservatively

[3] https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets

estimated to average $4 PMPM in the CY 2021 Advance Notice based on preliminary data. The KAC carve out factors for CY 2021 MA rates are published with this Rate Announcement at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/.

Because some hospitals perform only a few kidney transplants, a five percent sample will likely have no transplants for some of these hospitals. To reemphasize, kidney acquisition costs paid through the pass-through amount are allocated over all Medicare discharges for these hospitals and added to the beneficiaries' counties of residence. Hence, counties with no transplant centers can have kidney acquisition costs because beneficiaries use transplant centers in nearby counties.

Comment: One commenter noted that according to the data that we provided in tables 26 and 27 in the CY 2021 and 2022 Proposed Rule (CMS-4190-P), there were approximately 75,000 kidney transplants paid by FFS during 2014-2018 (the data period used to compute the KAC carve-out amounts). The commenter expressed concern regarding the credibility of using 75,000 events to develop 3,225 county specific carve-out factors, and requested that the KAC factors be developed across broader geographic areas than counties in order to mitigate variability and potential credibility issues that may exist when forecasting county level carve-out amounts.

A second commenter also suggested that the KAC factors be developed at the state level, rather than county level, to reduce county variability, and citing the state-level determination of ESRD rates.

Response: The kidney acquisition costs included in the pass-through amounts are added to all discharges from kidney transplant centers by the county of the beneficiary's residence. Since the number of these discharges greatly exceeds the number of transplants, there is sufficient data to calculate credible kidney carve out factors and there is no need to adjust for credibility. Kidney acquisition costs are not allocated by the number of transplants. Since the pass-through KAC amounts are calculated and included at the county level, the carve-out factors must be developed at the county level to be consistent. We will continue to consider refinements for the future but are finalizing and using the methodology described in the Advance Notice to calculate the KAC carve-out amounts for the CY 2021 MA rates and benchmarks (for ESRD enrollees and non-ESRD enrollees).

Comment: Two commenters requested a quantitative example of the calculations in Step 5 of the KAC methodology, whereby the KAC per discharge is multiplied by the number of Medicare discharges in the kidney transplant center's FFS inpatient claims.

Response: The following table shows discharges from two transplant centers for residents in four counties. The transplant center in New Castle County has an average kidney acquisition cost per discharge of $300 whereas the transplant center in Philadelphia County has an average kidney acquisition cost per discharge of $600. The number of discharges of residents in a county is multiplied by the average KAC from the institution from which they are discharged to calculate the subtotal costs. The total costs is the sum of the subtotal costs.

County and State	Transplant center in New Castle, DE			Transplant center in Philadelphia, PA			Total Costs
	KAC per Discharge	Discharges	Subtotal Costs	KAC per Discharge	Discharges	Subtotal Costs	
Kent, DE	300	1,600	480,000	600	300	180,000	660,000
New Castle, DE	300	15,000	4,500,000	600	2,000	1,200,000	5,700,000
Sussex, DE	300	3,000	900,000	600	100	60,000	960,000
Philadelphia, PA	300	4,000	1,200,000	600	25,000	15,000,000	16,200,000

Comment: Two commenters expressed concern that the kidney acquisition carve-out methodology may disadvantage counties with a transplant center in or near them and recommended that the methodology be adjusted accordingly. The commenter believes that the methodology assumes that within a transplant facility, the percentage of kidney transplant discharges of total discharges by patient or county is equal. The commenter believes that counties farther from the transplant center may have a larger percentage of kidney transplant discharges since beneficiaries not receiving transplants may be utilizing hospitals closer to their residence.

Response: In the KAC methodology, the KACs are included in the county payment rate based on where the beneficiary resides, not based on the location of the transplant center. Since MA plans will no longer be required to cover the KACs, these costs have been carved out of each county's payment rate.

Comment: One commenter had interpreted that the KAC methodology was associated with determining whether the FFS beneficiary that was about to receive a transplant was in ESRD status. That is, the commenter believed that the KAC factors were applied to county versus state rates based on whether the FFS beneficiary was non-ESRD versus ESRD status. The commenter also questioned why/how non-ESRD beneficiaries would be in line for a kidney transplant and therefore have KAC factors applied to non-ESRD rates.

Another commenter stated that it was unclear why CMS is removing KACs from non-ESRD county rates, since kidney transplants typically occur in the ESRD population.

Response: The KAC methodology (detailed on pages 24-26 of Part II of the CY 2021 Advance Notice) does not distinguish costs based on whether the FFS beneficiary about to receive a

transplant was in ESRD status. Section 17006(b) of the 21st Century Cures Act (Pub. L. 114-255) amends sections 1853(k)(1) and 1853(n)(2)(E) of the Act to exclude the costs for kidney acquisitions from MA capitation rates and benchmarks beginning with 2021 (including the non-ESRD county rates). Therefore, while the cost of kidney acquisition is included in the total FFS data used to estimate the USPCC (that is, the FFS per capita cost) that forms the basis for the MA non-ESRD rates, the KAC carve-out factor is used to exclude those costs in order to comply with the statute.

As previously stated, kidney acquisition costs in the pass-through amounts are allocated to all Medicare discharges by county of residence. The carve-out methodology uses each provider's kidney acquisition cost per discharge for both the non-ESRD county rates and ESRD state rates. Because the distribution of discharges among providers differs between non-ESRD and ESRD, the sizes of the carve-outs are not the same.

Comment: One commenter suggested that the kidney acquisition carve-out be phased-in over time. Two commenters suggested that we consider MA organizations' data and actual experience with kidney acquisition costs in the KAC methodology. One commenter suggested that the KAC not be applied to the pre-ACA benchmark determination.

Response: While we appreciate the suggestions of commenters, these specific suggestions are not consistent with the statutory requirements for MA rate calculation and KAC carve-out. As amended by the 21st Century Cures Act, the statute is explicit that the KAC is to be removed from the pre-ACA applicable amount (per section 1853(k)(5)) and the ACA specified amount (per section 1853(n)(2)(A)(i) and (n)(2)(G)).

Comment: One commenter expressed concern that the KAC carve-out has negative consequences for MA payments. The commenter noted that plans will need to re-contract for transplant services to remove the cost of kidney acquisition, and believes it is unlikely the new contracts would carve out costs that are comparable to (or lower than) the costs being removed from the MA benchmarks. Another commenter expressed concern regarding a disproportionate impact the reduction in benchmarks will have with minimal or no claims reductions to offset the loss in revenue.

Response: We appreciate the concerns submitted by commenters regarding this issue but must comply with the statutory requirement to carve out the KAC amount.

Comment: Three commenters expressed concern that the KAC proposed methodology will impose disproportionate reductions for benchmarks in Puerto Rico, citing the preliminary carve-out factors that we published with the Advance Notice. One commenter stated that their own internal analysis estimates an average 1.3 percent reduction in Puerto Rico benchmarks.

One of the commenters suggested that the higher costs reflected in Puerto Rico may originate in any one of a number of factors: higher expenses for items, services, and transportation relative to

the mainland; historical low FFS funding to the Island health care system which delays implementing innovations and efficiencies; or an ever-diminishing number of FFS patients from which to extract average costs making outlier-driven swings more likely.

Three commenters recommended that we use the national average carve-out factor as a KAC proxy for the counties in Puerto Rico.

Response: We appreciate the concerns commenters have raised regarding KAC factors in Puerto Rico. As we stated in the CY 2018 Rate Announcement, we believe that the FFS data in Puerto Rico is sufficient for establishing accurate MA rates. Our approach to the KAC factor is consistent with that analysis and the statutory requirements.

Section E. ESRD Rates

Comment: Three commenters expressed appreciation for the additional transparency CMS will provide through the forthcoming publication of a rate calculation file with key components of the rate development to support the MA ESRD rates. Another commenter expressed appreciation for the enhancements made to derive the factors used in calculating the ESRD rates, such as the inclusion of innovation model payments.

Response: We appreciate the support.

Comment: A large number of commenters urged us to further evaluate the ESRD rates to assess whether they appropriately estimate the cost of care for the ESRD population, expressing concern regarding ESRD payment adequacy and accuracy, given the expected increased ESRD enrollment in MA beginning in CY 2021 as a result of the 21st Century Cures Act, which allows individuals with ESRD to enroll in MA.

Most commenters expressed concern that the ESRD benchmarks are not representative of the costs for ESRD beneficiaries in MA, resulting in underpayment. Many commenters highlighted potential consequences of inadequate rates, including the adoption of discriminatory benefit and network designs to discourage ESRD beneficiaries' enrollment, inhibited ability to deliver high quality care and services, increased premiums, and reduced benefits. Many commenters encouraged CMS to exercise its authority to adjust the ESRD rates to more accurately reflect costs.

Several commenters cited prior studies conducted by other organizations, where one such study estimated higher medical loss ratios for ESRD beneficiaries compared to non-ESRD beneficiaries and another study estimated ESRD payment shortfalls by Metropolitan Statistical Area. One commenter cited internal analysis of their plan data, which estimated higher medical loss ratios for ESRD beneficiaries compared to non-ESRD beneficiaries.

Response: We appreciate the concerns commenters have raised. We will continue to analyze these issues and consider whether, consistent with the statutory requirements for setting ESRD

rates in section 1853(a)(1)(H) of the Act, any refinements to the methodology may be warranted in future years.

Comment: One commenter appreciated that, in the CY 2021 and 2022 Proposed Rule (CMS-4190-P), we provided projections of the magnitude of ESRD migration from FFS to MA in 2021 and in future years, and that OACT also provided, in the February Actuarial User Group Call Bid Questions document, a projection of the financial impact of ESRD migration from FFS to MA.

The commenter expressed concern with the data available for such projections. The commenter noted that the Bid Pricing Tool Worksheet 1 data includes all ESRD beneficiaries (dialysis, transplant, and post-graft), and the commenter believes that dialysis beneficiaries would be more financially incentivized to migrate from FFS to MA and therefore concludes that the impacts are underestimated.

Also, the commenter disagreed with the projected MLRs for ESRD beneficiaries, given their expected migration pattern of dialysis patients. Further, the commenter noted that the projections did not reflect expected changes in ESRD risk scores and also disagreed with the projections regarding ESRD beneficiaries in EGWPs.

The commenter suggested that we produce a range of financial impacts based on the size of the possible migrating population.

Another commenter recommended that we conduct and share the results of an analysis of the adequacy of ESRD rates and further suggested that we evaluate ESRD rates against dialysis provider payments in the commercial and MA markets.

Response: We appreciate the feedback provided by the commenters and will continue to analyze these issues as additional data emerges.

Comment: A number of commenters requested that we study the development of ESRD rates on a smaller geographic basis to better reflect cost differences between urban and rural areas, such as developing ESRD rates by county or Metropolitan Statistical Area with the use of ESRD credibility factors, expressing concern that the state-level ESRD rates would not accurately reflect the variation in costs of care for ESRD patients in different geographic areas within a state.

Response: We appreciate the suggestion submitted by commenters regarding this issue. We will continue to analyze these issues and consider whether, consistent with the statutory requirements for setting ESRD rates in section 1853(a)(1)(H) of the Act, any refinements to the methodology may be warranted in future years regarding the geographic level of ESRD rates. Further, we believe that significant changes to the current methodology, especially of the magnitude described by the commenters, should be fully examined and included in the Advance Notice and subject to notice and comment before they are adopted.

Comment: Commenters provided additional suggestions for revisions to ESRD benchmarks and payment.

Four commenters indicated that quality bonus payments should be applied to ESRD rates, with one commenter also suggesting a separate ESRD benchmark cap and another recommending that we apply quartile adjustments to the ESRD rates. One of the commenters believed that the statute directs us to apply quality bonuses at the contract/plan level, and therefore the quality bonuses should be applied to the entire contract/plan rather than only to non-ESRD beneficiaries.

Some commenters suggested that we adjust MA rates for ESRD Dialysis beneficiaries to reflect the impact of maximum out-of-pocket (MOOP) cost requirements in MA.

One commenter suggested that MA plans should be compensated for ESRD beneficiaries' supplemental benefits via MA rebates paid to plans for their ESRD beneficiaries. Another commenter suggested that we may need to consider alternate revenue models.

Response: While we appreciate the suggestions of commenters, we do not find these specific suggestions to be consistent with our interpretation of section 1853 as a whole that the legislative intent is for us to more closely align MA payment rates with fee-for-service costs and the statutory requirements for ESRD rate calculation. Section 1853(o) is clear that the quality bonus payment is applied to the applicable percentage used to calculate the applicable amount under section 1853(n) while ESRD rates are set pursuant to section 1853(a)(1)(H). Further section 1854 is clear that beneficiary rebates are set based on the amount by which the benchmark exceeds the MA plan's bid; as MA plans do not submit bids for ESRD capitation payments, there is no authority to calculate and pay rebates with ESRD rates.

Comment: A number of commenters suggested the creation of a voluntary nationwide transitional demonstration to help plans manage risk related to ESRD enrollment through risk corridors either based on a plan's ESRD-specific MLR, structured as a cost-based reimbursement formula with shared savings if actual costs are less than a target benchmark, or structured similarly to the Part D risk corridors.

One commenter suggested a demonstration to carve out the dialysis bundle from MA payment, paying dialysis providers directly at FFS levels, citing the carve-out of certain services rendered in clinical trials.

One commenter suggested a demonstration to adjust ESRD benchmarks to reflect the impact of maximum out-of-pocket (MOOP) cost requirements in MA.

Three commenters suggested that the MA Bid Pricing Tool be revised to permit ESRD costs to be included in the plan bid.

Response: We appreciate the suggestions submitted by commenters. Potential demonstrations and changes to the MA Bid Pricing Tool are outside the scope of this document.

Comment: Commenters suggested that the underlying ESRD Prospective Payment System (PPS) does not adequately cover the costs of care for beneficiaries and leads to the development of inadequate MA ESRD rates, citing analyses of the PPS by MedPAC and another outside organization. One commenter believed that MA's comparatively higher utilization for care of ESRD beneficiaries would indicate that the care provided by Medicare FFS for ESRD beneficiaries is inadequate. Two commenters noted that the high costs of ESRD drives bad debt.

Response: We appreciate the feedback provided by commenters regarding this issue. The development of the ESRD PPS is outside of the scope of this document and we encourage commenters to review and respond to the appropriate rulemaking for that payment system.

Comment: Numerous commenters expressed concern about the highly-concentrated nature of the dialysis provider market, citing the small number of organizations operating most of the dialysis stations in the United States. These commenters indicated that the concentration of dialysis providers and network adequacy requirements affect an MA organization's ability to negotiate reasonable reimbursement for dialysis services.

Response: We appreciate the feedback provided by commenters regarding this issue.

Comment: One commenter requested additional opportunities and timely information to better understand the development of payment components, such as changes in FFS payment systems. This commenter expressed concern that the data used to construct the dialysis-only USPCC may not capture and reflect MA plans' ESRD-related costs in a timely manner. This commenter expressed concern regarding any lags in the data used for rate development to reflect changes such as a coverage shift or the introduction of a new treatment, which could undermine enrollees' access to new and innovative treatments. The commenter suggested that we adopt approaches to reimburse plans for services before FFS expenditures fully incorporate such changes, and noted that we could accomplish this objective by establishing a direct pass-through payment to MA plans or by applying a separate adjustment to MA ESRD payments.

Further, the commenter expressed concern that the Comprehensive ESRD Care (CEC) model has a lag time in determining savings and losses that could impact FFS ESRD costs used for rate development.

Response: The CY 2021 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, as applicable, CY 2020 or FY 2020.

The expected net aggregate performance payments of Medicare trust fund experience and projections for alternative care delivery models are reflected in the national USPCC calculations. Further, similar to the methodology used for non-ESRD FFS cost tabulations, we only include in

historical claims performance payments that have been reconciled with providers and/or sponsoring organizations, since the adjustments can vary geographically.

Comment: Commenters cited decreases in the ESRD rates in Puerto Rico, which they indicated results in funding inadequacies for ESRD beneficiaries in Puerto Rico. These commenters expressed concern that we underrepresent the actual costs for dialysis in Puerto Rico in the ESRD rates, and commented on the level of ESRD rates in Puerto Rico being lower than the nationwide average.

Commenters provided suggestions for rate adjustments that we should consider, such as establishing an AGA floor or using a proxy benchmark.

One commenter indicated that since there are only two dialysis providers in Puerto Rico, ESRD patients have limited options and MA organizations face difficulty in negotiating reasonable rates.

One commenter expressed concern with the wage index data used in the ESRD PPS for Puerto Rico.

Response: We appreciate the concerns and suggestions that commenters have raised regarding ESRD rates in Puerto Rico. We will continue to analyze these issues and consider whether, consistent with the statutory requirements for setting ESRD rates in section 1853(a)(1)(H) of the Act, any refinements to the methodology may be warranted in future years. As we stated in the 2018 Rate Announcement, we believe that the FFS data in Puerto Rico is sufficient for establishing accurate MA rates as well as consistent with the statutory requirements. Finally, the development of the ESRD PPS is outside of the scope of this document and we encourage commenters to review and respond to the appropriate rulemaking for that payment system.

Section F. MA Employer Group Waiver Plans

The bid-to-benchmark ratios applied in calculating 2021 MA EGWP Payment Rates are:

Applicable Percentage	Bid to Benchmark Ratio
0.95	84.2%
1	85.1%
1.075	84.9%
1.15	85.1%

We will continue to use the steps in the payment methodology for 2021, as well as the applicable rules, as described in the CY 2021 Advance Notice.

Comment: The majority of commenters expressed support for the proposal to continue the 2020 payment methodology that differentiates between PPO and HMO EGWP and individual market plans and expressed a desire to maintain stability in the EGWP market.

The majority of commenters expressed appreciation and support for the proposal to continue the 2020 payment methodology enhancement to permit EGWPs to buy-down the Part B premium for their enrollees.

Response: We appreciate the support.

Comment: Several commenters recommended that we publish preliminary bid-to-benchmark ratios in the Advance Notice or earlier, using prior year bids weighted by either December or the most current enrollment available at the time of release.

Response: As described in the Advance Notice, in order to have the most accurate and up-to-date data about enrollment incorporated into the payment methodology, the bid-to-benchmark ratios used for 2021 payment have been calculated using February 2020 enrollment, which was not available at the time Part II of the CY 2021 Advance Notice was published. We finalized use of the February enrollment in calculating the bid-to-benchmark ratios in the CY 2020 Rate Announcement in order to have the most accurate data available incorporated into the payment methodology for the bid-to-benchmark ratios used for payment. We note that there are usually updates to enrollment data from the beginning of the contract year reflected by February. We are concerned that if we were to use either December or January enrollment as a proxy to calculate preliminary bid-to-benchmark ratios for the Advance Notice or an earlier release, they may not be representative of the final bid-to-benchmark ratios that use February enrollment in the calculation. Notwithstanding the foregoing, we appreciate these commenters' concerns and will consider whether publishing preliminary information in future years would be helpful to have a more robust understanding of this policy.

Comment: One commenter recommended a refinement to the proposed implementation of the Part B premium buy-down whereby CMS would establish segment IDs that correspond to different Part B premium buy-down amounts in the plan benefit package (PBP) to reduce the number of EGWP PBPs submitted for various Part B premium buy-down amounts.

Response: As described in the CY 2021 Advance Notice, when an individual market MA organization submits a plan bid to us, the MA organization is permitted to use MA rebates to buy-down a portion of the Part B premiums for its enrollees in each plan by identifying the buy-down amount in the bid pricing tool. We then retain the rebate amount specified by the MA organization for each plan and coordinate directly with the Social Security Administration (SSA) to ensure that each beneficiary's Part B premium is appropriately calculated and withheld from the beneficiary's Social Security check or billed to the beneficiary. Implementing the waiver as described facilitates the communication of this information from CMS to SSA by maintaining a similar operational structure to that which exists for individual market MA organizations and puts MA EGWPs on equal footing with individual market plans. Notwithstanding the foregoing, we appreciate the considered thoughts on this issue, and will continue to analyze and explore suggestions for refinements to this policy in the future.

Comment: One commenter opposed continuing to waive Part C bidding requirements for sponsors of Part C EGWPs, asserting that we should reinstate the annual Part C EGWP bidding process that existed prior to 2017.

Response: As we have stated previously, we continue to believe that the policy of allowing MA organizations 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 in prior years, the alternative to the composite bids submitted prior to 2017 would require significantly more information to be collected, submitted, and reviewed by us. Moreover, it would require reverting to the statutory and regulatory requirement of requiring EGWP sponsors to submit for our review and approval benefit packages and bids for each of their employer plans. We have consistently concluded that the administrative burden for not just the government, but for MA organizations and employers, of such an approach would substantially hinder the offering of these plans as MA organizations 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 would be more difficult, or perhaps impermissible. We continue to believe that the policy being finalized for 2021 has the correct balance of facilitating the offering of these valuable products by reducing significant burden and increasing payment accuracy for these offerings.

Section G. CMS-HCC Risk Adjustment Model for CY 2021

Comment: Most commenters expressed support of the 2020 CMS-HCC risk adjustment model (Alternative Payment Condition Count, or APCC, model) as proposed for CY 2021. They noted its improved accuracy in predicting costs for beneficiaries with multiple chronic diseases and indicated that a full phase-in of the 2020 model would reduce the complexity and administrative burden of having two models. Commenters also appreciated the inclusion of specific conditions, including chronic kidney disease, mental health and substance abuse, and dementia, in the model. The majority of commenters were in support of the current phase-in of the 2020 CMS-HCC risk adjustment model, having a weight of 75% for CY 2021. A couple of commenters proposed full implementation of the 2020 model for CY 2021.

Response: We thank the commenters for their support of phasing in the 2020 CMS-HCC risk adjustment model, which meets the requirements of the 21st Century Cures Act and includes additional HCCs for dementia and pressure ulcers, as well as variables that account for the number of conditions a beneficiary may have, and makes an adjustment as the number of conditions increase. For CY 2021, we are finalizing the phase-in of the 2020 CMS-HCC model as proposed: 75 percent of the risk score will be calculated with the 2020 CMS-HCC model and 25 percent of the risk score will be calculated with the 2017 CMS-HCC model.

Comment: Several commenters expressed concern around the accuracy of the 2020 CMS-HCC risk adjustment model for predicting costs, particularly for certain demographic categories such as gender and dual eligibility, with a request for us to review the predictive accuracy of the model. One commenter questioned the need for the inclusion of condition counts in the current model, given that the model is already additive.

Response: We appreciate concerns regarding the predictability of the 2020 CMS-HCC model for certain demographic categories. A 2017 major model revision was aimed at improving the prediction of dual eligible beneficiaries. Recent updates made to the model were aimed at improving the accuracy of cost across subgroups of beneficiaries in the program, including beneficiaries with dementia and pressure ulcers, who as a group are a medically complex, high cost population, and those with multiple chronic conditions; these model improvements were made in response to the 21st Century Cures Act.

The count variables in the 2020 model count the 86 conditions (HCCs) that are included in that model for payment. Including a count of payment conditions in the model (most of which are chronic conditions) improves the accuracy of prediction by count of payment conditions (the predictive ratios are closer to 1.0). The 21st Century Cures Act requires that a specific adjustment for the number of conditions that a beneficiary has be included in the model and that this adjustment be fully phased-in by 2022.

We will continue to explore options for improving the accuracy of the model for other subgroups.

Comment: Some commenters recommended different methods for updating the CMS-HCC risk adjustment model, including recalibration based on the most current diagnostic data available to include ICD-10 codes, using two years of data, making updates on an annual basis, the addition of risk adjustment conditions to the risk adjustment model (e.g., COVID-19, Chronic Kidney Disease Stages 3A and 3B (CKD3a and CKD3b)), and calibration of the model using encounter data. Other commenters appreciated having a predictable risk adjustment model. A couple of commenters recommended that we allow telehealth encounters for risk adjustment purposes and requested clarifying guidance regarding the inclusion of diagnoses from telehealth encounters in risk adjustment.

Response: We appreciate commenters' suggestions on updating the CMS-HCC risk adjustment model. As discussed in the 2018 Report to Congress: Risk Adjustment in Medicare Advantage[4], calibrating a model with ICD-10 diagnoses will be one of our primary considerations moving forward. Individual HCC variable coefficients are influenced by a number of factors, such as the prevalence rate of the HCC variable in the population used to calibrate the risk adjustment

[4] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/RTC-Dec2018.pdf

model, and the prevalence rate of associated HCCs. We acknowledge the important implications that certain conditions, including COVID-19 may have on certain populations, and will take commenters' concerns and suggestions into consideration for future years. Regarding telehealth, CMS has considered comments and recommendations we have received and is issuing separate guidance on this topic.

Comment: A few commenters stated they would like to see increased transparency in the methodology used to update the model, and the release of sufficient details and data for plans to adequately assess model revisions. Commenters also expressed a desire for increased collaboration and engagement with stakeholders, with requests that we work with stakeholders to design and develop a model for use in future payment years. Commenters expressed appreciation for the 60-day review and comment period, urging us to continue our efforts to enhance transparency and engagement with stakeholders by providing at least 60 days for stakeholders to comment on future risk adjustment proposals.

Response: We will consider additional ways in which we can engage with stakeholders as we consider changes to the CMS-HCC risk adjustment model for future years. We also thank commenters for their support of the 60-day comment and review period. As amended by the 21st Century Cures Act, section 1853(a)(1)(I)(iii) of the Act requires that we provide at least 60 days for public review and comment of proposed changes under section 1853(a)(1)(I) to the Part C risk adjustment model.

Comment: A commenter requested that we clarify why some HCCs, such as HCC 115 (Pneumococcal Pneumonia, Empyema, and Lung Abscess), HCC 76 (Muscular Dystrophy), and HCC 74 (Cerebral Palsy) are constrained to zero in some segments in the 2020 model and not constrained in the 2017 CMS-HCC model. The commenter also asked for clarification as to who is being counted in the condition count.

Response: As explained in the CY 2020 Advance Notice Part I,[5] HCCs are constrained to zero if the coefficient is negative. While a model with negative coefficients would have produced reliable estimates, a long-standing principle of the risk adjustment model is that plans should not be penalized for submitting additional diagnostic information. Implementing a model with negative coefficients for HCCs would have, in some cases, reduced risk scores if an additional HCC were submitted.

When the data years and model specifications change, the coefficients for some HCCs that are less prevalent can become negative. The data years for the 2017 CMS-HCC model versus the 2020 model differ. The 2017 CMS-HCC model was calibrated with 2013 diagnoses and 2014 costs, while the 2020 model was calibrated based on 2014 diagnoses and 2015 costs. In addition, the specification is different between the 2017 CMS-HCC model and the 2020 models: the 2020

[5] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part1.pdf

model has more conditions and includes count variables for the number of conditions a beneficiary may have. We found that HCC 74's coefficient is frequently affected by changes in associated paralysis HCCs, especially in the segments where the count of HCCs starts higher, and that HCC 76 in the partial dual aged segment and HCC 115 in disabled segments have small sample sizes.

The count variables in the 2020 model count the 86 conditions (HCCs) that are included in that model for payment. A beneficiary is credited with having an HCC if any diagnosis that maps to one of the HCCs in the model (even if that HCC has a coefficient of zero) is submitted to CMS.

Section H. ESRD Risk Adjustment Model for CY 2021

For 2021, CMS is finalizing its proposal and will sum 25% of the risk score calculated with the 2019 ESRD models, using diagnoses from RAPS and FFS with 75% of the risk score calculated with the 2020 ESRD models, using diagnoses from encounter data, RAPS inpatient records, and FFS. For PACE organizations, we will continue to calculate ESRD risk scores for CY 2021 using the 2019 ESRD dialysis and ESRD functioning graft models.

Comment: Many commenters encouraged CMS to continue efforts to evaluate and further refine the ESRD risk adjustment model, particularly in light of the 21st Century Cures Act permitting broader enrollment of ESRD beneficiaries in MA plans in 2021. One commenter noted that the true cost among future MA beneficiaries with ESRD is uncertain and expressed concern that modeling will rely on broad assumptions that all ESRD patients, regardless of duration of ESRD, are financially similar. Another commenter was concerned that ESRD payment is currently inadequate to properly manage these complex ESRD patients and noted that CMS should undertake a full review of the ESRD risk adjustment model, including a review of the appropriateness of the dialysis and transplant segments of the model.

Response: We appreciate the comments and acknowledge the commenters' concerns and will continue to evaluate the ESRD risk adjustment model in the future. For 2021, we will calculate risk scores for payment of ESRD beneficiaries in MA plans and certain demonstrations by continuing to use the ESRD models implemented in 2019 and 2020 as proposed in the 2021 Advance Notice Part II. Specifically, 75% of the risk score calculated with the 2020 ESRD models will be summed with 25% of the risk score calculated with the 2019 ESRD models.

Comment: In the 2020 Rate Announcement, CMS implemented an adjustment to the coefficients for the dialysis new enrollee segment to address the over-prediction of costs for this segment. Several commenters expressed concern about this dialysis new enrollee adjustment and disagreed with CMS' approach to adjusting the coefficients for this segment and questioned the validity of the adjustment. The commenters requested that CMS either reassess the dialysis new enrollee adjustment or, at a minimum, not apply the adjustment for 2021. The commenters also noted that if CMS maintains that a larger dialysis new enrollee sample is necessary, they urged CMS to consider other options, such as calibrating on the true new enrollee sample, or multi-year

cohorts, to achieve a sample that better reflects costs for this segment. One commenter was concerned that including the costs of beneficiaries on dialysis for three years or more distorts the risk score for beneficiaries newly on dialysis. Another commenter noted their belief that postponing the proposed reduction would not impact the ESRD dialysis normalization factor.

Response: We appreciate comments suggesting possible alternative ways to calibrate the dialysis new enrollee segment of the model. Since the new enrollee segment of the ESRD dialysis risk adjustment model distinguishes predicted costs by a set of demographic attributes (age, sex, Medicaid status, and Originally Disabled status), it is necessary to have a large enough model sample to achieve sufficient sample sizes for each variable in order to generate coefficients for each variable in the model. Even when using the entire set of new enrollee dialysis beneficiaries, there is an inadequate number of beneficiaries to calibrate each variable in the dialysis new enrollee model. Thus, the ESRD dialysis new enrollee model segment is calibrated using a combined modeling sample of dialysis new enrollees and continuing enrollees who have been on dialysis for three years or less.

As a reminder, the "new" in the description of this cohort is about Medicare Part B enrollment, not length of time on dialysis or enrollment in a Medicare Advantage plan. New enrollees are those who have fewer than 12 months of Part B in the data collection period; new enrollees include any beneficiaries who have been on dialysis for more than 12 months, but are not enrolled in Part B for part or all of the data collection period. Continuing enrollees are those who have 12 months of Part B in the data collection year; continuing enrollees include beneficiaries who are within the first 12 months of dialysis, but have been enrolled in Part B for all 12 months of the data collection period. For example, a Medicare beneficiary who is entitled to Part A and enrolled in Part B for two years before beginning dialysis would be in the continuing enrollee dialysis group, and we would calculate their risk score with HCCs. As we described in Part II of the CY 2020 Advance Notice, the dialysis new enrollee modeling sample comprises both true new enrollees as well as a supplement of continuing enrollees who have been on dialysis for three years or less to increase the sample size for the purpose of establishing coefficients for the new enrollee model. We note that true new enrollees have lower overall costs than the continuing enrollees included in the dialysis new enrollee model sample, indicating that the average cost of the continuing enrollees is increasing the average cost of the entire dialysis new enrollee model sample (i.e., combined true new enrollee and supplemental continuing enrollees) that we used to calibrate the new enrollee model. These higher costs are driven by a large group of beneficiaries among the continuing enrollees in the new enrollee model sample who are within the first 12 months of dialysis.

We would also like to clarify that the dialysis new enrollee relative factors are applied in payment only to enrollees who do not have 12 months of Part B enrollment in the data collection period. Enrollees who are newly enrolled in an MA plan, or who are newly on dialysis, but who have 12 months of Part B enrollment in the data collection period, are considered continuing

enrollees and we calculate their risk scores using the continuing enrollee dialysis segment, which includes HCCs.

The dialysis new enrollee model sample has mean expenditures of $72,243 in our 2015 expenditure year data. In our model recalibration and evaluation, we conducted predictive ratio analyses for true dialysis new enrollees (e.g., those without full year Part B enrollment in the data collection period), excluding the continuing enrollees who were part of the modeling sample. We examined age-sex breakouts for the full set of these true new enrollees, the non-Medicaid subgroup, and the Medicaid subgroup. The predictive ratios consistently showed over-prediction for the true dialysis new enrollees: as we described in the 2018 Report to Congress and the CY 2020 Advance Notice, the average over-prediction was 14.9 percent. For broad groups of dialysis new enrollees, including the Non-Aged (age<65) and Aged (age 65+) subgroups, the over-prediction ranged from 10 percent (for the Medicaid Aged subgroup) to 20 percent (for the non-Medicaid Non-Aged subgroup). For every age-sex variable (e.g., Males, Age 65-69), the model over-predicted the true dialysis new enrollees, ranging from 5 percent to more than 45 percent over-prediction.

We note that we also made adjustments for the post-graft new enrollee and institutional segments as a result of our analysis of the predictive ratios – these segments under-predicted the costs of the applicable population, and we increased the factors in the model segments for these groups. The need for these changes is a result of the need to use alternate model samples for a similar reason (i.e., because the true post-graft new enrollee and LTI samples are not large enough to generate all the coefficients in the post-graft model for these segments), we have, therefore, amended the samples with additional diagnoses. We believe that we have balanced the need for accurate payment by increasing the factors where there are under-predictions, and reducing the factors where there are over-predictions, due to small sample sizes.

For the reasons described above, we will continue to apply the adjustments finalized in the CY 2020 Rate Announcement to the dialysis new enrollee, post-graft new enrollee, and post-graft LTI segments of the model to improve payment accuracy. We will continue to evaluate the ESRD models and potential model calibration methodologies that improve the predictive accuracy of the models.

Comment: Some commenters requested specific modifications to the ESRD model for CY 2020, including:

- developing a concurrent risk adjustment model,
- risk score adjustments to account for high risk beneficiaries with multiple co-morbidities,
- recalibrating the ESRD model more frequently to increase the accuracy of the model and decrease the impact of the normalization factor,

- calculating risk scores for beneficiaries with the ESRD model immediately after they have a dialysis diagnosis instead of waiting for notification from the dialysis center,
- amending how CMS calculates new enrollee factors by allowing members to be considered full risk for risk score calculations if an HCC is identified during the calendar year, and
- that CMS consider if the removal of the organ acquisition costs from the MA county and state ESRD benchmarks may impact the accuracy of the ESRD risk adjustment models.

Some commenters requested that CMS release any related data and analysis related to these recommendations.

Response: We appreciate the comments and recommendations for updates to the ESRD model. We are not implementing these commenters' recommendations for the ESRD model used for risk adjusted payments in CY 2021 because we believe that the existing 2020 model (which is calibrated on more recent data, is calibrated using diagnoses filtered based on the same approach used to filter encounter data, and includes adjustments to correct for the under-prediction and over-prediction of costs for small subpopulations), will improve risk adjustment payments for beneficiaries with ESRD. As previously noted, we will continue to analyze and consider these recommendations and whether any refinements to the methodology for the ESRD model calibration may be warranted in future years.

The 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 enrollment 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.

Comment: A few commenters raised concern over the transplant factors. One commenter expressed concern that the ESRD model undervalues costs associated with transplantation and encouraged CMS to revisit the model for ESRD kidney transplant beneficiaries. Specifically, the commenter recommended that CMS consider the costs of multi-organ transplants. The commenter also indicated that it is unclear how the costs of dialysis during the month of transplantation are factored into the model. Another commenter noted that there may be significant variation in the non-organ acquisition costs of transplantation within a state, and transplant factors based on a state-wide average transplant cost rate may significantly underpay some transplant centers. The commenter recommended that CMS consider modifying the payment formula to determine the transplant factor based at least in part on the historical costs of the transplant center involved.

Response: We believe that the risk adjustment model and payment for MA enrollees in the month of and two months after the transplant are appropriately calibrated. As with all the other risk adjustment models, the transplant factors are national risk factors. To account for geographic cost differences, we multiply these factors by the dialysis state rates in payment. CMS calibrated the transplant factors by including FFS expenditures for the transplant and physician and other services rendered for the hospital stay and the two months after discharge. Therefore, the transplant factors would include the cost of dialysis that occurred during the hospital stay.

Transplant factors are used to pay for a transplant over three months: the month of transplant and the two months following a transplant. To accommodate the high one-time cost of a transplant, CMS makes these payments over three months to cover the transplant and immediate subsequent services. The first month's factor is the largest, as that is the month within which the transplant takes place, while the factors for months two and three are smaller for post-transplant recovery. Most of the costs of a transplant accrue in the month of the transplant and the ESRD transplant factors account for this fact. By paying the majority of the cost in the month of transplant, CMS is ensuring that MA organizations are not disadvantaged if the enrollee dies in the month of transplant.

Comment: One commenter requested that CMS engage with stakeholders regarding further revisions to the ESRD model for 2021 and requested that future updates to the ESRD risk adjustment model be communicated under a similar timeline as the CMS-HCC model (i.e., CMS should allow stakeholders at least 60 days to review and submit comments on all risk adjustment model proposals) to ensure effective feedback. Another commenter asked that CMS provide information regarding the impact of the 2019 revisions of the ESRD risk adjustment model.

Response: We appreciate the comment. We will consider ways that we can engage with stakeholders, share additional information, and provide time for public feedback for model changes as we continue to explore ways to improve the predictive accuracy of the ESRD risk adjustment model and in future reports to Congress.

When we proposed the 2019 ESRD model changes, we provided additional information that we believed would be helpful to plans and commenters. In addition to providing the ESRD model relative factors in the CY 2019 Rate Announcement, CMS provided ESRD risk scores under the ESRD risk adjustment model described in the CY 2019 Advance Notice. Specifically, we released plan level risk scores in HPMS on February 12, 2019 under the 2019 and 2020 ESRD models, which are the same models that will be used for calculating CY 2021 ESRD risk scores, so that MAOs could assess the impact of the update of the 2020 ESRD model, including the impact of beneficiaries in different segments of the model (e.g., dialysis versus transplant). We note that the 60-day comment period for changes to the CMS-HCC model that we are continuing to phase-in is required by the Cures Act.

Section I. CMS-HCC Risk Adjustment Used for PACE Organizations in CY 2021

Comment: Commenters supported CMS' decision to utilize the 2017 CMS-HCC model for PACE payment in 2021, acknowledging that the 2017 CMS-HCC model is an improvement over the prior model applied to PACE; however, they also expressed concern that the model excludes dementia and other chronic conditions (such as pressure ulcer, moderate chronic kidney disease, and mental health and substance use disorders) that are prevalent in the PACE population. Commenters requested that the 2020 CMS-HCC model, which includes dementia HCCs, be used for PACE enrollees as expeditiously as possible.

Response: We appreciate the support for use of the 2017 CMS-HCC model for PACE payment in 2021, which will be a continuation of the 2020 risk adjustment policy. We acknowledge concerns from commenters that the 2017 CMS-HCC model does not include the dementia HCCs and the request by some commenters to expeditiously implement the 2020 CMS-HCC model for payment to PACE organizations. The 2020 CMS-HCC model is calibrated using the same approach to identifying risk adjustment eligible diagnoses as is used to identify diagnoses on encounter data records. As such, the 2020 model is intended to calculate risk scores using diagnoses submitted on encounter data records. Since we are not calculating separate encounter data and RAPS risk scores for PACE in 2021, we cannot implement the 2020 model for PACE at this time. CMS will continue to work closely with PACE organizations to develop further guidance and provide technical assistance with encounter data submissions in anticipation of implementing the risk adjustment model used for MA for PACE payment in the future.

Comment: Commenters are concerned that the increases in frailty factors implemented in the 2017 CMS-HCC model do not fully account for the level of dementia diagnosed in PACE participants and the costs associated with their care. The commenters also believe that the frailty factors are not representative of the PACE population because response rates to the Modified Health Outcomes Survey (HOS-M) are low among many PACE organizations and are likely even lower among patients with dementia. To this end, the commenters are requesting flexibility in the administration of the HOS-M survey for patients with dementia if the 2020 model cannot be implemented for PACE enrollees in 2021. Commenters are requesting that PACE organizations be allowed to proactively offer their participants with dementia assistance in completing the survey.

Response: For beneficiaries with conditions that are not directly incorporated in the 2017 CMS-HCC model, such as dementia, the associated costs can be predicted by comorbid conditions and demographic factors; to the extent that these costs are not predicted by the model, they are more likely to be reflected in the frailty factors. However, while the costs are included in the calibration, results for individual plans may differ due to differences between the calibration sample and the population enrolled in the plan.

We acknowledge the concerns related to the response rates for the HOS-M survey for PACE enrollees, especially those enrollees with dementia. The responses from this survey are used to determine a beneficiary's limitations in activities of daily living that are accounted for in the calculation of a contract's frailty score. We collect survey data in a consistent manner for all PACE organizations, as this helps to ensure equitable frailty results for payment. Permitting variation in how the survey is administered for participants with certain specific conditions might disproportionately affect the frailty scores for certain organizations, depending on what proportion of an organization's participants has that condition. For the HOS-M, a proxy response will remain under the control of the beneficiary, but PACE staff may check with family or a caregiver to determine if participants with dementia need assistance with the survey.

Section J. Frailty Adjustment for PACE Organizations and FIDE SNPs

Comment: Commenters expressed continued support of the proposal to blend the frailty scores from the frailty factors associated with the 2017 CMS-HCC risk adjustment model and the frailty factors associated with the 2020 CMS-HCC risk adjustment model to determine the payment to qualifying FIDE SNPs.

Response: CMS appreciates the support.

Comment: A commenter expressed concern regarding the impact of blending the frailty score on plans that serve a high proportion of dual eligible individuals who have three or more ADL limitations since frailty factors for those ADL groups decrease under the 2020 CMS-HCC model. The commenter also requested more information on the impacts of the frailty factor changes.

Response: For each CMS-HCC risk adjustment model calibration, CMS also calibrates a unique set of frailty factors. This is because the frailty factors predict costs that a CMS-HCC model does not predict. When a risk adjustment model predicts higher costs for some beneficiaries (e.g., dual eligible beneficiaries), the related frailty factors tend to decrease, since there are fewer costs left to predict outside the risk score. Because there is a unique set of frailty factors for each CMS-HCC model, when we blend risk scores calculated with two different risk adjustment models, we need to also blend frailty scores calculated with the sets of frailty factors associated with each risk adjustment model. Like the blend applied to the risk adjustment scores used in MA payment for 2021 (including FIDE SNPs), the frailty score will also be calculated as a blend for FIDE SNPs. The frailty score used in payment for FIDE SNPs will be calculated using the data from beneficiaries who respond to the survey; these frailty scores for payment will be calculated by blending the frailty scores calculated using the set of frailty factors associated with the APCC risk adjustment model and the set of frailty factors associated with the 2017 CMS-HCC model. The two frailty scores will then be blended such that 75% of the frailty score calculated from the APCC model frailty factors is summed with 25% of the frailty score calculated from the 2017 CMS-HCC model frailty factors. The blended frailty score will be compared to the PACE level

of frailty in the same manner as for CY 2020 to determine whether that FIDE SNP has a similar average level of frailty as PACE.

Comment: Some commenters recommended that CMS include frailty and functional status as risk adjustment factors for MMPs or for all MA programs and for all MA beneficiaries.

Response: By law, CMS must use the same payment methodology for non-ESRD enrollees in MA plans, including Special Needs Plans (SNPs), except as explicitly provided for in statute. For example, section 1853(a)(1)(B)(iv) of the Act authorizes CMS to make frailty-adjusted payments to certain dual SNPs – those with fully integrated, capitated contracts with states for Medicaid benefits, including long term care, and which have similar average levels of frailty as the PACE program. Thus, CMS cannot make frailty payments to any SNP that does not meet these criteria without implementing frailty payments program-wide.

CMS has explored ways of incorporating frailty into the risk adjustment model in order to account for frailty when making risk adjusted payments to all plans and found challenges with a number of approaches (see the "Evaluation of the CMS-HCC Risk Adjustment Model," published March 2011, at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Evaluation_Risk_Adj_Model_2011.pdf). The CMS-HCC model is intended to accurately pay plans with average risk profiles, unlike PACE organizations and qualifying FIDE SNPs that have higher than average risk profiles and are eligible to receive frailty payments. Because the frailty factors are calibrated using the residual of the CMS-HCC model (the difference between the predicted expenditure amounts and the actual expenditure amounts), and frailty scores have an average value of zero, the application of a frailty adjustment to all MA plans would result in some plans receiving a negative frailty adjustment. Finally, frailty adjustments are calculated using survey data gathered from enrollees of PACE organizations and FIDE SNPs and are calculated at the contract level for PACE organizations and at the plan level for FIDE SNPs. Because of the timing of these data collections, implementing the commenter's recommendation would require all plans to submit their bids prior to the payment year without knowing what their frailty adjustment would be for that year. While this process is in place for FIDE-SNPs, we are concerned that using such a process for all plans, especially with the risk of decreases to risk scores overall, would cause disruption in the bidding process.

For PACE organizations, we will continue to use the 2017 CMS-HCC model to calculate risk scores used to pay for Part A and B services in CY 2021. Consistent with the proposal in Part I of the 2021 Advance Notice, we will use the frailty factors associated with the 2017 CMS-HCC model to calculate frailty scores for PACE organizations in CY 2021.

Determination of whether the frailty adjustment will be applied to MMPs as part of that demonstration is outside the scope of this Rate Announcement.

Section K. Medicare Advantage Coding Pattern Adjustment

Comment: The majority of commenters were pleased that we proposed the statutory minimum and supported our application of the proposed 5.90% for the 2021 coding pattern adjustment.

Response: We appreciate the support of the commenters. We are finalizing the proposed adjustment of 5.90% for 2021.

Comment: Some commenters noted various considerations CMS should account for and provided alternative recommendations to the proposed statutory minimum coding pattern adjustment. One commenter requested that CMS revisit and lower the MA coding pattern adjustment based on CMS' estimate of the underlying coding trend increase in risk scores of 3.56 percent (on average). The commenter also supported developing a CMS-HCC risk adjustment model completely calibrated with MA data from the encounter data system as doing so would eliminate across-the-board coding pattern adjustment. Another commenter encouraged CMS to evaluate the MA coding pattern adjustment in light of the recent increasing trends in the FFS risk scores used to calculate the normalization factors. One commenter indicated that coding patterns across the MA landscape were very heterogeneous and failure to recognize these differences across plans by applying an across the board coding pattern adjustment could result in an inequitable outcome regardless of the method used to calculate the adjustment. The commenter suggested a segmented approach to coding pattern adjustments that recognizes different levels of coding intensity among plans, such that the lowest coding factor is applied to lower coding plans while the highest factor is applied to higher coding plans. Another commenter recommended that CMS adopt a one-year moratorium on the application of adjustments, including the coding pattern adjustment.

Response: CMS appreciates commenters' feedback. 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.

Section 1853(a)(1)(C)(ii) of the Act requires application of a minimum MA coding pattern adjustment to risk scores; we believe that using a uniform adjustment is an appropriate and efficient approach to achieving the requirements of the statute and that the statutory minimum adjustment level provides an equitable approach for 2021 payments.

Comment: A few commenters believed that it is fundamentally incorrect to assume any observed coding differentials between the FFS and MA populations are driven by inappropriate coding on the part of MA plans and urged CMS to recognize that higher coding does not necessarily equate to wrong coding.

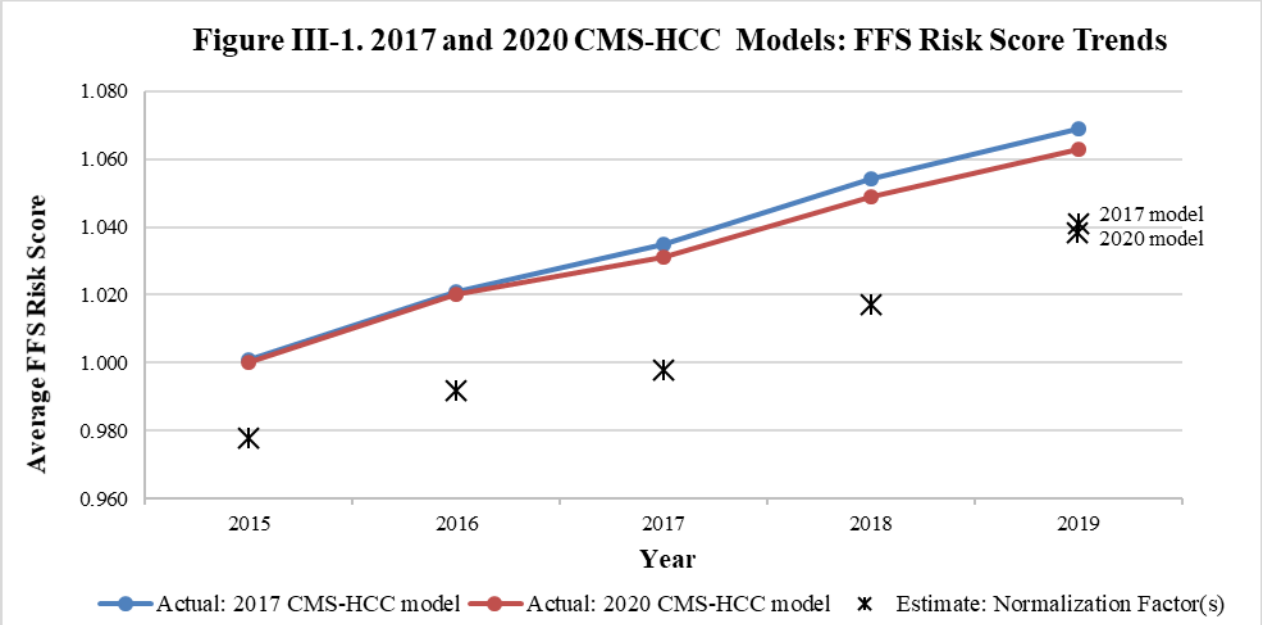
Response: As we have noted in previous Advance Notices and Rate Announcements, we are not assuming that MA coding is inaccurate in calculating the MA coding pattern difference factor. Rather, we assume that coding is accurate and, as required by statute, apply the MA coding

pattern difference factor to address differences in coding patterns. By applying this coding pattern difference factor, we are adjusting for the impact on MA risk scores of coding patterns that differ from FFS coding, which is the basis of the CMS-HCC model and the Part C normalization factor.

Section L. Normalization Factors

Comment: While some commenters supported a linear methodology for calculating the normalization factor, many suggested we make an adjustment to how we apply the current methodology for calculating the normalization factor, and a couple commenters suggested we make a change to our methodology. Commenters generally believed that the proposed methodology resulted in an increase in the normalization factor that was artificially high due to the implementation of ICD-10, and questioned the reasoning behind CMS' previous statement that the impact of ICD-10 on the FFS risk score trend would stabilize over time. Commenters provided a number of options for how CMS could adjust for the increasing trend, including adding more or less years of data to the calculation of the slope, adjusting the underlying data for the effect of ICD-10, recalibrating the model with more recent data, applying a nonlinear method to calculate the trend, and applying the linear trend additively rather than multiplicatively. A couple of commenters suggested that there be a moratorium on applying the normalization factor for ESRD for CY 2021.

Response: We are finalizing the normalization methodology as proposed. While we appreciate the suggestions to change how we calculate the normalization factors, we believe that the proposed methodology – using a linear approach with five years of data – will produce an appropriate estimate of the applicable 2021 average risk score under each model. The goal of the normalization factor for Part C is to accurately predict the FFS risk score in the payment year; thereby maintaining an average FFS risk score of 1.0. Updating the normalization factors annually stabilizes payment between model calibrations. In addition, we have consistently used five years of historical data when calculating normalization factors with the linear slope methodology. While there is inherent uncertainty with any prediction of future values, using five years of data to calculate the slope provides a smoothing effect. Since 2016, the first full year of ICD-10 implementation, the FFS risk score has increased by 1.5 percent per year on average. By including 2015, the average increase in FFS risk score decreases to 1.3 percent per year. We acknowledge concerns regarding the increasing normalization factor, however, as Figure III-1 shows, CMS' projection of the FFS risk score (i.e., the normalization factor) has underestimated the actual FFS risk score since 2015 by an average of 2.75%.



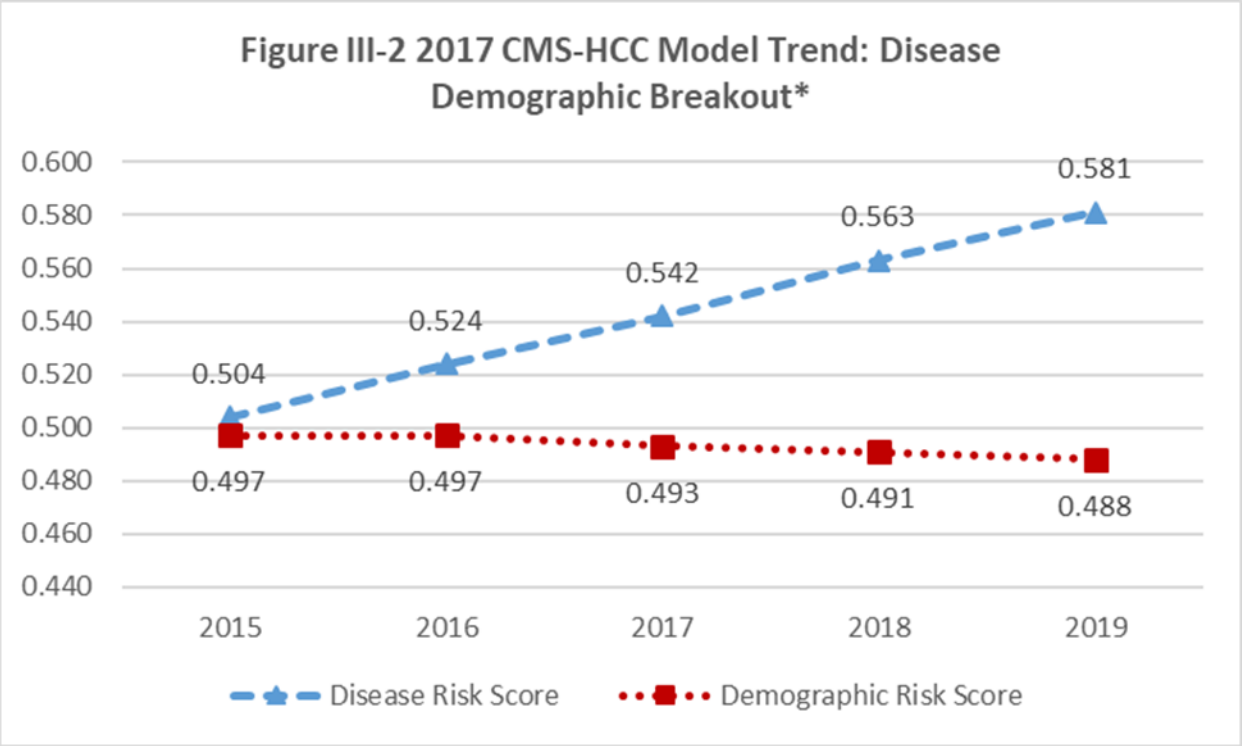
As stated in the CY 2021 Advance Notice, our analysis indicates there are multiple factors contributing to the recent increase in average FFS risk scores, and of those, the implementation of ICD-10 is one that we expect to stabilize moving forward as providers have more experience using the ICD-10 code set and establish their coding practices. However, as we also noted, we do not expect the average Medicare FFS risk score to decrease. Instead, we believe that other factors, such as more complete reporting of diagnosis codes as a result of the changing incentives due to the implementation of alternative payment models in Medicare FFS and a changing case-mix will continue to put upward pressure on the FFS risk score.

Comment: A number of commenters requested that CMS provide more information on the methodology for developing the normalization factor and asked for more transparency regarding why more recent years' risk scores were increasing. Many commenters specifically requested that we provide more detail on the factors driving the increase in the Part C normalization factor, including quantifying the impact of demographics, reported health status of the Original FFS Medicare population, and ICD-10 implementation. One commenter asked whether CMS considered the possibility that an increase in FFS coding error could be part of the increase in the risk score trend. There was a general concern over the increase in the Part C normalization factor and that the aforementioned drivers are inflating the factor. Several commenters made suggestions to address their concerns, including that CMS analyze the FFS normalization factors in relation to the FFS growth rate, that CMS recalibrate the model with ICD-10 diagnoses, and that CMS make an adjustment for one-time events like the implementation of ICD-10 in 2015 and the separation of the model into more refined community segments in 2017.

Response: The normalization factor for each model is an estimate of the average applicable risk score in the payment year. We project the normalization factors from a set of annual average risk scores calculated using the risk adjustment model that will be used in payment, thereby removing

any effect on the risk score trend that could be model driven. For Part C, PACE, and ESRD post-graft, the historical risk score for each year is calculated as the average risk score for all beneficiaries in FFS who are entitled to Part A, enrolled in Part B, and not in ESRD or hospice status. We then compute the trend over five years by calculating the slope in risk scores from the beginning to the end of the historical period, then compounding the average change from the denominator year (1.0) to the payment year. In determining the ESRD dialysis and RxHCC normalization factor, we follow the same method, except we use the population of beneficiaries in dialysis status for the ESRD dialysis model normalization factor, and beneficiaries who are enrolled in MA-PD or PDP Part D plans for the RxHCC model normalization factor.

Under any model, the average risk score can change from year to year for a number of reasons, including changes in demographics, disease prevalence, coding practices, and utilization. Figure III-2 shows the trend in risk score by disease and demographic variables for the 2017 CMS-HCC model. The increase in the average FFS risk score is driven by an increase in the disease component of the risk score (HCCs and interactions) that is not being offset by a decrease in the demographic component of the risk score. The disease component of the FFS risk score is increasing by approximately three percent per year on average, while the demographic components have decreased by approximately 0.3 percent per year on average. We believe that there are multiple aspects to the implementation of the ICD-10 that could drive the increase in the disease component of the risk score, including concept changes, greater availability of codes to report, differences between how the model is calibrated and risk scores are calculated, and increasing incentives to report more diagnosis codes in the alternative payment models implemented in FFS. However, we cannot distinguish the individual impacts of these factors. We note that, since MA risk scores are calculated with the same ICD-10 – to –HCC mappings, that similar increases are likely to be reflected in MA risk scores.



*The FFS risk scores included in the 2017 CMS-HCC model trend that was used to estimate the normalization factor are each equal to the sum of the demographic and disease sub-components displayed.

Comment: A couple of commenters stated that CMS should take into consideration the MA coding pattern adjustment when calculating the normalization factor. They asserted that CMS should consider the evolving relationship between the FFS risk score trends and normalization factor with the coding pattern adjustment.

Response: While the normalization factor is applied to pay plans appropriately by accounting for changes in FFS treatment and coding practices between the denominator year of the model and the payment year to keep the average FFS score at 1.0 in the payment year, the MA coding factor measures coding differences between MA and FFS. Because they address different things, these are not duplicative adjustments. CMS reassesses these factors each year.

Comment: One commenter suggested that the FFS normalization factor constitutes a substantive change in payment that must be made through regulation.

Response: The normalization factor for 2021 was calculated using the linear methodology, which is the method CMS has used for almost all years since the normalization factor was applied to risk scores (since 2007). We are not changing our methodology for calculating the normalization factor in 2021 from the method used from 2018 through 2020. However, if we did ever decide to do so, as we did for years 2015 through 2017, we believe that the statute authorizes that such a change be implemented via the Advance Notice and Rate Announcement. The normalization factor is a component of the methodology used to adjust payments to MA plans in accordance with section 1853(a)(1)(C) of the Act and, therefore, is appropriately finalized using the process

specified in section 1853(b)(2). As we have previously discussed in the CY 2012 Rate Announcement (pp. 27-28), section 1853(b) of the Act specifies the process through which CMS proposes, adopts, and announces the capitation rates and risk adjustment methodology for the MA program. Subsection (b)(2) provides that CMS provide notice and an opportunity to submit comment on "proposed changes to be made in the methodology from the methodology and assumptions used in the previous announcement." Subsection (b)(1) provides for a final notice in which the rates and the risk and other factors used in adjusting payment will be published.

CMS has consistently applied section 1853(b) of the Act to adopt MA payment methodologies in a manner intended to provide notice to interested parties, including MA organizations, and used section 1871 of the Act and APA rulemaking to adopt rules to govern other aspects of the payment process (e.g., appeals, bidding processes) for MA plans.

Section M. Encounter Data as a Diagnosis Source for 2021

Comment: A majority of commenters concurred with CMS' proposal to increase the encounter data risk score blend to 75%, while only a few commenters recommended that CMS maintain the current blend of 50%, and one commenter recommended that CMS cease the use of encounter data risk score calculations altogether. A few commenters noted appreciation that CMS is continuing to align the phase-in of encounter data with the phase-in of the 2020 model to minimize the complexity of blending multiple data sources and multiple models. Many commenters continue to raise concerns regarding challenges they believe to be problematic for calculating risk scores with encounter data and cited the 2017 GAO, 2018 OIG, and other external non-CMS reports that have made recommendations to improve the quality of encounter data. Some commenters acknowledged that CMS continues to make significant improvements to support the complete collection and accuracy of encounter data.

Others note that the move to encounter data creates a more complete data source than RAPS, improves the ability to predict risk scores, provides transparency on the source of the encounter, and provides a single source of data for MA benchmarks and risk score calibration. In addition, some commenters continue to agree that encounter data-based risk scores and RAPS-based risk scores are converging. Some commenters requested that we include the industry in the development of a new model, maintain transparency with stakeholders, and work toward codifying updates to the filtering logic in regulation as we complete the transition to 100% encounter data-based risk scores, study the impact of using ICD-10 data in the recalibration on payment, and look to calibrating a new risk adjustment model based on encounter data. In addition, they asked CMS to consider the removal of hard rejection edits for situational data elements and limiting edits to required data elements.

One commenter supported the inclusion of RAPS inpatient data as part of easing the transition to using encounter data, while others were interested in what the data is showing with regard to inpatient visits in RAPS versus ED. One commenter disagreed with the inclusion of diagnoses

from RAPS inpatient records in the encounter data risk score based on their independent research findings that some RAPS inpatient records could not be matched to an inpatient stay in the MedPAR (Medicare Provider Analysis and Review) data or encounter data and instead may have matched to a physician or outpatient encounter record. Some commenters continue to express 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. CMS continues to work with stakeholders to improve encounter data submissions and integrity, and will work to include the industry in future encounter data policy and model development. Following GAO's and OIG's recommendations, CMS developed and implemented an MA encounter data integrity plan, which includes a range of activities aimed at improving the completeness and validity of encounter data. Core activities include submission outreach, data analysis, and monitoring. These activities have improved the completeness and validity of encounter data, as evidenced by the increasing volume of encounter data records overall and per beneficiary, and reduced error rates in submissions. Increased communication with stakeholders has resulted in a single consolidated guidance document (i.e., the Encounter Data Processing Guide), a revised user-friendly website, and additional submission guidance.

Furthermore, in conversations with MA organizations, CMS has asked whether the encounter data system prevents MA organizations from successfully submitting data and the magnitude of the problem. The feedback has been positive. We note that a number of the reports cited by commenters are based on analyses of older submissions of encounter data records. As both CMS' and MA organizations' encounter data systems have matured and stabilized, MA organizations have stated that they refrain from submitting less than 1% of data due to anticipated submission issues. Further, we take this feedback into account as we develop additional technical assistance efforts.

We are not making any changes to the current filtering logic used to identify risk adjustment eligible diagnoses, which is outlined in the December 22, 2015 HPMS memo "Final Encounter Data Diagnosis Filtering Logic."[6] We will take recommendations for the various updates commenters raised into consideration, as well as the means by which we make updates in the future, including the regulatory process. In addition, we have done extensive work in recent years to improve reporting to MA organizations regarding their encounter data submissions, 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

[6] Final Encounter Data Diagnosis Filtering Logic HPMS Memo, available at https://csscoperations.com/internet/cssc4.nsf/files/Final%20Industry%20Memo%20Medicare%20Filtering%20Logic%2012%2022%2015.pdf/$FIle/Final%20Industry%20Memo%20Medicare%20Filtering%20Logic%2012%2022%2015.pdf.

Encounter Data System. Since the beginning of encounter data collection, CMS has provided MA organizations with transactional reports (277CA and MAO-002) that provide all of the information necessary for MA organizations to correct and resubmit rejected data in order to meet the requirement that they submit complete and accurate data for all services provided.

As a result of these efforts by CMS and MA organizations to improve the accuracy and completeness of encounter data, CMS believes that substantial improvements continue to be made to both CMS and plan systems to increase the accuracy and completeness of encounter data in order to proceed with this policy. Therefore, CMS is finalizing the proposal to calculate 2021 risk scores by adding 75% of the risk score calculated using encounter data and FFS diagnoses (with inpatient RAPS data to supplement encounter data) and 25% of the risk score calculated using RAPS and FFS diagnoses. As previously noted, it remains CMS' intention that the inclusion of RAPS inpatient data be temporary. We continue to observe a limited number of plans with low encounter data submission rates, both relative to RAPS and relative to submissions from similar organizations, and understand that some plans may require additional time or technical support to improve submissions. The overall impact of the supplementation with RAPS inpatient data is small, and the inclusion of RAPS inpatient diagnoses will help to minimize any potential impact from incomplete data for the limited number of plans that may face operational challenges submitting encounter data records. We will continue to monitor the completeness of encounter data submissions for all plans and determine whether to continue supplementing diagnoses from RAPS inpatient records each year.

CMS analysis, along with the analysis of some outside groups, continues to show that when comparing RAPS-based risk scores calculated using the 2017 CMS-HCC model to encounter data-based risk scores calculated using the 2020 CMS-HCC model, the difference is negligible. In addition, since the 2020 model is calibrated specifically to calculate risk scores based on encounter data, we proposed the 75/25 encounter data and RAPS data risk score blend consistent with the 75/25 blend of the 2020 model and old risk adjustment model. Therefore, finalizing as proposed aligns the 2020 model phase in percentage with the RAPS/encounter data blend for 2021 and minimizes the potential burden to stakeholders and CMS of calculating multiple blends between each of the models.

Comment: Most commenters acknowledged that CMS has improved communication and engagement with stakeholders. However, many commenters request that as we move to greater reliance on encounter data in payment, we address operational challenges related to the submission and processing of encounter data for payment, including corrections to the encounter data system reports that identify diagnoses eligible for risk adjustment and processing re-runs of final payment reconciliations going back to 2016.

Response: We appreciate the feedback and understand that there are operational concerns. As part of our broader encounter data integrity plan, CMS has been conducting outreach to provide technical assistance and solicit feedback on technical issues through various channels, including

1-on-1 calls, user group calls, and listening forums. In response to feedback, we have done extensive work on the reports to MA organizations that indicate which diagnoses submitted to the Encounter Data System are eligible for risk adjustment. These improvements have resolved the vast majority of technical issues and satisfied stakeholder requests for enhancements to the content and format of these reports. With the exception of a few remaining issues (less than 1% of all encounter data record submissions in 2019 are affected), these reports have stabilized and stakeholder feedback on the format and content of these reports has generally been positive. We expect to resolve these remaining issues in the near future and, as such, commenters' concerns related to data submitted for payment in prior years do not preclude CMS from increasing the percentage of encounter data in the risk score blend for 2021. We are committed to continuing our work with stakeholders to resolve technical challenges with encounter data reports and risk score calculation and welcome additional feedback moving forward.

Comment: A couple commenters recommended that CMS consider the relevance of increasing the reliance on encounter data for risk scores in MA given the industry move to value-based payment arrangements.

Response: We appreciate the comments. Section 1853(a)(1)(C) of the Act requires that MA payments be adjusted based on such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including adjustment for health status. In addition, section 1853(a)(3)(B) and (C) require data collection and use of certain information. Therefore, to risk adjust payments, CMS requires organizations offering MA plans and certain other Medicare private health plans to submit risk adjustment data that characterize the context and purpose of each item and service provided to a Medicare enrollee, as well as clinical condition information, as described in regulation at 42 C.F.R. § 422.310. While CMS does not dictate the price structures or amounts that MA organizations pay their contracted providers, we believe that MA organizations collect either claims or encounters from providers for their own use and, therefore, have this data available to them.

Comment: Some commenters raised concern that the transition to encounter data is a method to reduce funding to the MA program. These commenters highlighted the President's Budget as an example.

Response: As noted in Part I of the CY 2021 Advance Notice, CMS projects that the differential between the RAPS-based risk score and the encounter data-based risk score, calculated using the risk adjustment models proposed for 2021, is 0.00%. 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, the differences between risk scores using encounter data versus RAPS will continue to be negligible.

Comment: Some commenters expressed support for CMS' decision to continue the method of calculating risk scores using encounter data, RAPS, and FFS claims for PACE Organizations.

Response: We appreciate the support and for 2021 are finalizing the proposal to pool risk adjustment-eligible diagnoses from the following sources to calculate a single risk score for each PACE participant (with no weighting): (1) encounter data, (2) RAPS, and (3) FFS claims. This approach will apply to risk scores calculated using the CMS-HCC risk adjustment model (i.e., the risk adjusted payments for the Part A and B services), ESRD models, and for Part D for PACE participants. For 2021 we will continue to use the 2019 ESRD models to calculate PACE ESRD risk scores. Non-ESRD PACE risk scores will be calculated using the 2017 CMS-HCC model.

Comment: A few commenters expressed concern regarding the administrative burden that encounter data creates for providers.

Response: We appreciate the concerns of the commenters. In providing submission guidance to plans, our goal is to minimize 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.

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

Section A. RxHCC Risk Adjustment Model

Comment: Two commenters requested an update to the RxHCC model to align with current proposed legislation and the current Part D prescription drug market.

One commenter more specifically recommended the release of more analysis and data to support recalibration of the RxHCC model, noting that current Part D redesign proposals would impact the risk-adjusted direct subsidy. In addition, the commenter suggested that CMS consider a number of methodological changes to the model that are consistent with the HHS-HCC model, including: adding RXCs to the RxHCC model similar to the HCC-RXC coefficients that are currently included in the HHS-HCC risk adjustment model, adopting a policy to update the model a minimum of every three years, and developing a hybrid prospective-concurrent RxHCC model, where the markers for drug classes are measured and included in the model concurrently. The commenter believed such methodological changes could improve the model's accuracy in predicting relative costs by distinguishing enrollees who were prescribed certain medications from others with the same medical condition who were not, enhance the predictive power of the model overall and for specific disease, and resolve data latency issues.

Response: We appreciate the commenters' concerns and suggestions. We understand that in certain programs where a combined medical and drug model is utilized, there may be methodological differences in the approach for predicting relative costs that are population specific. CMS uses the RxHCC risk adjustment model to adjust the direct subsidy payments for Part D benefits offered by stand-alone prescription drug plans (PDPs) and MA-Part D plans (MA-PDs). By using a separate RxHCC model – one that separately predicts plan liability for different subgroups such as the low income population – from the CMS-HCC model that is used to predict medical costs, the RxHCC model accounts for differences in predicted cost patterns for prescription drugs among distinct subgroups of Part D eligible beneficiaries. For CY 2021, CMS will continue to use the 2020 RxHCC model to calculate Part D risk scores. The model was updated for CY 2020 based on the CY 2020 Part D coverage gap parameters, which are still applicable in 2021. We appreciate commenters' concerns regarding the benefit of calibrating the RxHCC model on more recent utilization and cost information and the consideration of the model's reflection of Part D payment policy. We will evaluate the model methodology and specifications, and intend to update the underlying data used to calibrate the model in the near future.

Section B. Encounter Data as a Diagnosis Source for 2021 (RxHCC Section)

Please refer to Section M in Attachment III, above, for comments and responses on the use of encounter data as a diagnosis source in 2021.

Section C. Part D Risk Sharing

Comment: One commenter expressed concern that if current congressional proposals to redesign Part D become law, they will create more pricing and payment uncertainty, particularly with respect to rebates. The commenter recommended that CMS explore adjustments to risk sharing (e.g., tighter risk corridors during implementation or for key subpopulations such as LIS individuals) to mitigate problems if legislative changes are enacted.

Response: We appreciate the concern raised by the commenter. We will monitor and analyze legislative changes to the Part D program and consider whether any adjustments within our discretion and authority may be warranted.

Section D. Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2021

Comment: One commenter expressed concern over how the steep increase in the Part D out-of-pocket cost threshold (an increase of over $1,000 from 2019 to 2020) could impact beneficiaries with significant chronic health needs. The commenter stated that beneficiaries with significant chronic health needs may linger in the coverage gap phase longer than those without, and given the high out-of-pocket costs faced by these beneficiaries, the increase in the out-of-pocket threshold could drive therapy abandonment. To remedy this problem, the commenter suggested that CMS work with Congress to map out viable solutions.

Response: We appreciate the comment and acknowledge the concerns raised about the impact that the increased out-of-pocket threshold may have on beneficiaries with significant chronic health conditions. We do not have discretion to alter the statutory formulas for calculating the out-of-pocket threshold and other Part D benefit parameters, and therefore will implement the benefit parameters for 2021 in accordance with the statutory requirements. We remain committed to monitoring their effect on beneficiaries in the Part D program and will continue seeking opportunities to implement policies within our legal authority to make drugs more affordable.

Comment: One commenter noted that on page 55 of Part II of the CY 2021 Advance Notice, the formula for calculating the annual percentage increase in the September CPI for 2021 is shown as “Projected September 2019 CPI / Actual September 2017 CPI”, whereas this seemingly should have been “Projected September 2020 CPI / Actual September 2019 CPI”.

Response: We thank the commenter for bringing this to our attention. We confirm that the formula for calculating the annual percentage increase in the September CPI for contract year 2021 should have been presented as “Projected September 2020 CPI / Actual September 2019 CPI”.

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 2020	Prior year revisions	API for 2021
API: Applied to all parameters except those noted	3.16%	-0.30	2.85%
September CPI (all items, U.S. city average) (1)	2.44%	-0.54	1.88%

Part D Benefit Parameters

	2020	2021
Standard Benefit		
Deductible	$435	$445
Initial Coverage Limit	$4,020	$4,130
Out-of-Pocket Threshold	$6,350	$6,550
Total Covered Part D Spending at Out-of-Pocket Threshold for Non-Applicable Beneficiaries (2)	$9,038.75	$9,313.75
Estimated Total Covered Part D Spending for Applicable Beneficiaries (3)	$9,719.38	10,048.39
Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit		
Generic/Preferred Multi-Source Drug	$3.60	$3.70
Other	$8.95	$9.20
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] (4)	$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 (5)	$1.30	$1.30
Other (5)	$3.90	$4.00
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	$3.60	$3.70
Other	$8.95	$9.20
Above Out-of-Pocket Threshold	$0.00	$0.00

	2020	2021
Full Subsidy-Non-FBDE Individuals		
Applied or eligible for QMB/SLMB/QI or SSI, income at or below 135% FPL and resources ≤ $9,360 (individuals, 2020) or ≤ $14,800 (couples, 2020) [category code 1] (6)		
Deductible	$0.00	$0.00
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$3.60	$3.70
Other	$8.95	$9.20
Maximum Copayments above Out-of-Pocket Threshold	$0.00	$0.00
Partial Subsidy		
Applied and income below 150% FPL and resources below $14,160 (individual, 2020) or $29,160 (couples, 2020) [category code 4] (6)		
Deductible (5)	$89.00	$92.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$3.60	$3.70
Other	$8.95	$9.20
Retiree Drug Subsidy Amounts		
Cost Threshold	$435	$445
Cost Limit	$8,950	$9,200

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

(2) 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.

(3) For a beneficiary who is 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.

(4) Per section 1860D-14(a)(1)(D)(i), 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.

(5) The partial LIS deductible is increased from the unrounded 2020 value of $89.49. Increases to the maximum copayments for non-institutionalized FBDE individuals with incomes no greater than 100% of the FPL are applied to the unrounded 2020 values of $1.30 for generic/preferred multi-source drugs and $3.90 for all other drugs.

(6) These resource limit figures will be updated for contract year 2021. Additionally, these amounts include $1,500 per person for burial expenses. See the HPMS memorandum titled, "2020 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 $435 in 2020 and rounded to the nearest multiple of $5.

Initial Coverage Limit: From $4,020 in 2020 and rounded to the nearest multiple of $10.

Minimum Cost-Sharing after the Out-of-Pocket Threshold (i.e., in the catastrophic phase): From $3.60 per generic or preferred drug that is a multi-source drug and $8.95 for all other drugs in 2020, 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 $3.60 per generic, preferred drug that is a multi-source drug, or biosimilar and $8.95 for all other drugs in 2020, rounded to the nearest multiple of $0.05.

Deductible for Low Income (Partial) Subsidy Eligible Enrollees: From $89.00[7] in 2020 and rounded to the nearest $1.

Maximum Copayments above the Out-of-Pocket Threshold for Low Income (Partial) Subsidy Eligible Enrollees: From $3.60 per generic, preferred drug that is a multi-source drug, or biosimilar and $8.95 for all other drugs in 2020, rounded to the nearest multiple of $0.05.

Out-of-Pocket Threshold: From $6,350 in 2020 and rounded to the nearest multiple of $50.

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 CMS 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 $1.30 per generic, preferred drug that is a multi-source drug, or

[7] 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 2020 value of $89.49.

biosimilar, and from $8.95 for all other drugs in 2020 and rounded to the nearest multiple of $0.05 and $0.10 respectively.[8]

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 2021 benefit parameters, Part D program data is used to calculate the annual percentage trend as follows:

$$\frac{August\ 2019 – July\ 2020}{August\ 2018 – July\ 2019} = \frac{\$4{,}037.06}{\$3{,}913.47} = 1.0316$$

In the formula, the average per capita cost for August 2018 – July 2019 ($3,913.47) is calculated from actual Part D PDE data, and the average per capita cost for August 2019 – July 2020 ($4,037.06) is calculated based on actual Part D PDE data incurred from August 2019 – December 2019 and projected through July 2020.

The 2021 benefit parameters reflect the 2020 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 calculated as summarized by Table IV-1.

[8] Per section 1860D-14(a)(4)(A) of the Act, the copayments are increased from the unrounded 2020 values of $1.30 for multi-source generic or preferred drugs, and $3.90 for all other drugs.

Table IV-1. 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	2.15%	2.15%
2013	2.53%	2.53%
2014	−3.14%	-3.14%
2015	10.12%	10.12%
2016	9.90%	9.90%
2017	3.98%	3.99%
2018	1.90%	1.89%
2019	4.09%	4.08%
2020	5.25%	4.94%

Accordingly, the 2021 benefit parameters reflect a multiplicative update of -0.30 percent for prior year revisions. In summary, the 2020 parameters outlined in Section A are updated by 2.85 percent for 2021, as summarized by Table IV-2.

Table IV-2. Annual Percentage Increase

Annual percentage trend for July 2020	3.16%
Prior year revisions	-0.30%
Annual percentage increase for 2021	2.85%

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 for Out-of-Pocket Threshold

In accordance with section 1860D-2(b)(4)(B), we calculated the change in the out-of-pocket threshold using the 2020 threshold value of $6,350 as our starting point. To calculate the 2021 value, we applied the 2021 API described above and rounded to the nearest $50. The resulting 2021 out-of-pocket threshold value is $6,550.

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 2020, an estimate of the September 2020 CPI based on projections from the President's FY2021 Budget.

The September 2019 value is from the Bureau of Labor Statistics. The annual percentage trend in the September CPI for contract year 2021 is calculated as follows:

$$\frac{\text{Projected September 2020 CPI}}{\text{Actual September 2019 CPI}} \; or \; \frac{263.0}{256.8} = 1.0244$$

(Source: President's FY2021 Budget and Bureau of Labor Statistics, Department of Labor)

The 2021 benefit parameters reflect the 2020 annual percentage trend in the September CPI of 2.44 percent, as well as a revision to the prior estimate for the 2019 CPI increase over the 12-month period ending in September 2019. Based on the actual reported CPI for September 2019, the September 2019 CPI increase is now estimated to be 1.71 percent. Accordingly, the 2021 update reflects a -0.54 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 1.88 percent for 2021, as summarized by Table IV-3.

Table IV-3. Cumulative Annual Percentage Increase in September CPI

Annual percentage trend for September 2020	2.44%
Prior year revisions	-0.54%
Annual percentage increase for 2021	1.88%

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 $415 and $8,500, respectively, for plans that end in 2019, and as $435 and $8,950 for plans that end in 2020. For 2021, the cost threshold is $445 and the cost limit is $9,200.

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

For 2021, the estimated total covered Part D spending at out-of-pocket threshold for applicable beneficiaries is $10,048.39. 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.
- 25 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 0.097 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 0.068 percent to 94.932 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:

$$\text{ICL} + \frac{\text{100\% beneficiary cost sharing in the gap}}{\text{weighted gap coinsurance factor}} \; or \; \$4{,}130 + \frac{\$5{,}183.75}{87.582\%} = \$10{,}048.39$$

- *ICL* is the Initial Coverage Limit equal to $4,130.

- *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* $6,550 − $1,366.25 = $5,183.75

Weighted gap coinsurance factor is calculated as follows:

(Brand Gross Drug Cost Below Catastrophic [GDCB] % for non-LIS × 94.932% gap cost-sharing for applicable drugs) + (Generic GDCB % for non-LIS × 25% gap cost-sharing for non-applicable drugs)

or

(89.50% × 94.932%) + (10.50% × 25%) =87.5872%

- *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 2019 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

    94.932% = [(99.903% ×95%) + (0.097% × 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 2019 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. Updates for Part C and D Star Ratings

Part C and D Star Ratings and Future Measurement Concepts

The Part C and D Star Ratings measure the quality of and reflect the experiences of beneficiaries in MA and prescription drug plans (PDPs or Part D plans), assist beneficiaries in finding the best plan for their needs, and determine MA Quality Bonus Payments. The Star Ratings support CMS's efforts to make the patient the focus in all of our programs.

CMS codified the methodology for the Part C and D Star Ratings program in the CY 2019 Medicare Part C and D Final Rule, published in April 2018, for performance periods beginning with 2019; that final rule lays out the methodology for the 2021 Star Ratings. In Part II of the CY 2021 Advance Notice, we provided updates that are required by regulation to be made through the process described for changes in, and adoption of, payment and risk adjustment policies in section 1853(b) of the Act. In addition, we solicited input on future measures and concepts as we continue to enhance the Star Ratings over time.

In the Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency Interim Final Rule (CMS-1744-IFC) put on display at the Office of the Federal Register website on March 31, 2020, CMS adopted a series of changes to the 2021 Star Ratings to accommodate the disruption to data collection posed by the COVID-19 pandemic. Specifically, the IFC:

(1) eliminates the requirement to collect and submit Healthcare Effectiveness Data and Information Set (HEDIS) and Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) data otherwise collected in 2020 and replaces the 2021 Star Ratings measures calculated based on those HEDIS and CAHPS data collections with earlier values from the 2020 Star Ratings (which are not affected by the public health threats posed by COVID-19);

(2) establishes how we will calculate or assign Star Ratings for 2021 in the event that CMS's functions become focused on only continued performance of essential Agency functions and the Agency and/or its contractors do not have the ability to calculate the 2021 Star Ratings;

(3) modifies the current rules for the 2021 Star Ratings to replace any measure that has a systemic data quality issue for all plans due to the COVID-19 outbreak with the measure-level Star Ratings and scores from the 2020 Star Ratings;

(4) in the event that we are unable to complete Health Outcomes Survey (HOS) data collection in 2020 (for the 2022 Star Ratings), replaces the measures calculated based on HOS data collections with earlier values that are not affected by the public health threats posed by COVID-19 for the 2022 Star Ratings;

(5) removes guardrails for the 2022 Star Ratings by delaying their application to the 2023 Star Ratings;

(6) expands the existing hold harmless provision for the Part C and D Improvement measures to include all contracts for the 2022 Star Ratings; and

(7) revises the definition of "new MA plan" so that for purposes of 2022 quality bonus payments based on 2021 Star Ratings only, new MA plan means an MA contract offered by a parent organization that has not had another MA contract in the previous 4 years, in order to address how the 2021 Star Ratings will be based in part on data for the 2018 performance period.

Please see the IFC for further information on these changes for the 2021 and 2022 Star Ratings.

We appreciate the feedback we received on the Star Ratings in response to the Advance Notice. As noted, the methodology and measures used to calculate the 2021 Star Ratings were finalized in the CY 2019 Final Rule at §§ 422.160, 422.162, 422.164, 422.166, 423.180, 423.182, 423.184, and 423.186. We cannot make changes to the methodology for the 2021 Star Ratings. We reviewed all comments received and will take them into consideration for future rulemaking.

Reminders for 2021 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. As described at §§ 422.164(h)(1) and 423.184(h)(1), CMS must annually set and announce a deadline for MA organizations or Part D sponsors to request that CMS or the Independent Review Entity (IRE) review its appeals data or CMS review its Complaints Tracking Module (CTM) data. CMS is announcing a deadline of June 30, 2020 for all contracts to make their requests for review of the 2021 Star Rating appeals and CTM measure data. Commenters were generally in support of this deadline. Sponsoring organizations can view their Part C appeals data on the website medicareappeal.com/AppealSearch, and Part D plan sponsors should use the medicarepartdappeals.com website to monitor their appeal timeliness and effectuation compliance data. Sponsoring organizations should refer to the May 10, 2019 HPMS memo, Complaints Tracking Module (CTM) File Layout Change and Updated Standard Operating Procedures, for instructions on how to make a request for review of CTM data.

Measure Updates for 2021 Star Ratings

Improvement Measures (Part C & D). Under §§ 422.164(f) and 423.184(f), improvement measures are calculated using performance on measures that meet specific conditions. We received many comments about the improvement measure methodology. For example, we received support for the inclusion of the annual flu vaccine measure, and various recommendations, such as to remove CAHPS and HOS measures from the calculation, to modify the "hold harmless" policy, and not to limit the application of the improvement measures to plans receiving a minimum Star Rating. We also received comments on the weights assigned to patient

experience/complaints and access measures as well as to the Statin Use in Persons with Diabetes measure.

The improvement measure methodology was finalized at §§ 422.164(f) and 423.184(f) (including the methodology for identifying the measures used in the improvement measure), and the weights for measures used in the 2021 Star Ratings were finalized in §§ 422.164(e) and 423.184(e). Since we will be using the 2020 Star Ratings data for the HEDIS and CAHPS measures, we will carry forward the measure-level improvement change score as described at §§ 422.164(f)(4)(i) and 423.184(f)(4)(i) from the 2020 Star Ratings for all HEDIS and CAHPS measures for the 2021 Star Ratings Part C and D improvement measure calculations. We codified this at §§ 422.166(j)(1)(iii) and 423.186(j)(1)(ii) as part of the IFC.

Please note that for the 2022 Star Ratings, we have revised the methodology for the Part C and D improvement measures to expand the hold harmless rule to include all contracts at the overall and summary rating levels recognizing that the public health emergency for the COVID-19 pandemic may result in a decline in industry performance. We have codified a new paragraph (g)(3) at §§ 422.166 and 423.186 and added text at the end of the existing text at §§ 422.166(f)(1)(i) and 423.186(f)(1)(i) to implement this new hold harmless provision for the 2022 Star Ratings only.

We appreciate all comments received on methodology and will consider them for future rulemaking. The measures that will be used to calculate the 2021 Star Ratings and whether they are included in the improvement measures are listed in Table 1.

Table 1: 2021 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
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	Rheumatoid Arthritis Management	Process Measure	1	Yes

Part C or D	Measure	Measure Type	Weight	Improvement Measure
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	Getting Needed Care	Patients' Experience and Complaints Measure	2	Yes
C	Getting Appointments and Care Quickly	Patients' Experience and Complaints Measure	2	Yes
C	Customer Service	Patients' Experience and Complaints Measure	2	Yes
C	Rating of Health Care Quality	Patients' Experience and Complaints Measure	2	Yes
C	Rating of Health Plan	Patients' Experience and Complaints Measure	2	Yes
C	Care Coordination	Patients' Experience and Complaints Measure	2	Yes
C	Complaints about the Health Plan	Patients' Experience and Complaints Measure	2	Yes
C	Members Choosing to Leave the Plan	Patients' Experience and Complaints Measure	2	Yes
C	Health Plan Quality Improvement	Improvement Measure	5	No
C	Plan Makes Timely Decisions about Appeals	Measures Capturing Access	2	Yes
C	Reviewing Appeals Decisions	Measures Capturing Access	2	Yes
C	Call Center – Foreign Language Interpreter and TTY Availability	Measures Capturing Access	2	Yes
C	Statin Therapy for Patients with Cardiovascular Disease	Process Measure	1	Yes
D	Call Center – Foreign Language Interpreter and TTY Availability	Measures Capturing Access	2	Yes
D	Appeals Auto–Forward	Measures Capturing Access	2	Yes
D	Appeals Upheld	Measures Capturing Access	2	Yes
D	Complaints about the Drug Plan	Patients' Experience and Complaints Measure	2	Yes
D	Members Choosing to Leave the Plan	Patients' Experience and Complaints Measure	2	Yes
D	Drug Plan Quality Improvement	Improvement Measure	5	No
D	Rating of Drug Plan	Patients' Experience and Complaints Measure	2	Yes
D	Getting Needed Prescription Drugs	Patients' Experience and Complaints Measure	2	Yes
D	MPF Price Accuracy	Process Measure	1	No
D	Medication Adherence for Diabetes Medications	Intermediate Outcome Measure	3	Yes
D	Medication Adherence for Hypertension (RAS antagonists)	Intermediate Outcome Measure	3	Yes
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	3	Yes

2021 Star Ratings Program and the Categorical Adjustment Index

The methodology for the Categorical Adjustment Index (CAI) is described at §§ 422.166(f)(2) and 423.186(f)(2), as well as in the annual Medicare Part C & D Star Ratings Technical Notes available on the CMS webpage at https://go.cms.gov/partcanddstarratings. As finalized at §§ 422.166(f)(2)(iii) and 423.186(f)(2)(iii), all measures identified as candidate measures will be included in the determination of the 2021 CAI values. The candidate measure set for the 2021 CAI [for both Part C and Part D] is as follows: Adult BMI Assessment, Annual Flu Vaccine, Breast Cancer Screening, Colorectal Cancer Screening, 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, Reducing the Risk of Falling, Rheumatoid Arthritis Management, Medication Adherence for Diabetes Medications, Medication Adherence for Hypertension, Medication Adherence for Cholesterol, Statin Therapy for Patients with Cardiovascular Disease, and Statin Use in Persons with Diabetes. The IFC does not address CAI adjustments for the 2021 Star Ratings because the CAI values are based on the 2019 HEDIS data and CAHPS data collected in 2019.

In keeping with our commitment to transparency, a summary of the analysis of the candidate measure set that includes the minimum, median, and maximum values for the within-contract variation for the low-income subsidy (LIS)/dual eligible (DE) differences is posted at http://go.cms.gov/partcanddstarratings.

Most commenters supported adjustment for socio-economic status, but a few suggested to modify the policy for contracts with few dual/LIS or disabled enrollees by not providing a negative adjustment. A couple of commenters did not understand why the adjustments may change from year to year. The methodology for the CAI was finalized at §§ 422.166(f)(2) and 423.186(f)(2). We encourage readers to review the April 2018 final rule for a detailed discussion of these topics and explanation for the CAI.

Many commenters are awaiting the next Report to Congress by ASPE and look forward to future enhancements to our adjustments for socio-economic status based on the report's recommendations. We appreciate all comments received on the CAI. We will continue to collaborate with ASPE and advance work on whether and how to address the impact of socio-economic status on quality ratings.

2021 Categorical Adjustment Index (CAI) Values

MA contracts have up to three mutually exclusive and independent CAI 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 2-13 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 2 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 3 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 42.483931%, the contract's LIS/DE initial category is L8. The exception for the upper limit exclusion for an initial group is the final category: (i) tenth initial category for the percentage of LIS/DE beneficiaries in the MA contract.

Table 2: 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 6.226272
L2	6.226272 to less than 9.492635
L3	9.492635 to less than 11.700648
L4	11.700648 to less than 15.731573
L5	15.731573 to less than 21.329120
L6	21.329120 to less than 30.242072
L7	30.242072 to less than 42.483931
L8	42.483931 to less than 74.172176
L9	74.172176 to less than 100.00000
L10	100.000000

Table 3: 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 15.391010
D2	15.391010 to less than 22.218675
D3	22.218675 to less than 28.749095
D4	28.749095 to less than 40.962138
D5	40.962138 to 100.000000

Table 4 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.

Table 4: Final Adjustment Categories and CAI Values for the Overall Rating

Final Adjustment Category	LIS/DE Initial Group	Disability Quintile	CAI Value
1	L1-L3	D1	-0.044353
2	L4-L8 L1-L7	D1 D2	-0.010315

Final Adjustment Category	LIS/DE Initial Group	Disability Quintile	CAI Value
3	L1-L4 L5 L6-L7	D3-D5 D3-D4 D3	0.008868
4	L9-10 L8-L9 L6-L8 L5-L7	D1 D2-D3 D4 D5	0.059906
5	L10 L9 L8	D2-D4 D4-D5 D5	0.109975
6	L10	D5	0.202674

Tables 5 and 6 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 5: 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 5.887522
L2	5.887522 to less than 9.054903
L3	9.054903 to less than 11.512945
L4	11.512945 to less than 15.627683
L5	15.627683 to less than 20.944993
L6	20.944993 to less than 28.388132
L7	28.388132 to less than 41.562546
L8	41.562546 to less than 73.400323
L9	73.400323 to less than 100.00000
L10	100.000000

Table 6: 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 14.650120
D2	14.650120 to less than 21.841155
D3	21.841155 to less than 28.561203
D4	28.561203 to less than 40.733564
D5	40.733564 to 100.000000

Table 7 provides the description of each of the final adjustment categories for the Part C summary rating and the associated values of the CAI.

Table 7: Final Adjustment Categories and CAI Values for the Part C Summary Rating

Final Adjustment Category	LIS/DE Initial Group	Disability Quintile	CAI Value
1	L1-L3	D1	-0.006188
2	L4-L9 L1-L5 L6-L7 L8 L9	D1 D2-D5 D2-D4 D2-D3 D2	0.007997
3	L10 L9-L10	D1-D2 D3-D4	0.049144
	L8 L6-L7	D4-D5 D5	
4	L9-L10	D5	0.082496

Tables 8 and 9 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 8: 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 6.888285
L2	6.888285 to less than 9.784551
L3	9.784551 to less than 12.684900
L4	12.684900 to less than 17.276374
L5	17.276374 to less than 23.019521
L6	23.019521 to less than 34.571784
L7	34.571784 to less than 50.696749
L8	50.696749 to less than 83.010704
L9	83.010704 to less than 100.00000
L10	100.000000

Table 9: 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 15.753425
D2	15.753425 to less than 23.065548
D3	23.065548 to less than 30.125523
D4	30.125523 to less than 42.781053
D5	42.781053 to 100.000000

Table 10 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.

Table 10: 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
1	L1-L6 L1	D1 D2	-0.088634
2	L7 L2-L7 L1-L4	D1 D2 D3	-0.027026
3	L5-L6	D3	0.009996
4	L8-L10 L7-L8 L1-L7 L8	D1-D2 D3 D4-D5 D4	0.073898
5	L9-L10 L8-L9	D3-D4 D5	0.176661
6	L10	D5	0.289172

Tables 11 and 12 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 11: Categorization of PDP Contracts into LIS/DE Quartiles for the Part D Summary Rating

LIS/DE Quartile	Percentage of Contract's LIS/DE Beneficiaries
1	0.000000 to less than 1.602465
2	1.602465 to less than 3.809318
3	3.809318 to less than 14.050885
4	14.050885 to 100.000000

Table 12: Categorization of PDP Contracts into Disability Quartiles for the Part D Summary Rating

Disability Quartile	Percentage of Contract's Disabled Beneficiaries
1	0.000000 to less than 7.288366
2	7.288366 to less than 11.838028
3	11.838028 to less than 17.788557
4	17.788557 to 100.000000

Table 13 provides the description of each of the final adjustment categories for the Part D summary rating for PDPs and the associated values of the CAI.

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. Under §§ 422.166(f)(2)(i)(A) and 423.186(f)(2)(i)(A), categories are chosen to enforce monotonicity (i.e., values increase as percent LIS/DE and disabled increases) in the final adjustment categories. There are three final adjustment categories for PDPs for the Part D summary rating.

Table 13: Final Adjustment Categories and CAI Values for the Part D Summary Rating for PDPs

Final Adjustment Category	LIS/DE Quartile	Disability Quartile	CAI Value
1	L1-L2 L1	D1-D2 D3	-0.267247
2	L3 L2-L3 L1	D1-D2 D3-D4 D4	-0.138287
3	L4	D1-D4	0.128671

Extreme and Uncontrollable Circumstances Policy

Extreme and uncontrollable circumstances such as natural disasters can directly affect Medicare beneficiaries and providers, as well as the Parts C and D organizations that provide beneficiaries with important medical care and prescription drug coverage. These extreme and uncontrollable circumstances may negatively affect the underlying operational and clinical systems that CMS relies on for accurate performance measurement in the Star Ratings program.

In the CY 2020 Final Call Letter and the CY 2020 Final Rule, published in the Federal Register on April 16, 2019 (84 FR 15830–15831), we finalized a set of rules for adjusting the calculation of Star Ratings for the Parts C and D organizations that are impacted by extreme and uncontrollable circumstances during the measurement period, which is the 2019 calendar year for the 2021 Star Ratings. The same policy as used for adjustments to 2020 Star Ratings based on extreme and uncontrollable circumstances will be continued for CY 2021 Star Ratings for all

measures that do not revert back to the 2020 measure-level Star Ratings, and associated measure scores, as a result of the adjustments to the 2021 Star Ratings codified in the IFC as a result of the COVID-19 pandemic. That is, 2021 Star Ratings measures that come from HEDIS and CAHPS, as well as any measures that have systemic data quality issues as a result of the COVID-19 pandemic, will revert back to the measure-level stars and scores from the 2020 Star Ratings pursuant to the IFC so that these measures would not need to revert back as a result of any extreme and uncontrollable circumstances during the 2019 measurement year. The extreme and uncontrollable circumstances policy used in prior years will continue to be used for the 2021 Star Ratings for all other measures.

Table 14 lists the Section 1135 waivers that could affect the 2021 Star Ratings.

Table 14: 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	Declared Major Disaster
01/08/2020	Puerto Rico as the result of earthquakes	DR-4473	Earthquakes	PR	12/28/2019	01/16/2020

Table 15 lists the Individual Assistance counties from the FEMA major disaster declaration.

Table 15: Individual Assistance Counties in FEMA Major Disaster Declared States

FEMA Declaration	State	FEMA Individual Assistance Counties
DR-4473	Puerto Rico	Adjuntas, Aguada, Anasco, Arecibo, Barceloneta, Cabo Rojo, Ciales, Coamo, Corozal, Guanica, Guayanilla, Hormigueros, Jayuya, Juana Diaz, Lajas, Lares, Las Marias, Maricao, Mayaguez, Moca, Morovis, Naranjito, Orocovis, Penuelas, Ponce, Sabana Grande, Salinas, San German, San Sebastian, Santa Isabel, Utuado, Villalba, Yauco

To ensure it is applied to those contracts most likely to have experienced the greatest adverse effects, this policy is limited to Individual Assistance disaster declarations. 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 (https://www.fema.gov/disaster-declaration-process). We focus on counties or county-equivalent areas eligible for Individual Assistance as a result 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 areas where beneficiaries were eligible for individual and household assistance as a result of the extreme and uncontrollable circumstance.

To determine whether a contract was impacted (such that it would be an "affected contract" eligible for adjustments), we compare the number of enrollees in the Individual Assistance area at the time of the extreme and uncontrollable circumstance to the number of enrollees outside the Individual Assistance area. Using the Individual Assistance major disaster declaration as a

requirement for the extreme and uncontrollable circumstance policy ensures that the policy applies only when the event is extreme, meriting the use of special adjustments to the Star Ratings, and targeting the specific area affected by the extreme and uncontrollable circumstance.

In cases where contracts with at least 25% of enrollees residing in FEMA-designated Individual Assistance areas were affected by consecutive year disasters (2018-2019), for all measures except HOS, these doubly-affected contracts would receive the higher of the 2021 Star Rating or what the 2020 Star Rating would have been in the absence of any adjustments that took into account the effects of the 2018 disaster for each measure (we will use the corresponding measure score for the Star Ratings year selected). For HOS, these doubly-affected contracts would receive the higher of the 2021 Star Rating or what the 2020 Star Rating would have been in the absence of any adjustments that took into account the effects of the 2017 disaster for each measure (we will use the corresponding measure score for the Star Ratings year selected). This is due to the longitudinal nature of the HOS data collection.

Nearly all commenters support adjustment for extreme and uncontrollable circumstances but requested that CMS expand our criteria for determining qualifying disasters or modify how we measure quality improvement for contracts affected by disasters. Some noted specific examples that do not meet our current criteria for determining eligible disasters for 2021 Star Ratings adjustments, and several suggest that we take a more ad hoc approach when determining the impact of disasters. A few asked for more information or expressed confusion about how we calculate the percentage of enrollees impacted by the policy, especially when there are multiple disasters across several states. One commenter pointed out that the list of qualifying counties in Puerto Rico was updated after the Advance Notice was published. Given our limited flexibility in making changes to the methodology for 2021 Star Ratings, we will finalize as outlined in the Advance Notice with the exception of updating the list of qualifying counties in Puerto Rico. We note that the disaster policy is the same as used for the 2020 Star Ratings and is described in detail in the 2020 Star Ratings Technical Notes (e.g., pages 7-9 and Attachment Q). We appreciate all comments received about extreme and uncontrollable circumstances and will consider them for future rulemaking.

Changes to Existing Star Ratings and Display Measures

CMS will continue to solicit feedback on new measure concepts as well as new and updated measures through the process described for changes in, and adoption of, payment and risk adjustment policies in section 1853(b) of the Act. We will also continue to provide advance notice regarding measures considered for implementation as future Star Ratings measures. As codified at §§ 422.164(c)(2)-(4), 423.184(c)(2)-(4), 422.164(d)(2), and 423.184(d)(2), new measures and measures with substantive specification changes must remain on the display page for at least two years prior to becoming a Star Ratings measure. We will announce non-substantive specification changes as described at §§ 422.164(d)(1) and 423.184(d)(1).

Display measures on CMS.gov are published separately from the Star Ratings, and include measures that are transitioned from inclusion in the Star Ratings, new or updated measures before inclusion into the Star Ratings, or informational-only measures. Organizations and sponsors have the opportunity to preview the data for their display measures prior to release on our website. We anticipate all 2020 display measures will continue to be shown on CMS.gov in 2021 unless noted below.

As a result of amending the requirement to submit HEDIS 2020 data for the 2019 measurement year and to curtail the CAHPS data collection during 2020, any display measures that come from these data sources will not have updated data for the 2021 display page.

Care for Older Adults – Functional Status Assessment Indicator (Part C). NCQA is moving forward with refining the hybrid specification for the Functional Status Assessment indicator in the Care for Older Adults measure. Currently, the specification states that documentation of a complete functional status assessment must include (1) notation that Activities of Daily Living (ADLs) were assessed; (2) notation that Instrumental Activities of Daily Living (IADLs) were assessed; (3) result of assessment using a standardized functional assessment tool; or (4) notation that at least three of the following four components were assessed: (a) cognitive status; (b) ambulation status; (c) hearing, vision and speech (i.e., sensory ability); (d) other functional independence (e.g., exercise, ability to perform job). Because the clinical field of functional status assessment is moving toward agreement on assessment using ADLs, IADLs, or another standardized tool, and to improve the clarity of the specification, NCQA is removing the fourth option for meeting the numerator requirements for this indicator. Given the potential impact of removing this fourth option on measure scores, NCQA is implementing this change for HEDIS 2021 based on the 2020 measurement year. About half of commenters supported this change without qualifications. The few that did not support suggested modifications to the specification. We will share comments received on this measure with NCQA. We consider this change a substantive update under § 422.164(d)(2), and the measure will be moved to display for the 2022 and 2023 Star Ratings. We would propose to include the updated measure in the Star Ratings through future rulemaking.

Reviewing Appeals Decisions (Part C). Currently, if a reopening occurs and is decided prior to May 1 of the subsequent measurement year, the reopened decision is used in place of the reconsideration decision. However, reopenings decided on or after May 1 are not reflected in the Star Ratings data, so the original reconsideration decision is used. Over the past several years, we have received feedback from plans that we should extend the date for reopenings as any decision the IRE overturns in a reopening could positively impact a contract's measure rating. It has been our longstanding policy that any necessary changes to 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 2019 IRE data must be made by June 30, 2020 for the 2021 Star Ratings).

We believe allowing reopenings through June 30 is a non-substantive change since this adds additional cases that would meet the numerator requirements. *See* § 422.164(d)(1)(iv)(A). Although this change will increase the numerator, we expect the increase to only be by a small amount as reopenings are infrequent. All commenters supported this non-substantive change so we are finalizing as proposed.

Controlling High Blood Pressure (Part C). The current denominator specification for this measure looks for two outpatient visits with a diagnosis of hypertension in the measurement year or the year prior. For measurement year 2020, NCQA is exploring modifying the timing of the denominator to look for two outpatient visits with a diagnosis of hypertension in the first six months of the measurement year or the year prior. The numerator would still assess the most recent blood pressure reading on or after the date of the second qualifying denominator event. This change to the denominator provides a minimum six-month window for interventions that might assist in bringing members' blood pressure under control. CMS appreciates feedback received on this potential update. Most commenters supported this change, and some provided suggestions for changes to the specification. We will share all comments with NCQA.

We believe this is considered a non-substantive change as described at § 422.164(d)(1)(i) as it will effectively narrow the denominator or population covered by the measure. Please note that this measure is on the display page for the 2020 and 2021 Star Ratings and we finalized returning it to the 2022 Star Ratings in the recent final rule published April 16, 2019 (84 FR 15761–15762).

Transitions of Care (Part C). This measure includes four rates that are averaged to calculate the measure score. For measurement year 2020, NCQA is exploring three updates to the Transitions of Care (TRC) measure. First, NCQA proposes to revise the requirement of using one medical record from a specific provider to, instead, allow numerator information to be captured from "the outpatient medical record as well as other information accessible to the primary care provider (PCP) or ongoing care provider". This change would help the specification capture additional communication forms (e.g., admissions, discharges, and transfers (ADT) feeds, shared electronic medical records (EMRs)) that occur regularly in the field and meet the intent of the measure. This change would also ensure that scores for the TRC measure and the standalone Medication Reconciliation Post-Discharge (MRP) measure would match. As such, the additional stand-alone MRP measure would no longer need to be separately reported. Second, NCQA proposes revising the timeframe for the Notification of Inpatient Admission and Receipt of Discharge Information indicators to "the day of admission or discharge, respectively, or within the following two calendar days." This change would clarify expectations for documentation related to admissions or discharges that take place over the weekend. Third, NCQA proposes to more broadly allow "instructions for patient care post-discharge" to count in the numerator of the Receipt of Discharge Information indicator rather than limiting it to only instructions given specifically to the PCP; thus, allowing additional data sources. This change would align these indicator criteria

with a more standard element found within all hospital summaries generated. If approved, measure updates would be implemented in measurement year 2020.

Although this measure is currently a display page measure, we believe all of these changes are non-substantive since they add additional tests that would meet the numerator requirements as described at § 422.164(d)(1)(iv)(A); add alternative data sources as described at § 422.164(d)(1)(v); and do not change the population covered by the measure. This measure received mixed support from stakeholders. Although the measure has already been implemented, some commenters requested clarifications or more time to implement. Some are concerned that administrative limitations can prevent health plans from receiving communication that enrollees have transitioned from hospital to home and about coordination of information especially with out-of-network providers. CMS appreciates feedback received on these potential updates and will share comments with NCQA. The current measure is on the display page and we will follow these potential updates from NCQA for future changes to the display page measure.

Patient-Used Device Data for HEDIS (Part C). As technology is changing, HEDIS is continuing to add additional sources of data to meet the numerator requirements of their measures. One HEDIS advancement is incorporating data from patient-used devices. For example, for the Controlling High Blood Pressure measure, readings are allowed from home blood pressure machines (which digitally store and transfer data on patient's blood pressure) to be used to fulfill the numerator of the measure. The following CPT codes are included in the 2019 version of the measure: 99091, 93784, 93788, 93790. (Note: There are newer codes NCQA is considering adding as well.) NCQA is looking forward to the wider use of other technologies that facilitate the incorporation of patient data into clinical data repositories in the future. Most commenters supported NCQA's interest in adding patient-used device data to the HEDIS specifications. We will share all comments with NCQA.

Digital Specifications for HEDIS (Part C). NCQA is continuing to develop digital specifications for existing HEDIS Effectiveness of Care measures. The process of converting the measures to a digital format allows for improvements to the HEDIS specifications by providing greater specificity and standardization of the language used to define the measure data elements. The digital specifications are produced using clinical quality language (CQL) and standard terminologies and may reference clinical concepts directly in addition to using claims-based proxies for measure definitions. Digital specifications provide both human readable and executable files of the measure logic, which can aid programmers in producing consistent results for the measure and reduce the need for interpretation of specifications. Selected HEDIS measures already have digital specifications available. NCQA will continue this digitalization process, converting another subset of existing HEDIS measures to the digital format in the coming year. Please note that as NCQA creates digital specifications for existing HEDIS measures, that process does not change the existing measure specification under § 422.164(d). We strongly encourage MA contracts to begin using and referencing the digital specifications.

Most commenters support this measure, however some expressed concern with the timing and pace of implementation. We will share all comments with NCQA.

HEDIS: Cross-Cutting Exclusions (Part C). NCQA is continuing work on cross-cutting exclusions for HEDIS measures. While HEDIS measures are designed to assess the quality of care provided to general populations or disease-specific care provided to individuals with a chronic condition, the measures may not be clinically appropriate for certain individuals and may overlook the quality of care issues that are specific to these patients. NCQA is exploring if there are additional methods that could be used to identify individuals who require nursing home level care but who reside in the community. Additionally, NCQA is exploring the development of a new cross-cutting exclusion for individuals receiving palliative care. NCQA is exploring how to identify individuals receiving palliative care, what their clinical needs are, and for which measures this exclusion would be appropriate. If approved, updates to existing exclusions and the new potential exclusion for palliative care would be implemented for measurement year 2020. All of the comments received supported the concept but some ask for additional information or suggest modifications to the proposal. CMS appreciates the feedback and will share comments with NCQA.

Initiation and Engagement of Alcohol and Other Drug Abuse and Dependence Treatment (Part C). This measure, which is currently included on the display page, assesses the percentage of adolescents and adult members with a new episode of alcohol and other drug abuse or dependence who 1) initiate treatment within 14 days of the start of their new episode, and 2) engage in ongoing treatment within 34 days of their treatment initiation. The reevaluation of the measure will include potential revisions to all aspects of the measure, including the denominator, numerator, and overall structure. Potential revisions include: the replacement of the single measure with three diagnosis-specific measures (opioid, alcohol, and other drug use disorder treatment); updates to the definitions for both "new episode" and "initiation and engagement of treatment"; consideration of comorbid mental health and substance use conditions; and the allowance for pharmacotherapy alone, without the concurrent use of psychosocial treatment, to satisfy the measure numerator. NCQA's testing of these potential revisions is ongoing. There was some support for these proposals, as well as requests for clarification. Commenters expressed concern about plans' abilities to collect enough accurate data, as well as increased burden on providers, due to disconnects between primary and behavioral health providers. CMS appreciates feedback received on these potential updates and will share it with NCQA. We will continue monitoring this measure on the display page.

Hospitalization for Potentially Preventable Complications (Part C). NCQA is considering updates to this HEDIS measure, which is currently on the display page. NCQA is considering removing hospitalizations without an overnight stay from the measure numerator and aligning the value sets with those in the related AHRQ Prevention Quality Indicators as well as updates to the risk adjustment model used for the measure. If approved, these measure updates would be implemented in measurement year 2020. All commenters supported this measure and a few

asked for clarifications, such as whether emergency department visits and overnight observation stays would be included. We appreciate feedback about these potential updates and will share comments with NCQA.

Concurrent Use of Opioids and Benzodiazepines (COB), Use of Opioids at High Dosage in Persons Without Cancer (OHD), Use of Opioids from Multiple Providers in Persons Without Cancer (OMP), and Use of Opioids at High Dosage and from Multiple Providers in Persons Without Cancer (OHDMP) (Part D). As discussed in the 2020 Call Letter, the COB, OHD, OMP, and OHDMP measures will be added to the display page for 2021 (using 2019 data). In the April 17, 2019 HPMS memo, UPDATES - 2019 Medicare Part D Patient Safety and Overutilization Monitoring System Reports, we announced updates to the measures for the 2019 measurement year based on clarifications received from the Pharmacy Quality Alliance (PQA).

When calculating the denominator requirement of ≥15 total days' supply of opioid medication the following steps are applied: i) when dispensed on different days, the days' supply is summed for the total days' supply, and ii) in the case of multiple prescriptions dispensed on the same day, total days' supply will only include the supply of the prescription with the longest days' supply.

Starting with the 2020 year of service (YOS) data, per the updated PQA specifications, beneficiaries with a sickle cell diagnosis at any time during the measurement year will be excluded from these measures.

Commenters commended CMS for its efforts to address the opioid epidemic. Many commenters supported the updates to this measure. Additionally, some commenters reiterated support for the inclusion of these measures on the display page but requested more clarification if these measures will become Star Ratings measures. CMS will continue to monitor these measures on the display page. As noted in the 2020 Call Letter, we will consider adding all or some of these measures to Star Ratings, which would be proposed through rulemaking. Furthermore, CMS emphasizes that these measures are not prescribing limits. We will continue to monitor for potential unintended consequences to ensure access to medically necessary opioid regimens.

A few commenters recommended additional exclusions be considered for these measures: hospice care; non-hospice palliative care; end of life care; or care delivered to a resident of a long-term care facility. As a reminder, per the PQA specifications, beneficiaries in hospice care or with cancer during the measurement year are already excluded from the denominator of these opioid measures. However, CMS will share comments with the PQA about the additional populations that were recommended for exclusion.

Antipsychotic Use in Persons with Dementia Overall (APD), Antipsychotic Use in Persons with Dementia, for Community-only Residents (APD-COMM), and Antipsychotic Use in Persons with Dementia, for Long-term Nursing Home Residents (APD-LTNH) (Part D). In the April 17, 2019 HPMS memo referenced above, we also described updated methodology for

the APD, APD-COMM, and APD-LTNH measures for the 2019 measurement year for the 2021 display page.

The denominator requirement of $\geq$ 2 prescription claims must have different dates of service. The PQA clarified that >60 days' supply is cumulative for any cholinesterase inhibitor or NMDA receptor antagonist. The days' supply of eligible antipsychotic drugs in the numerator is cumulative.

Also, when calculating the numerator and denominator total days' supply requirements, the following steps are applied: i) when dispensed on different days, the days' supply is summed for the total days' supply, and ii) in the case of multiple prescriptions dispensed on the same day, total days' supply will only include the supply of the prescription with the longest days' supply.

The majority of commenters supported this measure update. A few commenters recommended that beneficiaries enrolled in a hospice be excluded from the denominator. CMS appreciates the feedback and will share comments with the PQA.

Medication Adherence (ADH) for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications, and Medication Adherence for Cholesterol (Statins) (Part D). As discussed in past Call Letters, the PQA tested their medication adherence measures, which are used for the Star Ratings, for potential risk adjustment of the measures (i.e., adjustment for socioeconomic status (SES) or sociodemographic status (SDS)). PQA included the following draft recommendations in their Measure Manual:

- All three adherence measures should be risk adjusted for SDS characteristics to adequately reflect differences in patient populations.
- The measures should be adjusted for the following beneficiary-level SDS characteristics: age, gender, dual eligibility/low-income subsidy (LIS) status, and disability status.
- The 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 risk-adjusted adherence measures were endorsed by the National Quality Forum (NQF) in the 2019 Spring cycle (NQF endorsed #0541). CMS will consider implementation of the PQA recommendations in the future for these Star Ratings measures (i.e., for the 2022 measurement year or beyond). Substantive measure changes must be proposed and finalized through rulemaking.

As discussed in the 2020 Call Letter and the April 17, 2019 HPMS memo, UPDATES - 2019 Medicare Part D Patient Safety and Overutilization Monitoring System Reports, CMS included stratifications by age, gender, dual eligibility/LIS status, and disability status in the Medication Adherence Patient Safety Reports to Part D sponsors for the 2019 measurement year.

The majority of commenters strongly supported the risk adjustment for SDS characteristics of the adherence measures. However, commenters have requested more information on how the adherence measures will be risk adjusted and how the changes could impact the Star Ratings. Such details would be provided through the rulemaking process if CMS proposes a rule to add the measure adjustments to the Star Ratings system. CMS will continue to work with the PQA to incorporate the risk adjustment specifications into the adherence measures under development. We appreciate the comments and will consider them as we make decisions about future measures.

Retired Display Measures for 2023

Osteoporosis Testing in Older Women (Part C). NCQA is retiring the Osteoporosis Testing in Older Women measure, which assesses if women 65 years and older have ever received a bone mineral density test to screen for osteoporosis. This current display page measure is fielded through the Medicare Health Outcomes Survey and assesses the number of eligible respondents who "ever had" a central dual-energy X-ray absorptiometry (DXA) of the back and hip to detect osteoporosis. During the last HEDIS reevaluation cycle, concerns about the validity of this survey measure and the ability of women to accurately recall their screening history spurred the decision to retire the measure for measurement year 2020. This measure will be retired from the 2020 measurement year so it will be removed from the display page starting in 2023. Most commenters supported retiring this measure. We will share feedback received about the measure with NCQA.

Potential New Measure Concepts

End-Stage Renal Disease (ESRD) Measures (Part C). The 21st Century Cures Act (CURES; P.L. 114-255) allows beneficiaries with End-Stage Renal Disease (ESRD) the option to start enrolling in MA plans in 2021. Most of the measures currently in the Part C & D Star Ratings capture the health care quality of beneficiaries with ESRD. NCQA is working to develop a new kidney health evaluation measure that may in the future replace the *Diabetes Care – Kidney Disease Monitoring* measure that is currently in the Star Ratings. The kidney health evaluation measure would assess whether adults who have diabetes received an annual kidney profile evaluation, defined by an estimated Glomerular Filtration Rate (eGFR) and a Urine Albumin-Creatinine Ratio (UACR). This new measure that is being tested aligns with recommendations from the American Diabetes Association and will provide critical information for screening and monitoring of kidney health for patients with diabetes. It may also be useful to add other new measures focused on ESRD and/or Chronic Kidney Disease. We solicited comments on ESRD measures that may be reliably measured at the contract level. Nearly all commenters support the adoption of ESRD measures, and several suggested specific measures that could be used. We appreciate all comments and will consider them for potential future ESRD measures. We will also share comments with NCQA.

Prior Authorizations (Part C). CMS is beginning work to develop a measure for the display page related to prior authorizations and is considering proposing it in the future as a Star Ratings measure to support beneficiary access to necessary and reasonable care. Prior authorization is a critical aspect of plan performance since it affects how quickly plan enrollees can get needed care and services. Although prior authorization has proven to be an effective process for controlling improper payments and managing costs, CMS recognizes that when processes are not in place to quickly review and approve requests for tests, services and supplies that may be medically necessary for the beneficiary, this can affect access to needed patient care.

Some commenters gave recommendations on areas to potentially pursue for measure development such as evaluating denial/approval rates, automated systems, transparency, timeliness, or adherence to standards. Some suggested it was duplicative with other monitoring efforts, or would favor larger sponsors that have more technological resources. We appreciate comments received and will consider them in development of a prior authorization measure.

HOS Measures (Part C). Patients are the ultimate source of information on patient outcomes. CMS proposed using new and more targeted patient-reported outcome measures to hold contracts accountable for the outcomes of care for their members. Longitudinal measures are key to assessing plans' success in improving or maintaining their members' functioning. CMS proposed the new longitudinal measure from the Medicare Health Outcomes Survey (HOS) to complement the measurement of the physical health status of MA beneficiaries. We stated we planned to post the longitudinal Physical Functioning Activities of Daily Living (PFADL) change measure on the 2021 and 2022 display pages and that we may consider the measure for the Star Ratings in the future, pending rulemaking.

The PFADL scale combines two physical functioning (PF) questions (limitations in moderate activities and climbing stairs) with the six activities of daily living (ADL) questions to create a Likert-type scale. PFADL scale scores are created from the baseline and the two-year follow up questions. The newly developed change measure can be interpreted as the percent of function retained by average MA beneficiaries over two years compared to a maximum decline. In contrast to most HEDIS measures, the PFADL change measure for an MA contract would be its mean change score rather than the proportion passing the measure. The PFADL change score is positively correlated with both physical component summary (PCS) and mental component summary (MCS) scores. Please see https://www.hosonline.org/globalassets/hos-online/survey-results/mhos_pfadl_change_measure.pdf for a more detailed methodology used to score the PFADL change measure.

Many commenters expressed support for the methodologically simpler PFADL measure and one commenter recommended CMS consider replacing the existing Physical Health measure with the PFADL measure. Most request additional information before the measure is proposed as an addition to the Star Ratings program. Others raised questions about the reliability and validity of the new measure. Commenters also continue to struggle with the complexities of the existing

Improving or Maintaining Physical and Mental Health measures. We are planning to proceed to introduce the simpler PFADL measure to the display page and will provide additional information about the reliability as it becomes available. Given the complexities of the existing HOS measures, CMS is committed to exploring alternative patient-reported measures to replace the existing HOS outcome measures; we are particularly interested in replacements that would be simpler and more direct for plans to use and to focus their quality improvement efforts.

CMS also sought comment on expanding the existing HOS measures (Improving or Maintaining Physical Health and Improving or Maintaining Mental Health) to the under 65 population. Currently, HOS measures are not calculated for beneficiaries under age 65, who are entitled to Medicare for reasons other than age (i.e., younger people with physical or mental disabilities, End-Stage Renal Disease (ESRD), and amyotrophic lateral sclerosis (ALS)). Enrollees under 65 are already included in the survey, so expanding analysis of the HOS measures to include the under 65 population would increase sample size for most contracts without increasing data collection costs. The majority oppose expanding the existing HOS measures to include beneficiaries under age 65 and cite significant differences between the under 65 and over 65 Medicare populations in terms of physical/mental disabilities and care needs. Some commenters recommended rigorous testing, social determinant risk adjustment, and segmented reporting by age category. We appreciate all comments received about HOS measures and will consider them for the future.

Osteoporosis Screening (Part C). NCQA is exploring the feasibility and impact of a new osteoporosis screening measure for older women. Testing of a new potential measure will help determine if osteoporosis screening can be accurately identified in claims and clinical data. If developed and approved, the new measure would be included in HEDIS for measurement year 2020. CMS may consider this measure for the display page and Star Ratings in the future. Most commenters supported CMS following consensus guidelines although a few expressed concern about excessive screening and unnecessary care. We appreciate all comments and will share them with NCQA.

Cardiac Rehabilitation (Part C). NCQA is exploring a new measure assessing whether adults who had certain cardiac conditions (e.g., heart attack, coronary angioplasty, coronary artery bypass, heart transplant, heart valve repair or replacement) received evidence-based cardiac rehabilitation. This concept comes from discussions with the Million Hearts Campaign and the American Heart Association. As part of the national goal to increase cardiac rehabilitation participation rates, Million Hearts has proposed development of a plan-level HEDIS measure based on the American College of Cardiology/American Heart Association claims-based quality measure for cardiac rehabilitation participation. NCQA tested this measure in the fall of 2019. If approved, this measure would be included in HEDIS for measurement year 2020. About half of commenters supported this measure, although a few stated that utilization of cardiac rehabilitation is outside the plans' control. CMS appreciates feedback from stakeholders on the feasibility and utility of this type of measure. We will share all comments with NCQA.

Diabetes Overtreatment (Part C). NCQA is exploring new measure concepts that will assess overtreatment in patients with type 2 diabetes. Several organizations, such as the American Diabetes Association, have recommended relaxing glycemic control in diabetic older adults with comorbidities as they are less likely to benefit from intensive glycemic control and are at higher risk of adverse events such as hypoglycemia. NCQA is considering a measure that assesses whether clinically complex members with type 2 diabetes are being overtreated (as defined by HbA1c level and medications). NCQA is also investigating a potential outcome measure that focuses on the identification of hospitalizations, emergency department visits, and observation stays among diabetic adults due to hypoglycemia as an alternative way to assess diabetes overtreatment. NCQA plans to continue the work and investigation on which measures can be operationalized and will potentially begin testing the new measure in 2020. If developed and approved, the new measure would potentially be included in HEDIS for measurement year 2021. Feedback on this measure concept was mixed, with many supporting, others asking for clarifications, and a few expressing concern that it could impact treatment negatively. CMS appreciates comments received and will share them with NCQA.

Home Health Services (Part C). NCQA is exploring a new measure concept assessing the quality of care coordination for MA beneficiaries requiring home health services. Relative to other beneficiaries in the Medicare program, beneficiaries requiring home health are disproportionately older and manage five or more chronic conditions. Successful home health outcomes require care coordination before, during, and after the home health episode. Potential measure development is on an extended timeline to account for the complexity of changing referral pathways and diversity in service intent. If developed and approved, a new measure would potentially be included in HEDIS for measurement year 2021. Nearly all commenters support this new measure concept, although a few offered suggestions or asked for additional details. CMS appreciates feedback received and will share it with NCQA.

Generic Utilization (Part D). CMS plans to develop measures to assess generic and biosimilar utilization in the Medicare Part D program. CMS encourages Part D sponsors to leverage favorable tier placement and effective formulary management tools to incentivize beneficiaries to fill generic alternatives over branded products. Generic dispensing and generic substitution rates, 82% and 91% respectively in 2017, are high on average across the Part D program. However, the remaining branded prescription fills represent a significant opportunity to reduce Medicare expenditures and lower out-of-pocket costs for beneficiaries through the use of generic alternatives.

CMS solicited comments on the following measure concepts:

1. Generic[9] Substitution Rate (higher is better): Total number of generic fills divided by the sum of brand and generic fills for drugs that had approved therapeutically equivalent generic products that were available on the market at the time of the fill.

2. Generic Therapeutic-Alternative Opportunity Rate (lower is better): Total number of brand fills divided by the sum of brand and generic fills within select drug classes or subclasses where both brands and generics are available. Classes consisting of only brand National Drug Codes (NDCs) or only generic NDCs will be excluded from the measure.

3. Biosimilar Utilization Rate (higher is better): Total number of biosimilar fills divided by the sum of reference biologics and biosimilar fills for biologics for which there were licensed biosimilars available on the market at the time of the fill.

We also sought input to help shape more detailed measure specifications, such as:

- What classification system should be used for the Generic Therapeutic-Alternative Opportunity Rate?

- What specific classes or subclasses (where both brands and generics are available) should be excluded, due to significant variability in the safety or effectiveness of the available generic(s) compared to the brand(s)?

- What are the current barriers to generic uptake?

We will continue to perform data analysis of current generic coverage, formulary placement, and generic utilization rates in Part D as well as consider the feedback on this measure concept. We will also work with measure developers to explore potential measure concepts. Our goal is to propose to adopt measures that reward sponsors for high rates of generic utilization.

CMS received an overwhelming response by commenters who were opposed to developing these measures. Commenters expressed that the measure concepts do not focus on quality or outcomes that are meaningful to beneficiaries when selecting Part D plans. Additionally, commenters were concerned that generic or biosimilar drugs were not always the most cost effective options for beneficiaries. Some commenters suggested that the measures would lead to unintended consequences such as: an increase in costs and premiums; inappropriate substitutions of therapy or switching from stabilized therapy; impacts on beneficiary access to medically necessary medications; interference with formulary management; creation of preferential biosimilar or generic manufacturer policies; and reduction in competition. We appreciate the comments received and will consider them for any potential future development of generic utilization measures.

[9] Brand and generic drugs, as defined in 42 CFR § 423.4.

Initial Opioid Prescribing (IOP) Measures (Part D). The PQA developed and endorsed three initial opioid prescribing (IOP) measures. These measures are aligned with the CDC Guideline for Prescribing Opioids for Chronic Pain. The new IOP measures, developed through a consensus process, will provide additional tools for Part D sponsors to monitor initial opioid prescriptions that increase risk for chronic opioid use and opioid use disorder.

- Initial Opioid Prescribing at High Dosage (IOP-HD): This measure assesses the percentage of individuals 18 years and older with one or more initial opioid prescriptions with an average daily morphine milligram equivalent (MME) of 50 or greater. To be included in the denominator, individuals would have filled one or more prescriptions for opioids, with a negative medication history for any opioid prescription claim during the lookback period. The opioid initiation period is the 7 day time period when the numerator is assessed and includes the date of the initial opioid prescription plus 6 days. A lower rate represents better performance.

- Initial Opioid Prescribing for Long Duration (IOP-LD): This measure assesses the percentage of individuals 18 years and older with one or more initial opioid prescriptions for more than 7 cumulative days' supply. To be included in the denominator, individuals would have filled one or more prescriptions for opioids, with a negative medication history for any opioid prescription claim during the lookback period. The opioid initiation period is the 3 day time period when the numerator is assessed and includes the date of the initial opioid prescription plus 2 days. A lower rate represents better performance.

- Initial Opioid Prescribing for Long-Acting or Extended Release Opioids (IOP-LA): This measure assesses the percentage of individuals 18 years and older with one or more initial opioid prescriptions for long-acting or extended-release opioids. To be included in the denominator, individuals would have filled one or more prescriptions for opioids, with a negative medication history for any opioid prescription claim during the lookback period. The opioid initiation period is the 7 day time period when the numerator is assessed and includes the date of the initial opioid prescription plus 6 days. A lower rate represents better performance.

Like the other Part D patient safety measures, CMS would apply the member-years of enrollment adjustment to account for beneficiaries who are enrolled for only part of the contract year. The initial opioid prescription, as defined by the PQA, is the earliest date of service for an opioid prescription during the measurement year following a negative medication history. Beneficiaries may have multiple initial opioid prescriptions and therefore multiple opioid initiation periods during the measurement year. The lookback period is the period of 90 days prior to each opioid prescription; however, the lookback period is not part of the member-year calculation. Additionally, a negative medication history is defined as individuals with no prescription claims for opioids during the lookback period. Beneficiaries enrolled in hospice, with a cancer diagnosis, or with a sickle cell disease diagnosis during the measurement year or the 90 days

prior to the earliest date of service for an opioid medication during the measurement year are excluded from all three IOP measures.

We tested the PQA specifications for these three measures using 2018 PDE data, adjusted the measure for member-years, and evaluated the number of contracts with greater than 30 member-years in the denominator. There were a total of 739 Part D contracts in year of service 2018; however, after adjusting the measure for member-years, 641 contracts met the eligibility requirements in the denominator. All three IOP measures had the same denominator population while the numerator population varied significantly based on the different numerator requirements for each IOP measure. The overall rates for all contract types for IOP-HD was approximately 13%, for IOP-LA was approximately 1%, and for IOP-LD was approximately 41%. The rate associated with the top 5% of PDP contracts for the IOP-HD was 25.01% while MA-PD contracts had a higher rate of 39.34%. The rate associated with the top 5% of PDP contracts for the IOP-LD was 63.64%, while MA-PD contracts had a higher rate of 86.58%. The rate associated with the top 5% of PDP contracts for the IOP-LA was 6.06% while MA-PD contracts had a higher rate of 11.50%.

Table 16: Distribution of Initial Opioid Prescribing Measure Rates by Medicare Part D Contract Type, 2018 Data

Part D Contracts			Percentiles							
Measure	**Type**	**Count**	**Mean**	**Min**	**10%**	**25%**	**50%**	**75%**	**95%**	**Max**
IOP-HD	All	641	11.94%	0.00%	4.95%	7.85%	11.47%	15.10%	22.54%	39.34%
	MA-PD	583	11.63%	0.00%	4.70%	7.59%	10.95%	14.80%	22.54%	39.34%
	PDP	58	15.09%	6.10%	9.66%	12.82%	14.95%	17.34%	23.50%	25.01%
IOP-LD	All	641	44.03%	14.06%	31.19%	36.71%	42.03%	49.81%	67.07%	86.58%
	MA-PD	583	44.41%	14.06%	31.01%	36.63%	42.56%	50.43%	67.60%	86.58%
	PDP	58	40.24%	28.53%	33.19%	37.24%	39.57%	42.44%	49.01%	63.64%
IOP-LA	All	641	1.07%	0.00%	0.22%	0.50%	0.79%	1.20%	2.90%	11.50%
	MA-PD	583	1.06%	0.00%	0.17%	0.48%	0.78%	1.18%	2.93%	11.50%
	PDP	58	1.14%	0.25%	0.46%	0.70%	0.99%	1.27%	2.20%	6.06%

CMS expects these rates may be lower for dates of service after 2018 due to Part D sponsor implementation of the opioid naïve point of sale (POS) edit in 2019.

CMS reviewed the IOP measures for potential inclusion in the Part D Patient Safety measure reporting. Of the three IOP measures, the IOP-LA and IOP-LD measures best align with the Medicare Part D opioid safety edit guidance. Although we found some variability within the contracts for all of the IOP measures, the overall rates for IOP-LA were low. In addition, the current Patient Safety measures based on the use of opioids from multiple providers and/or at high dosages (i.e., 90 MME) in persons without cancer and the Overutilization Monitoring System (OMS) monitors potential high-risk opioid use in the Part D program.

Therefore, CMS stated our plans to begin reporting only the IOP-LD in the Patient Safety reports for the 2020 measurement year. We plan to add this measure to the display page for 2023 (2021 data) and 2024 (2022 data). We will consider adding the IOP-LD measure to the Star Ratings in the future pending rulemaking once we gain experience with the measure. However, CMS will perform additional analyses of the IOP-HD and IOP-LA measures internally and monitor any notable utilization trends in the future. As a reminder, the Patient Safety opioid measures and the Medicare Part D opioid-related policies are not intended as a means to implement prescribing limits which could have unintended consequences that adversely impact a beneficiary's access to medically necessary prescribed opioids. CMS appreciates stakeholder feedback received on these new IOP measures.

Many commenters supported the IOP-LD measure concept. A few commenters supported adding the IOP-LD measure to the display page but were concerned about the impact this measure may

have on the Star Ratings. Commenters agreed with CMS that they would like to gain more experience with the IOP-LD measure before including the measure into the Star Ratings. Based on this feedback, CMS will begin reporting the IOP-LD measure in the Patient Safety reports for the 2020 measurement year, and we will add this measure to the display page for 2023 (2021 data) and 2024 (2022 data). We will monitor the IOP-LD measure data for consideration in the future for the Star Ratings, which would be proposed through rulemaking.

Some commenters requested additional exclusions to the IOP-LD measure such as beneficiaries residing in a long-term care, hospice care, those receiving palliative care, or end of life services. Currently, per the PQA specifications, the IOP-LD measure excludes beneficiaries in hospice care, those with cancer, and beneficiaries with a sickle cell diagnosis during the measurement year. One commenter also expressed concerns about the number of opioid measures in the pipeline. CMS carefully evaluates all of the patient safety measures and continues to monitor each of the measures. CMS will consider this feedback and will share specification related comments with the PQA.

A few commenters opposed the IOP-LD measure as they expressed concern the measure does not account for physician specialization or those beneficiaries with advanced illness who may need a higher or longer initial opioid dosing. CMS re-emphasizes that the IOP-LD measure is focused on beneficiaries who receive one or more opioid prescriptions for more than 7 cumulative days' supply and who do not have prescription claims for opioids in the 90 days prior to each opioid prescription. Therefore, generally we would not expect chronic opioid users to be captured in the IOP-LD measure. CMS also reiterates that the IOP-LD measure is not intended as a prescribing limit and we will continue to oversee that beneficiaries have access to medically necessary prescribed opioids.

Net Promoter Score (Part C & D). The Net Promoter Score (NPS) is a measure that focuses on the loyalty that exists between an organization and a consumer. To calculate an NPS score, the consumer answers one question ("How likely is it that you would recommend [organization] to a friend or colleague?") using a 0-10 scale where the greater the value the more likely the consumer is to give a favorable recommendation. Respondents to this question are grouped as follows:

- **Promoters** (score 9-10) are loyal enthusiasts who will keep buying and refer others, fueling growth.
- **Passives** (score 7-8) are satisfied but unenthusiastic customers who are vulnerable to competitive offerings.
- **Detractors** (score 0-6) are unhappy customers who can damage a brand and impede growth through negative word-of-mouth.

The NPS is calculated by subtracting the percentage of Detractors from the percentage of Promoters, resulting in a score that can range from a low of -100 (if every respondent is a Detractor) to a high of 100 (if every respondent is a Promoter).

Many commenters were against adding this measure. In addition to volatility and reliability concerns, there were concerns that a consumer would (or would not) recommend a health plan based on factors other than the plan's quality (e.g., brand loyalty, cost, geographic availability of services). Commenters stated the NPS has been shown to be correlated with other key outcome measures, such as the CAHPS Health Plan Rating and Health Care Rating; adding such a question would be duplicative and further increase the burden on members. We appreciate feedback received on NPS.

Attachment VII. Economic Information for the CY 2021 Rate Announcement

Below, we provide the economic information for significant provisions in the Rate Announcement. Provisions not specifically addressed below are intended to represent a continuation of the policies established for CY 2020 and, as a result, do not have an impact associated with them. As we are finalizing as proposed all policies listed below, only the economic information related to the MA and PACE ESRD and non-ESRD ratebooks has been updated from that presented in the Advance Notice, to reflect more current data. Comments related to the economic information presented in Parts I and II of the Advance Notice have been summarized and addressed in the applicable sections above with the remainder of the comments.

A. Changes in the Payment Methodology for Medicare Advantage and PACE for CY 2021

1. CMS-HCC Risk Adjustment Model for 2021

The impact of the transition of the risk adjustment model revision for CY 2021 is the effect of changes in the blend of risk scores calculated under the 2017 CMS-HCC model and the 2020 CMS-HCC model. This is the effective impact on MA risk scores of blending 75% of the 2020 CMS-HCC model and 25% of the 2017 CMS-HCC model, consistent with the policy being finalized in the 2021 Rate Announcement, relative to the policy finalized for 2020, 50% of the 2020 CMS-HCC model and 50% of the 2017 CMS-HCC model. The CY 2021 impact on MA risk scores of the transition to the 2020 CMS-HCC model, relative to CY 2020, is 0.25%, which represents a $565.5 million net cost to the Medicare Trust Funds in 2021. This estimate takes into account the portion of the difference between benchmarks and bids that the government retains and the portion of the program costs covered by Part B premiums.

The CY 2021 impact on MA risk scores of the transition to a greater percent of the risk score being calculated with encounter data, FFS claims, and RAPS inpatient records is 0.00%. This impact is 0.00% because we project that the differential between the RAPS-based risk score and the encounter data-based risk score, calculated using the risk adjustment models proposed for 2021, to be 0.00%.

2. Medicare Advantage and PACE non-ESRD Ratebook

The FFS growth percentage for the 2021 MA non-ESRD rates is estimated to be 3.64 percent, and the MA growth percentage for the 2021 non-ESRD rates is estimated to be 5.62 percent. As a result, the effective growth rate for 2021 MA non-ESRD rates is estimated to be 4.07 percent. The MA non-ESRD ratebook impact is calculated by comparing 2021 Part C expenditures reflecting these growth rate assumptions to the expected 2021 Part C expenditures assuming the MA non-ESRD ratebook remains unchanged from that finalized for 2020. The net cost to the Medicare Trust Funds for CY 2021 is expected to be $10.08 billion. This figure accounts for the impact of the benchmark rate cap, MA rebate, and MA EGWP policies, as well as the portion of

the difference between benchmarks and bids that the government retains and the portion of the program costs covered by Part B premiums.

To calculate the CY 2021 PACE non-ESRD rates, CMS applies the MA growth percentage for the 2021 MA non-ESRD rates, estimated to be 5.62 percent, to the CY 2020 PACE rates. The PACE non-ESRD ratebook impact is calculated by comparing the 2021 PACE expenditures reflecting this growth rate assumption to the expected 2021 PACE expenditures assuming that the PACE non-ESRD ratebook remains unchanged from the CY 2020 PACE non-ESRD ratebook. The net impact on the Medicare Trust Funds for CY 2021 for the PACE ratebook change is expected to be $79 million. This figure accounts for the portion of the program costs covered by Part B premiums.

For the impact assessment for the exclusion of standardized costs for kidney acquisitions from MA benchmarks starting in 2021, see the CY 2021 proposed rule (CMS-4190-P) to codify the statutory requirement.

Note that outside of the exclusion of organ acquisition costs for kidney transplants from MA county rates, the methodology for calculating the CY 2021 MA and PACE rates remains unchanged from the methodology used for CY 2020.

3. Indirect Medical Education (IME) Phase Out

Section 161 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110-275) amended section 1853(k)(4) of the Act to require CMS to phase out indirect medical education (IME) amounts from MA capitation rates. Per statute, the maximum incremental IME phase-out is 0.60 percent of the FFS rate per year. OACT estimated the impact of the IME phase-out change between 2020 and 2021. Since the maximum IME reduction is 6.6 percent in 2020 and 7.2 percent in 2021, we calculate the impact as the difference for those counties with IME percentages of at least 6.6 percent, with the maximum impact of 0.6 percent (i.e., the difference between 7.2 and 6.6 percent). Also, since the IME reduction to MA benchmarks is increasing, the impact is considered to be a net savings to the Medicare Trust Funds.

Only six counties in payment year 2021 have IME amounts greater than 6.6 percent of the FFS rate. All other counties have IME amounts less than 6.6 percent of their respective FFS rates and are not included in this analysis since their FFS rates, for purposes of the MA ratebook, are not impacted by the change in the IME phase-out percentage in 2021. For the ESRD ratebook, IME amounts are calculated at the state level, and all IME amounts aggregated at the state level are less than 6.6 percent of the FFS rate, so there is no impact from the IME phase-out change on the ESRD ratebook for 2021.

The results are a net savings of $13.90 million to the Medicare Trust Funds for CY 2021. This result takes into account the portion of the difference between benchmarks and bids that the government retains and the portion of the program costs covered by Part B premiums.

Note that the statutorily prescribed methodology for calculating the IME phase-out in 2021 is the same as that provided by statute for CY 2020; we are providing this impact assessment for informational purposes.

4. Medicare Advantage and PACE ESRD Ratebooks

The FFS growth percentage for the 2021 ESRD state rates is estimated to be 4.04 percent. The impact on the MA and PACE ESRD ratebooks is calculated by comparing projected 2021 Part C expenditures with this growth rate assumption to the expected 2021 Part C expenditures with the assumption that the MA and PACE ESRD ratebooks remain unchanged from those finalized for 2020. The net impact on the Medicare Trust Funds for CY 2021 is expected to be $580 million. This figure accounts for the portion of the program costs covered by Part B premiums.

Note that outside of the exclusion of organ acquisition costs for kidney transplants from non-PACE MA ESRD rates, the impact of which is addressed in the CY 2021 proposed rule, the methodology for calculating the CY 2021 ESRD rates remains unchanged from the methodology used for CY 2020.

5. ESRD Risk Adjustment Model for CY 2021

CMS will revise the blend of the risk scores calculated with the ESRD risk adjustment models for CY 2021 payments, with 75% of the risk score calculated with the 2020 ESRD model and 25% of the risk score calculated with the 2019 ESRD model. For CY 2020, CMS used a 50-50% blend of the risk scores calculated with the 2020 and 2019 ESRD models. The impact of the ESRD risk adjustment model transition is the effect of the changes in the blend. The CY 2021 blended impact on ESRD risk scores of the transition to the 2020 ESRD model, relative to CY 2020, is 0.31% for ESRD (dialysis and post graft combined), which represents a $44 million net impact on the Medicare Trust Funds in 2021. This impact takes into account the portion of the program costs covered by Part B premiums.

6. Frailty Adjustment for FIDE SNPs

For CY 2021, CMS will calculate frailty scores for FIDE-SNPs by blending 75% of the frailty score using the frailty factors associated with the 2020 CMS-HCC risk adjustment model and 25% of the frailty score using the frailty factors associated with the 2017 risk adjustment CMS-HCC model. For CY 2020, CMS calculated the frailty scores as the sum of 50% of the frailty score using the 2020 CMS-HCC model frailty factors and 50% of the frailty score using the 2017 CMS-HCC model frailty factors. The impact of the frailty adjustment transition is the effect of changes in the blend of frailty scores calculated using the frailty factors associated with the 2017

CMS-HCC model and with the 2020 CMS-HCC model. The CY 2021 impact of transitioning to frailty scores calculated using the frailty factors associated with 2020 CMS-HCC model, relative to CY 2020, is a change in frailty scores of -8.6%, which represents a net savings of $10.1 million dollars to the Medicare Trust Funds in 2021. This impact takes into account the portion of the difference between benchmarks and bids that the government retains and the portion of the program costs covered by Part B premiums.

7. Medicare Advantage Coding Pattern Adjustment

For CY 2021, we will apply the statutory minimum coding intensity adjustment (5.90%). There is no change in policy from CY 2020, and we applied the same factor for CY 2020, therefore the year-over-year impact is zero.

8. Normalization

The normalization factors serve to offset the trend in risk scores, and serves to maintain a 1.0 average FFS risk score. For CY 2021, CMS will apply the same methodology to calculate the normalization factors that was applied in CY 2020. To determine the CY 2021 normalization factors, we applied the CY 2020 methodology to the most current underlying data available, resulting in updated normalization factors. Since normalization is applied to risk scores to maintain the same level of the risk scores year-over-year, and there are no changes in the methodology being applied for CY 2021 from the prior year, the impact of normalization is zero.

B. Changes in the Payment Methodology for Medicare Part D for CY 2021

1. Encounter Data as a Diagnosis Source to Calculate Part D Risk Scores for CY 2021

The impact of the CMS decision to calculate Part D risk scores using the 2020 RxHCC model for CY 2021, by adding 75% of the risk score calculated with risk adjustment eligible diagnoses from encounter data (supplemented with RAPS inpatient records) and FFS claims with 25% of the risk score calculated using risk adjustment eligible diagnoses from RAPS data and FFS claims, is 0.00%. This impact is 0.00% because we project the differential between the RAPS-based risk score and the encounter data-based risk score to be 0.00%.

2. Annual Percentage Increase for Out-of-Pocket Threshold and Other Part D Parameters

The impact of the out-of-pocket threshold increase is the effect of implementing a statutorily required change in the methodology used to calculate the threshold. As required under section 1860D-2(b)(4) of the Act, the out-of-pocket threshold for 2021 and subsequent years is calculated by updating the previous year by the annual percentage increase in drug costs (API). In contrast, for 2020, the statutory methodology required that:

(A) the previous year (2019) threshold first be recalculated as if thresholds for each of years 2014 through 2019 had been updated using the API,[10] and then

(B) the recalculated prior year threshold be updated by the API.

If CMS were to apply the 2020 methodology for the out-of-pocket threshold increase for 2021, part (A) of the methodology would not have an impact on the calculations since the prior year (2020) threshold already accounts for the adjustment for 2014-2019, meaning only part (B) of the methodology – increase prior year threshold by API – would apply. Therefore, the 2020 and 2021 methodologies both result in the same 2020 threshold being increased by the API, and, thus, there is no impact for this provision.

The methodology for updating other Part D parameters for CY 2021 remains unchanged from that used for CY 2020. As a result, updating the other Part D parameters does not have an impact on the Medicare Trust Fund alone; the impact of such parameter updates is dependent on the behavior and bid assumptions of Part D plan sponsors.

[10] For 2014 and 2015, the Act required that the threshold be updated by the API minus 0.25 percentage point and that for contract years 2016-2019, the threshold be updated from the previous year by the lesser of (1) the API or (2) two percentage points plus the annual percentage increase in the consumer price index.