UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ELEVANCE HEALTH, INC., et al. Plaintiffs, v. **XAVIER BECERRA**, in his official capacity as Secretary of Health and Human Services, U.S. Department of Health and Human Services and **CHIQUITA BROOKS-LASURE**, in her official capacity as Administrator, Centers for Medicare and Medicaid Services Defendants.	Case No. 1:23-cv-03902-RDM

JOINT APPENDIX OF ADMINISTRATIVE RECORD CITATIONS

In accordance with the U.S. District Court for the District of Columbia Local Rule 7(n), the parties file this Joint Appendix containing copies of those portions of the Administrative Record cited in their respective briefs.[1]

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[1] In accordance with Local Civil Rule 7(n) and the Court's Standing Order, Plaintiffs are providing two printed courtesy copies of this Joint Appendix and the full set of cross-motion briefing in this case to the Court's chambers as the submissions exceed 100 pages.

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1	Excerpts from "Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly," 85 Fed. Reg. 9002 (Feb. 18, 2020) ("Tukey Outlier Deletion Proposed Rule").	• 85 Fed. Reg. 9009 (A.R. 000008) • 85 Fed. Reg. 9043-44 (A.R. 000042-43)
2	Public Submission, commenting on the Tukey Outlier Deletion Proposed Rule CMS-2020-0010-0002, by Ucare, Apr. 2, 2020.	• A.R. 000271-80
3	Public Submission, commenting on the Tukey Outlier Deletion Proposed Rule CMS-2020-0010-0002, by SCAN Health Plan, Apr. 6, 2020.	• A.R. 000377-85
4	Public Submission, commenting on the Tukey Outlier Deletion Proposed Rule CMS-2020-0010-0002, by Ass'n for Cmty. Affiliated Plans, Apr. 6, 2020.	• A.R. 000386-90
5	Public Submission, commenting on the Tukey Outlier Deletion Proposed Rule CMS-2020-0010-0002, by Blue Cross Blue Shield Ass'n, Apr. 6, 2020.	• A.R. 000391-440
6	Public Submission, commenting on the Tukey Outlier Deletion Proposed Rule CMS-2020-0010-0002, by Anthem (now Elevance Health, Inc.), Apr. 6, 2020.	• A.R. 000577-627
7	Public Submission, commenting on the Tukey Outlier Deletion Proposed Rule CMS-2020-0010-0002, by All. of Cmty. Health Plans, Apr. 6, 2020.	• A.R. 000825-37
8	Excerpts from "Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program," 85 Fed. Reg. 33796 (Jun. 2, 2020) ("Tukey Outlier Deletion Final Rule").	• 85 Fed. Reg. 33797 (A.R. 001026) • 85 Fed. Reg. 33833-36 (A.R. 001062-65) • 85 Fed. Reg. 33907 (A.R. 001136)
9	Excerpts from "Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost	• 87 Fed. Reg. 79625-26 (A.R. 001314-15) • 87 Fed. Reg. 79634-35 (A.R. 001323-24)

	Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications," 87 Fed. Reg. 79452 (Dec. 27, 2022) ("Tukey Technical Amendment Proposed Rule").	• 87 Fed. Reg. 79625-26 (A.R. 001612-13)[2]
10	Public Submission, commenting on the Tukey Technical Amendment Proposed Rule CMS-2022-0191-0001, by AHIP, Feb. 13, 2023.	• A.R. 001769-827
11	Public Submission, commenting on the Tukey Technical Amendment Proposed Rule CMS-2022-0191-0001, by UnitedHealth Grp., Feb. 13, 2023.	• A.R. 001894-940
12	Public Submission, commenting on the Tukey Technical Amendment Proposed Rule CMS-2022-0191-0001, by CVS Health, Feb. 13, 2023.	• A.R. 001974-2028
13	Public Submission, commenting on the Tukey Technical Amendment Proposed Rule CMS-2022-0191-0001, by Alignment Health, Feb. 13, 2023.	• A.R. 002147-62
14	Public Submission, commenting on the Tukey Technical Amendment Proposed Rule CMS-2022-0191-0001, by the Pharm. Care Mgmt. Ass'n, Feb. 13, 2023.	• A.R. 002169-231
15	Public Submission, commenting on the Tukey Technical Amendment Proposed Rule CMS-2022-0191-0001, by Elevance Health, Inc., Feb. 13, 2023.	• A.R. 002232-2308
16	Public Submission, commenting on the Tukey Technical Amendment Proposed Rule CMS-2022-0191-0001, by Village MD, Feb. 13, 2023.	• A.R. 002309-12

[2] The Tukey Technical Amendment Proposed Rule appears, in its entirety, twice in the Administrative Record (A.R. 001141-438 and A.R. 001439-736). Plaintiffs inadvertently cited to both copies in their Motion for Summary Judgment. We are including both Administrative Record citations in this Appendix for the convenience of the Court in cross-referencing Plaintiff's citations.

17	Public Submission, commenting on the Tukey Technical Amendment Proposed Rule CMS-2022-0191-0001, by Blue Shield of Cal., Feb. 13, 2023.	• A.R. 002313-26
18	Public Submission, commenting on the Tukey Technical Amendment Proposed Rule CMS-2022-0191-0001, by Cigna Grp., Feb. 13, 2023.	• A.R. 002449-69
19	Excerpts from "Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly," 88 Fed. Reg. 22120 (Apr. 12, 2023) ("Tukey Technical Amendment Final Rule").	• 88 Fed. Reg. 22121 (A.R. 002480) • 88 Fed. Reg. 22295 (A.R. 002654) • 88 Fed. Reg. 22332 (A.R. 002691)
20	Memorandum from Amy Larrick Chavez-Valdez, CMS Director Medicare Drug Benefit and C & D Data Group, "Part C and D Star Ratings Tukey Outlier Deletion Simulations," December 19, 2022.	• A.R. 002705-15

CERTIFICATE OF SERVICE

I hereby certify that on April 16, 2024, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system, which will send notification of this filing to the attorneys of record and all registered participants.

/s/ Lara E. Parkin
Lara E. Parkin

h. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186)	We are proposing routine measure updates and an increase in the weight of patient experience/complaints and access measures. We are also proposing some technical clarifications of the current rules for the QBP ratings methodology. We also propose the use of Tukey outlier deletion, which is a standard statistical methodology for removing outliers, to increase the stability and predictability of the star measure cut points.	Updating the patient experience/complaints and access measures weight would create a cost which is offset by using the Tukey outlier deletion. The net savings to the Medicare Trust Fund is $368.1 million in 2024; this will grow over time reaching $999.4 million by 2030. The net reduction in spending to the Medicare Trust Fund over 10 years is $4.9 billion.
i. Permitting a Second, "Preferred", Specialty Tier in Part D (§§ 423.104, 423.560, and 423.578)	CMS is proposing to (1) allow Part D sponsors to establish a second, "preferred," specialty tier at a lower cost-sharing threshold than the current specialty tier; (2) codify the existing maximum cost sharing for the highest specialty tier; (3) codify a methodology to determine annually the specialty tier cost threshold using ingredient cost and increase the threshold when certain conditions are met; (4) require sponsors to permit tiering exceptions between the two specialty tiers; and (5) permit sponsors to determine which drugs go on either tier.	Permitting Part D sponsors to establish a second, "preferred", specialty tier is unlikely to have a material impact on Part D costs.
j. Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128)	CMS is proposing to require that each Part D plan implement a beneficiary real time benefit tool. This tool should allow enrollees to view a plan-defined subset of the information included in the prescriber RTBT system which includes accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information (including cost, formulary alternatives and utilization management requirements) by January 1, 2022.	Adoption of a beneficiary RTBT will be an additional cost and burden on Part D sponsors. Based on our estimates, we believe this will cost Part D plans about $3.9 million for all plans in the first year based on the costs for them to reprogram their computer systems. Additionally, the voluntary provision of rewards by Part D sponsors to enrollees using RTBT will have an impact of $0.7 million in the first year, in order to implement the program, and $0.4 million in subsequent years in order to maintain the program.

only sell for one organization. We therefore propose to eliminate the current specific limit on finder or referral fees that is codified at paragraph (h). Currently, the definition of compensation already includes referral or finder fees, so the result of this specific proposal would be an overall limit on compensation for initial and renewal enrollments, which includes finder or referral fees. In section VI.H. of this proposed rule, we also propose additional changes for §§ 422.2274(g) and 423.2274(g) regarding agent and broker compensation for Part C and Part D enrollments. Under those proposals, the definition of compensation continues to include finder or referral fees, so the limits on compensation continue to include finder or referral fees. We solicit comment on whether removing the limit on referral/finder's fees would generate concerns such as those discussed in the 2010 Call Letter for MA organizations issued March 30, 2009, CMS's October 19, 2011, memo entitled ''Excessive Referral Fees for Enrollments,'' or the ''Medicare Program; Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' final rule that codified referral/finder's fees limits in regulation.

E. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186)

1. Introduction

In the April 2018 final rule, CMS codified at §§ 422.160, 422.162, 422.164, and 422.166 (83 FR 16725 through 83 FR 16731) and §§ 423.180, 423.182, 423.184, and 423.186 (83 FR 16743 through 83 FR 16749) the methodology for the Star Ratings system for the MA and Part D programs, respectively. This was part of the Administration's effort to increase transparency and give advance notice regarding enhancements to the Part C and D Star Ratings program. Under those regulations, CMS must propose through rulemaking any future changes to the methodology for calculating the ratings, addition of new measures, and substantive changes to the measures. Sections 422.164(e) and 423.184(e) provide authority and a mechanism for the removal of measures for specific reasons (low statistical reliability and when the clinical guidelines associated with the measure change such that the specifications are no longer believed to align with positive health outcomes). Generally, removal of a measure for other reasons would also occur through rulemaking. In the 2020 Call Letter, CMS announced the removal of the Adult Body Mass Index Assessment (Part C), Appeals Auto-Forward (Part D), and Appeals Upheld (Part D) measures due to low statistical reliability starting with the 2020 measurement year and associated 2022 Star Ratings following the rules codified at §§ 422.164(e) and 423.184(e). The collection of Part D Timeliness Monitoring Project (TMP) data was also stopped for the 2020 measurement year since it was used to validate the two Part D appeals measures. In the April 2019 final rule, CMS amended §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to update the methodology for calculating cut points for non-Consumer Assessment of Healthcare Providers and Systems (non-CAHPS) measures by adding mean resampling and guardrails, codify a policy to adjust Star Ratings for disasters, and finalize some measure updates.

At this time, we are proposing to further increase the stability of cut points by modifying the cut point methodology for non-CAHPS measures through direct removal of outliers. We are also proposing to increase the weight of patient experience/complaints and access measures, remove the Rheumatoid Arthritis Management (Part C) measure from the Star Ratings because the measure steward is retiring the measure from the HEDIS measurement set, implement substantive updates to the specifications of the Health Outcomes Survey (HOS) outcome measures, add two new Part C measures to the Star Ratings program, clarify the rules around consolidations when data are missing due to data integrity concerns, and add several technical clarifications. We are also proposing to codify additional existing rules for calculating MA Quality Bonus Payment (QBP) ratings. Unless otherwise stated, these changes would apply (that is, data would be collected and performance measured) for the 2021 measurement period and the 2023 Star Ratings.

2. Definitions (§ 422.252)

We propose to amend the definition at § 422.252 for new MA plans by clarifying how we apply the definition. We are proposing to modify the definition as follows: *New MA plan* means a plan that meets the following: (1) Is offered under a new MA contract; and (2) is offered under an MA contract that is held by a parent organization defined at § 422.2 that has not had an MA contract in the prior 3 years. For purposes of this definition, the parent organization is identified as of April of the calendar year before the payment year to which the final QBP rating applies, and contracts associated with that parent organization are also evaluated using contracts in existence as of April of the 3 calendar years before the payment year to which the final QBP rating applies. Under our current policy, we identify the parent organization for each MA contract in April of each year and then whether any MA contracts have been held by that parent organization in the immediately preceding 3 years to determine if the parent organization meets the 3 year standard. For example, if a parent organization is listed for an MA contract in April 2019, and that parent organization does not have any other MA contracts in April 2019, April 2018, or 2017, the plans under the MA contract would be considered new MA plans for 2020 QBP purposes.

3. Measure-Level Star Ratings (§§ 422.166(a), 423.186(a))

Over the past 2 years, we have codified and refined the methodology for calculating the Star Ratings from the performance scores for non-CAHPS measures. At §§ 422.166(a) and 423.186(a), we initially codified the historical methodology for calculating Star Ratings at the measure level in the April 2018 final rule. The methodology for non-CAHPS measures employs a hierarchical clustering algorithm to identify the gaps that exist within the distribution of the measure-specific scores to create groups (clusters) that are then used to identify the cut points. The Star Ratings categories are designed such that the scores in the same Star Ratings category are as similar as possible and the scores in different Star Ratings categories are as different as possible. The current methodology uses only data from the most recent Star Ratings year; therefore, the cut points are sensitive to changes in performance from 1 year to the next.

The primary goal of any cut point methodology is to disaggregate the distribution of scores into discrete categories or groups such that each grouping accurately reflects true performance. The current MA Star Ratings methodology converts measure-specific scores to measure-level Star Ratings so as to categorize the most similar scores within the same measure-level Star Rating while maximizing the differences across measure-level Star Ratings. We solicited comments in the Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit

Programs, and the PACE Program Proposed Rule (hereinafter referred to as the November 2017 proposed rule) regarding the approach to convert non-CAHPS measure scores to measure-level Star Ratings (82 FR 56397 through 56399). We requested input on the desirable attributes of cut points and recommendations to achieve the suggested characteristics in the Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Benefit, Programs for All-inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 Proposed Rule (hereinafter referred to as the November 2018 proposed rule). In addition, we requested that commenters either suggest alternative cut point methodologies or provide feedback on several options detailed in the November 2018 proposed rule, such as setting the cut points by using a moving average, using the mean of the 2 or 3 most recent years of data, or restricting the size of the change in the cut points from 1 year to the next.

The commenters identified several desirable attributes for cut points that included stability, predictability, and attenuation of the influence of outliers; commenters also suggested restricting movement of cut points from 1 year to the next and recommended that CMS either pre-announce cut points before the plan preview period or pre-determine cut points before the start of the measurement period. In the April 2018 final rule (83 FR 16567), we expressed appreciation for our stakeholders' feedback and stated our intent to use it to guide the development of an enhanced methodology while maintaining the intent of the cut point methodology to accurately reflect true performance.

Using the feedback from the comments we received in response to the November 2018 proposed rule, we considered enhancements to the methodology that would increase the stability and predictability of the cut points and finalized in the April 2019 final rule two enhancements to the historical methodology. In the April 2019 final rule, we amended §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to add mean resampling of the current year's data to the current clustering algorithm to attenuate the effect of outliers; we also added measure-specific caps in both directions to provide guardrails so that the measure-threshold-specific cut points do not increase or decrease more than the cap from 1 year to the next. Some commenters to the November 2018 proposed rule believed mean resampling would not be sufficient to address outliers and expressed support for directly removing outliers before clustering. We did not finalize an approach for directly removing outliers in the April 2019 final rule since the public did not have an opportunity to comment on a specific approach.

As we stated in the April 2019 final rule in response to public comments on this topic, we evaluated two options to address direct removal of outliers—trimming and Tukey outer fence outlier deletion. Under trimming, all contracts with scores below the 1st percentile or above the 99th percentile are removed prior to clustering. Although trimming is a simple way to remove extreme values, it removes scores below the 1st percentile or above the 99th percentile regardless of whether the scores are true outliers. This means in cases when true outliers are between the 1st and 99th percentile, they would not be removed by trimming, and in cases when the distribution of scores is skewed, scores that are not true outliers would be trimmed.

Tukey outer fence outlier deletion is a standard statistical method. Tukey outer fence outliers are sometimes called Whisker outliers. Under this methodology, outliers are defined as measure scores below a certain point (first quartile $-$ 3.0 $\times$ (third quartile $-$ first quartile)) or above a certain point (third quartile + 3.0 $\times$ (third quartile $-$ first quartile)). The Tukey outer fence outlier deletion will remove all outliers based on the previous definition and will not remove any cases that are not identified as outliers. Values identified by Tukey outer fence outlier deletion would be removed prior to clustering. If Tukey outer fence outlier deletion and a 5 percent guardrail had been implemented for the 2018 Star Ratings, 2 percent of MA–PD contracts would have seen their Star Rating increase by half a star, 16 percent would have decreased by half a star, and one contract would have decreased by 1 star. For PDP contracts, 2 percent would have increased by half a star, and 18 percent would have decreased by half a star. This simulation of the impact of Tukey outlier deletion also takes into account the removal of the two Part D appeals measures (Appeals Auto-Forward and Appeals Upheld) and the Part C measure Adult BMI Assessment in the simulations, because these measures will be removed starting with the 2022 Star Ratings. In general, there tend to be more outliers on the lower end of measure scores. As a result, the 1 to 2 star thresholds often increased in the simulations when outliers were removed compared to the other thresholds which were not as impacted.

The effect of Tukey outlier deletion would create a savings of $808.9 million for 2024, increasing to $1,449.2 million by 2030. Given the significant drawbacks of trimming, we are proposing to add Tukey outer fence outlier deletion to the clustering methodology for non-CAHPS measures. We request commenter feedback on Tukey outer fence outlier deletion as an additional step prior to hierarchal clustering. In the first year that this would be implemented, the prior year's thresholds would be rerun, including mean resampling and Tukey outer fence deletion so that the guardrails would be applied such that there is consistency between the years. We propose to amend §§ 422.162 and 423.182 to add a definition of the outlier methodology and amend §§ 422.166(a)(2) and 423.186(a)(2) to apply the outlier deletion using that methodology prior to applying mean resampling with hierarchal clustering. We welcome comments on this proposal.

4. Contract Consolidations (§§ 422.162(b)(3), 423.182(b)(3))

The process for calculating the measure scores for contracts that consolidate is specified as a series of steps at §§ 422.162(b)(3) and 423.182(b)(3). We propose to add a rule to account for instances when the measure score is missing from the consumed or surviving contract(s) due to a data integrity issue as described at §§ 422.164(g)(1)(i) and (ii) and 423.184(g)(1)(i) and (ii). CMS proposes to assign a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score. These rules would apply for contract consolidations approved on or after January 1, 2021. First, we propose minor technical changes to the regulation text in §§ 422.162(b)(3)(iv)(A) and (B) and 423.182(b)(3)(ii)(A) and (B) to improve the clarity of the regulation text. Second, we propose to redesignate the current regulation text (with the technical changes) as new paragraphs (b)(3)(iv)(A)(*1*) and (b)(3)(iv)(B)(*1*) and (b)(3)(ii)(A)(*1*) and (b)(3)(ii)(B)(*1*) of these regulations and to codify this new rule for contract consolidations approved on or after January 1, 2021 as §§ 422.162(b)(3)(iv)(A)(*2*) and (b)(3)(iv)(B)(*2*) and 423.182(b)(3)(ii)(A)(*2*) and (b)(3)(ii)(B)(*2*). We welcome comments on this proposal. We also propose an additional rule at §§ 422.164(g)(1)(iii)(A) and 423.184(g)(1)(iii)(A) to address how the Timeliness Monitoring Project

PUBLIC SUBMISSION

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Docket: CMS-2020-0010
Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2021 (CMS-4190-P)

Comment On: CMS-2020-0010-0002
Medicare and Medicaid Programs: Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly

Document: CMS-2020-0010-0209
Comment on CMS-2020-0010-0002

Submitter Information

Name: Anonymous Anonymous

General Comment

See attached file(s)

Attachments

20200402 UCare Comments (CMS-4190-P)



April 2, 2020

Delivered to: www.regulations.gov

Good Afternoon,

Thank you for the opportunity to submit comments on the *Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (CMS-4190-P)* proposed rule. UCare provides the following comments for consideration.

Improvements to Care Management Requirements for Special Needs Plans (SNPs)

Generally, UCare does not have concerns with CMS's proposal to apply the chronic condition special needs plan (C-SNP) enrollee management and model of care (MOC) submission requirements to dual eligible SNPs (D-SNPs) and institutional SNPs (I-SNPs). However, we do have a few suggestions.

UCare recommends that CMS provide additional definitions and details about the interdisciplinary team. The proposed regulation (42 CFR § 422.101(f)) reads:

> In the management of care, use an interdisciplinary team that includes a team of providers with demonstrated expertise and training, and, as applicable, training in a defined role appropriate to their licensure in treating individuals similar to the targeted population of the plan.

UCare recommends that CMS clarify that "providers," as used in this section, follows the definition of "provider" in 42 CFR § 422.2. UCare also recommends that CMS provide additional details about what constitutes "demonstrated expertise and training." Specifically, are there minimal expertise or training requirements that the provider must meet or does each plan have discretion to make this determination? UCare would not support an interpretation of this language that would require the plan to provide training.

UCare does not have concerns about the proposal to provide face-to-face encounters with enrollees, because this is our current practice.

Although MOCs require significant work for plans, especially when more than one MOC is submitted based on multiple SNPs, we agree with CMS's rationale for proposing these additional MOC requirements for D-SNPs and I-SNPs. That said, we are concerned this may be a slippery slope to requiring D-SNPs and I-SNPs to submit the MOC annually, which UCare would not support.

Beneficiaries' Education on Opioid Risks and Alternative Treatments

UCare believes this is important information for enrollees to receive, and we support this initiative. We recommend that CMS add a separate section in the Evidence of Coverage (EOC) and the Annual Notice of Change (ANOC) to call this information out to all enrollees. We also recommend that CMS give health plans flexibility to provide information in the EOC and ANOC that targets subsets of the plans' enrollee population.

Eligibility for Medication Therapy Management Programs (MTMPs)

UCare recommends that CMS treat these enrollees as "expanded eligibility members" for the MTMPs. This would help ensure that health plans are not disincentivized from enrolling these enrollees into a Drug Management Program to avoid a negative impact to plans' comprehensive medication review rates.

Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures

UCare recommends that CMS consider prescriber specialties when creating definitions or criteria for inappropriate prescribing.

Reinsurance Exceptions

UCare supports the additional flexibility provided under this arrangement and agrees that $10,000 is a reasonable level. UCare recommends that CMS allow additional flexibility to achieve a $10,000 actuarially equivalent attachment point, such as first dollar coverage for a subset of covered services (i.e., Part B drugs). UCare also recommends that CMS monitor this change to

ensure that this approach is not used by large national plans to financially underwrite smaller entities to use their Star ratings.

Out-of-Network Telehealth at Plan Option

UCare supports CMS's proposal to allow Medicare Advantage (MA) plans to provide additional telehealth benefits (ATBs) through non-contracted providers. This ATB option will give our enrollees more choices for care, especially in rural areas where we may have a less than optimal number of contracted providers.

MA and Part D Prescription Drug Program Quality Rating System

Cut Point Methodology. UCare supports the addition of Tukey outlier deletion to the cut point methodology for the Stars program. We are ultimately in support of all methodology that assists in stabilizing rate targets year over year. This supports more structured intervention work at the health plan level.

Proposed Measure Additions. UCare does not support the addition of the HEDIS Follow-Up after Emergency Department Visit for Patients with Multiple Chronic Conditions measure for 2021 performance period. There is minimal clinical utility to this measure given the lag time between network plans knowing of an emergency department visit and being able to connect with the enrollee.

Non-Substantive Changes to Transitions of Care. UCare supports the changes for admission notification and receipt of discharge information to two days and the inclusion of "patient instructions." Please consider clarifying that health plans are still limited to only what the primary care physician can access.

UCare is disappointed that the standalone Medication Reconciliation Post-Discharge (MRP) measure has not been retired. Double reviewing is a very burdensome process for medication reconciliation. CMS needs to release a retirement plan for the standalone MRP measure or consider removing it all together from the Transitions of Care measure.

Measure Weights. UCare does not support the weight increase from 2x to 4x for the patient experience, complaints and access measures in the Stars program. The increase undervalues Outcome measures and emphasizes factors outside of a health plan's control. We believe this

change will put too much weight on subjective measurements, and we have concerns with scenarios where we will be penalized unfairly (e.g., unhappy enrollees who chose a low-cost plan with network restrictions and less rich benefits).

Permitting a Second, "Preferred," Specialty Tier in Part D

UCare supports the second, preferred specialty drug tier. We agree that there needs to be a financial model that encourages use of lower cost, clinically effective specialty drugs, which is not currently in place. The current model favors rebate strategies. This additional specialty tier could generate health plan savings if manufacturers offer rebates for specialty drugs on a preferred tier, similar to how preferred non-specialty brand drugs are administered today. Health plans might also save on drug ingredient costs. We also encourage CMS to investigate alternative catastrophic reinsurance models to incentivize the most savings for health plans implementing a preferred specialty tier.

Beneficiary Real Time Benefit Tool (RTBT)

Although UCare supports this proposal, CMS must clarify the requirements for populating drugs on the RTBT. For example, for therapeutic alternative options, we would not realistically be able to populate every drug that could treat diabetes. Also, it would not be realistic to list alternatives for every nonformulary drug. If this proposal is finalized, UCare recommends that CMS develop an optional, model tool for all health plans to use. A CMS-developed tool could reduce costs for health plans and help ensure consistent functionality across health plans.

Medicare Advantage (MA) and Cost Plan Network Adequacy

UCare supports CMS's proposal to make health service delivery (HSD) reference files available in advance of network reviews. UCare recommends a process that allows health plans to provide feedback on county time and distance standard changes to ensure appropriate customization is consistent year after year. Plans have the clearest view of the localized provider supply, and CMS could team with health plans to develop appropriate county standards. Allowing CMS and health plans to tweak multiple aspects of the requirement, such as the percent of beneficiaries meeting the time and distance standards, will give our industry new tools to achieve fair monitoring.

UCare supports CMS's proposal to give plans a 10-percentage point credit towards the percentage of beneficiaries residing within the time and distance standards (for certain provider

specialty types) when the health plan contracts with one or more telehealth providers for those specified specialty types (Dermatology, Psychiatry, Cardiology, Neurology and Otolaryngology). If the adequate technology is available, UCare recommends that CMS add "Ophthalmology" and "Allergy and Immunology" to this list of provider specialty types.

When determining the credit, will CMS look at the relevance of the telehealth receiving site? For example, if a provider location offers both telehealth and in-person psychiatric services, the telehealth offering does not reduce travel distances and times, but it does make more appointments available. Would CMS offer the credit in this situation?

UCare suggests that CMS offer a 10-percentage point credit when telehealth services are present, but the services do not reduce travel distances and times and a 15-percentage point credit when they reduce travel distances and times. This could be monitored by plans submitting two HSD files. The first file would not include telehealth receiving site locations, and the second file would include telehealth receiving site locations. If the first file achieved at least 75% of the enrollees with access, CMS would offer the second submission and allow the plans to include the telehealth receiving site addresses and monitor for 90% of enrollees with access. We believe an additional credit is appropriate if the plan establishes telehealth services at a remote clinic that reduces the travel burden for enrollees.

Supplemental Benefit Requirements

UCare requests that CMS provide additional guidance on how health plans can ensure that allowance-based supplemental benefits meet the "primarily health related" requirement. Typically, enrollees have discretion in how they use these allowance-based dollars.

Requirements for Medicare Communications and Marketing

Examples. Although we understand that CMS is codifying longstanding policies and guidance currently found in its *Medicare Communications and Marketing Guidelines (MCMGs),* we do recommend that CMS add more examples to the definitions of "communications" and "marketing" to help provide consistency and clarity.

Open Enrollment Period. CMS specifically requested comments on how to implement prohibitions related to health plan marketing during the open enrollment period (OEP). UCare suggests that CMS provide specific examples of language health plans can and cannot use during

OEP. For example, would the use of the word "shop" in an unsolicited mailing that does not otherwise mention the OEP be considered a violation of OEP requirements? Also, health plans are currently allowed to include general information on their website about enrollment periods, including the OEP. UCare suggests that CMS provide optional, model language that qualifies as "general information" for use on health plan websites.

Sales Phone Lines. The MCMGs allow health plans to operate phone lines that are solely designated for sales and enrollment during business hours that differ from those required for customer service call centers. This policy does not appear to be codified in the proposed regulations. Is CMS eliminating this policy? See *MCMGs, § 80.1 - Hours of Operation for Telephone Lines Solely Designated for Sales and Enrollment*.

*Non-Renewal Notice*s. The proposed regulation (42 CFR § 422.2267(e)(10)) regarding non-renewal notices reads:

> Notice must be provided at least 90 calendar days before the date on which the nonrenewal is effective. For contracts ending on December 31, the notice must be dated October 2 to ensure national consistency in the application of Medigap Guaranteed Issue (GI) rights to all enrollees, except for those enrollees in special needs plans (SNPs).

The regulatory text does not address the earliest date that health plans may release this information, but the MCMGs do state:

> Information about non-renewals or service area reductions may not be released to the public, including current enrollees, until notice is received from CMS.

See *MCMGs, § 100.4 – List of Required Materials*. If this will continue to be the process, CMS could codify the process in the regulatory text. However, UCare suggests that CMS simply codify the earliest date that health plans may release this information. This would simplify the process and allow health plans to prepare for the mailing.

Subregulatory Guidance. Finally, although we appreciate CMS's steps to codify communications and marketing policies in regulations, we note that the MCMGs are a valuable tool, especially for health plan staff who are not accustomed to reading federal regulations. We strongly encourage CMS to continue to provide policy interpretations, examples and best practices in the easier to digest MCMGs.

Special Election Periods (SEPs) for Exceptional Conditions

SEP for Employer/Union Group Health Plan (EGHP) elections. Proposed 42 CFR § 422.62(b)(4) codifies the SEP for EGHP elections and reads:

> (4) The individual is making an MA enrollment request into or out of an employer sponsored MA plan, is disenrolling from an MA plan to take employer sponsored coverage of any kind, or is disenrolling from employer sponsored coverage (including COBRA coverage) to elect an MA plan. This SEP is available to individuals who have (or are enrolling in) an employer or union sponsored *MA plan* and ends 2 months after the month the employer or union coverage of any type ends. The individual may choose an effective date that is not earlier than the first of the month following the month in which the election is made and no later than up to 3 months after the month in which the election is made. (*emphasis added*.)

According to the *Medicare Managed Care Manual, Chapter 2 - MA Enrollment and Disenrollment, Section 30.4.4,* "this SEP is available to individuals who have (or are enrolling in) an employer or union sponsored plan and ends 2 months after the month the employer or union coverage ends." The manual does not require that the employer or union sponsored plan be "an employer or union sponsored MA plan." UCare suggests that CMS modify the proposed language so that it follows the manual language. UCare also suggests that CMS either add a definition of "employer sponsored coverage" or clarify that the employer sponsored coverage can be through the individual's own employer, the individual's spouse or the individual's domestic partner.

Continuous SEP for full-benefit dual eligible (FBDE) enrollees. UCare strongly believes CMS needs to reinstate a continuous SEP for FBDE enrollees. This is needed to simplify and allow more flexibility for health plans, including Minnesota's two dual eligible special needs plans (D-SNPs): the legacy (since 1997) Minnesota Senior Health Options (MSHO) and Special Needs Basic Care (SNBC). Individuals enrolling in these plans are either 65 years or older (MSHO) or people with disabilities aged 18-64.

In 2019, CMS changed its policy around the frequency that "at-risk" enrollees were permitted to change plans. Federal regulations (42 CFR § 423.100) define "at-risk" as those identified at risk of misuse or abuse of frequently abused drugs covered under Part D plans. With this change in policy, Minnesota's D-SNP enrollees went from being able to enroll in/disenroll from a D-SNP

plan each month, to being limited to changing plans each quarter for Q1-Q3 within a calendar year, and according to annual election period timelines during Q4 of each year.

We assert this change has placed undue burden on, and unnecessarily introduced administrative complexity for, all stakeholders of Minnesota's D-SNPs, including: enrollees and caregivers who help make health insurance decisions; county staffs who administer eligibility for Minnesota's Medicaid program for aged, blind and disabled populations; providers who serve these enrollees and must track enrollment/eligibility; Minnesota's Medicaid agency, which works closely with its contracted integrated D-SNPs and counties, toward a seamless, enrollee-friendly, integrated enrollment process for these enrollees; and finally, health plans, such as UCare, which offer D-SNPs in Minnesota. Adding the limitations on changing plans has added to the complexity aged and disabled FBDE enrollees already face related to health care eligibility and enrollment (e.g., this limitation adds a another, unnecessary layer to the existing complexity of maintaining Medicaid eligibility).

We believe our Medicaid agency engaged with CMS over the past two years to discuss/demonstrate to CMS that there was no evidence of any level of negatively-driven plan changing by "at-risk" enrollees enrolled in Minnesota's D-SNPs. We believe the Medicaid agency has tried to communicate to CMS the negative effect this policy would have, and has had, on Minnesota's programs. We maintain that Minnesota's programs have become more difficult to explain, understand and administer since the continuous special election period for full benefit dual eligibles was removed – without any positive impact on the program.

To return to more streamlined programs for these elderly populations and people with disabilities, we request CMS update its policy to re-create a continuous SEP for enrollment in and out of Minnesota's (and other states) for fully integrated dual eligible (FIDE) SNP (MSHO) and highly integrated dual eligible (HIDE) SNP (SNBC) plans.

Exclusion of Services Furnished Under a Private Contract

UCare supports the proposed changes to 42 CFR § 422.220 that will allow health plans to make payments for supplemental benefits to physicians and practitioners who opt out of Medicare. We agree that payments for supplemental benefits are outside the scope of the statutory restriction on payments to opt-out providers.

Disclosure Requirements

UCare understands that CMS is codifying current explanation of benefits (EOB) requirements, but we would like CMS to take this opportunity to provide health plans with more flexibility in the timing of the EOB. Plans must either send the EOB on a monthly cycle or a quarterly cycle with per-claim notifications. UCare suggests that CMS allow health plans to send the EOB every two weeks. Health plans use the EOB to satisfy enrollee notification requirements, so sending the EOB only on the monthly or quarterly cycle does not always allow health plans to meet these notification timeframes. See CMS's *Medicare Managed Care Manual, Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, Section 40.12.1 – Part C Notification Requirements*.

Definition of "Institutionalized" for Institutional Special Needs Plans (I-SNPs)

UCare supports the proposal to modify the definition of "institutionalized." This definition reconciles differences in the guidance and the regulatory text that have caused confusion about the open enrollment period for institutionalized individuals. We also support the new criteria that allows CMS to include additional facilities in the definition of "institutionalized" as forms of institutional care change.

Thank you for considering the above comments and recommendations.

Sincerely,



Ghita Worcester
Senior Vice President, Public Affairs and Chief Marketing Officer
UCare

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Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2021 (CMS-4190-P)

Comment On: CMS-2020-0010-0002
Medicare and Medicaid Programs: Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly

Document: CMS-2020-0010-0390
Comment on CMS-2020-0010-0002

Submitter Information

Name: Dan Elling
Organization: SCAN Health Plan

General Comment

On behalf of SCAN Health Plan, please accept the following comments pertaining to the proposed technical changes to MA and Part D for CY2021 and 2022.

Attachments

04.06.20. SCAN Health Plan Comment Letter Part C and D for CY2021 and 2022

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VIA ELECTRONIC SUBMISSION: **http://regulations.gov**

April 6, 2020

The Honorable Alex Azar
Secretary, Department of Health & Human Services

The Honorable Seema Verma
Administrator, Centers for Medicare & Medicaid Services

Department of Health & Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C4–26–05
Baltimore, MD 21244–1850

Re: SCAN Health Plan Comments on CMS–4190

Dear Secretary Azar and Administrator Verma:

SCAN Health Plan (SCAN) is pleased to submit comments in response to ***the Medicare and Medicaid Programs: Contract Year (CY) 2021 and 2022 Policy and Technical Changes to the Medicare Advantage (MA) Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly.*** The following includes background on SCAN and comments on selected provisions in the proposed rule.

SCAN applauds the Administration for its leadership in developing policies that improve the health care of Medicare beneficiaries, including those who are vulnerable and have complex conditions. SCAN also appreciates the Administration's efforts to address the COVID-19 pandemic. Because COVID-19 is especially fatal for older adults with underlying health conditions, SCAN is working diligently to ensure that our members (all of whom are MA beneficiaries) remain informed and healthy. We provide updated COVID-19 information on our website, https://www.scanhealthplan.com/members/coronavirus-information, and outreach to our members and the community. Efforts include calling members directly to check on their health, providing emergency funding for nonprofits, and offering a resource and referral line to support seniors and family caregivers. For more details on SCAN's COVID-19 activities, please go to: https://www.scanhealthplan.com/about-scan/press-room/april-2020/applauding-governor-newsoms-call-to-protect-california-seniors-scan-health-plan-expands.

I. SCAN Health Plan

SCAN is a nonprofit health plan serving over 200,000 Medicare beneficiaries in California and the third largest nonprofit Medicare Advantage Prescription Drug (MA-PD) plan in the country. Since 1985, SCAN has specialized in providing comprehensive, high quality care to the most vulnerable Medicare beneficiaries, including those who live with multiple chronic conditions, who are eligible for nursing home care, and who have difficulty performing activities of daily living. For beneficiaries who require additional

attention, SCAN offers institutional, chronic care, and dual eligible special needs plans (SNPs). SCAN is proud to have earned a 4.5 star rating on a five-point scale from the Centers for Medicare & Medicaid Services (CMS) in each of the last three years and named one of the best insurance companies for MA in California by *U.S. News and World Report* for the second straight year.

II. SCAN Comments on Selected Provisions

Implementation of Certain Provisions of the Bipartisan Budget Act (BBA) of 2018

Special Supplemental Benefits for the Chronically Ill (SSBCI) *(§ 422.102),* p. 9011[1]

- CMS Proposal: CMS proposes codifying in regulation existing SSBCI sub-regulatory guidance and statutory parameters. This includes defining SSBCI and chronic condition, allowing plans to apply SSBCI to chronic conditions that are not on the list established by the panel of clinical advisors, requiring plans to make information related to determining enrollee eligibility available to CMS upon request, and clarifying that SSBCI benefits determination is subject to the MA grievances and appeals rules.

- SCAN Comments: SCAN supports codifying existing SSBCI sub-regulatory guidance and statutory parameters in regulation and waiving the uniformity rule to provide individualized services. We also appreciate the decision to refrain from requiring a physician's orders to provide supplemental benefits.

Improvements to Care Management Requirements for SNPs *(§ 422.101),* p. 9013

- CMS Proposal: CMS proposes implementing new statutory requirements for SNPs with respect to enrollee care management (applies to interdisciplinary team composition and annual face-to-face encounters) and model of care (MOC) standards (requires assessments to be incorporated in the individualized care plan). It also requires CMS to consider MOC performance against prior year goals and CMS benchmarks when considering whether to approve an MOC.

- SCAN Comments: SCAN strongly supports providing individualized care plans. However, we believe that requiring annual SNP face-to-face encounters would negatively affect beneficiaries and be challenging plans to implement.

  Individual Care Plans. SCAN supports individualized care plans, as they provide a coordinated and agreed-upon plan and maintain a list of problem areas to consider for high quality care management. We agree that care plans should include areas of risk identified during the initial and annual health risk assessment and be person-centered. They should include the problems, goals, and interventions that the beneficiary is willing and able to address with the support of his/her interdisciplinary team. SCAN does not support adding items to the care plan not agreed to by the beneficiary because it violates the trust between the beneficiary and the care team. Further, a requirement to include risks that the beneficiary does not want to address is counterproductive to person-centeredness.

[1] Page numbers of provisions refer to the proposed rule included in the Federal Register: https://www.federalregister.gov/documents/2020/02/18/2020-02085/medicare-and-medicaid-programs-contract-year-2021-and-2022-policy-and-technical-changes-to-the

Face-to-Face Encounters. SCAN does not support a requirement for face-to-face encounters for SNPs. SNP members have varying degrees of complexity, which makes face-to-face encounters difficult for some members and geographies. This requirement also does not take into account beneficiary preference and capability. For example, although SCAN supports using tele-connected care, many of our beneficiaries do not have that capability (phone is easier and more uniformly acceptable for some beneficiaries). Additionally, face-to-face encounters would be difficult to track if conducted by the provider and not the plan. SCAN believes that plans' limited resources would be better utilized reserving face-to-face encounters for helping the neediest of the SNP population.

Contracting Standards for Dual Eligible Special Needs Plan (D-SNP) Look-Alikes *(§ 422.514),* p. 901

- CMS Proposal: CMS proposes not approving or renewing contracts for "D-SNP look-alike" MA plans, except in states that have no D-SNPs or other plans authorized by CMS to exclusively enroll duals (such as Medicare Medicaid demonstration plans). CMS would: 1) permit affected plans that have approved D-SNPs for the following plan year to transition members to those D-SNPs and 2) define "look-alike" for bid purposes as a plan that projects its enrollment to be 80 percent or more duals, or in the current year has actual enrollment of 80 percent or more duals (with exceptions for new plans with fewer than 200 enrollees).

- SCAN Comments: SCAN strongly supports integration and development of the MOC for D-SNP "look-alikes," but disagrees with limiting enrollment to states that have no D-SNPs or other plans authorized by CMS to exclusively enroll duals (such as Medicare Medicaid demonstration plans). Alternatively, SCAN recommends a federal level solution that applies to all states and takes a more deliberate approach to help "look-alikes" progress. Another suggestion is for CMS to slow down the timing of phasing out D-SNP "look-alikes." This would reduce state burden because not all contracts would have to be in place at one time and allow plans more time to make alternative arrangements for members.

    - *Integration Pathway.* SCAN recommends creating an integration path for "look-alike" plans and requiring them to provide MOCs. SCAN requests that CMS not identify these plans as "look-alikes," but rather as uncoordinated plans on a pathway to greater integration, such as D-SNPs evolving into a Highly Integrated Dual Eligible Special Needs Plan (HIDE-SNP) or Fully Integrated Dual Eligible Special Needs Plan (FIDE-SNP).
    - *MOCs.* SCAN supports plans coordinating care, but not requiring them to have a state Medicaid contract. Plans should have a MOC that outlines how they would coordinate benefits for duals and take on more responsibility. CMS could also require these plans to offer enhanced benefits above what the beneficiary would be able to get with Medicare and Medicaid.
    - *Beneficiary Choice.* SCAN supports giving beneficiaries a choice to enroll in high quality plans whether they are integrated or not. In some areas, the integrated options offered have lower quality (lower Star ratings) than non-integrated plans. We believe that if a "look-alike" plan offers a higher quality product than other plans in the area and better access to a larger network of high-quality providers, then beneficiaries should be able to continue in the plan of their choice. In brief, if CMS' is interested in moving beneficiaries into high quality plans, then this proposal runs counter to this goal.

Implementation of Several Opioid Provisions of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities First

Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs *(§ 423.100),* p. 9025

- CMS Proposal: CMS proposes to define ''history of opioid-related overdose'' to mean that for the Part D beneficiary, a recent claim has been submitted that contains a principal diagnosis code reflecting an opioid overdose, regardless of the type of opioid and at least one recent prescription drug event for an opioid dispensed.

- SCAN Comments: SCAN recommends expanding the ICD-10-CM to divide the Z91.5 code to describe cause of self-harm. Currently, there is no way to identify the cause/method of historical suicide attempts. This is important to know because if the patients were SCAN members, we would have data indicating their hospitalization was for an opioid overdose. If they were not members, we would only know they had a past suicide attempt with the method unknown, and potentially miss members who should be included in the mandatory drug management plan. SCAN recommends that the code for history of a suicide attempt be further defined to include the method of suicide attempt.

Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures *(§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2)*, p. 9033

- CMS Proposal: CMS proposes allowing MA organizations and Medicare Part D plan sponsors (including MA organizations offering MA–PD plans) to share data and information regarding bad actors and suspend payment if an investigation shows a credible allegation of fraud.

- SCAN Comments: SCAN recommends that CMS provide training programs for health plan fraud units and guidance regarding the definition of a credible allegation. Most plans do not have experience in these types of cases (not related to contract provisions).

Enhancements to the Part C and D Programs

MA and Part D Prescription Drug Program Quality Rating System *(§§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186),* p. 9043

- CMS Proposal: CMS proposes several changes to the Star ratings program, including:
  - Cut point methodology for non- Consumer Assessment of Healthcare Providers & Systems (CAHPS) measures by removing outliers.
  - Substantive updates to the specifications of Health Outcomes Survey (HOS) measures (Improving or Maintaining Physical Health and Improving or Maintaining Mental Health).
  - New Part C measure to the Star ratings program (Transitions of Care).
  - Weight of patient experience/complaints/access measures from 2 to 4.
  - Extreme and uncontrollable circumstances policy.

- SCAN Comments: SCAN recommends the following regarding specific Star rating proposals: 1) revising the cut point methodology for non-CAHPS measures by removing outliers, 2) increasing the weight of patient experience/complaints/access measures from 2 to 4, and 3) adding a new Part C measure to the Star ratings program (i.e., Transition of Care).

Cut Point Methodology for Non-CAHPS Measures, p. 9043

- CMS Proposal: SCAN proposes revising the cut point methodology for non-CAHPS measures by removing outliers.

- SCAN Comments: SCAN appreciates CMS' proposal to include outlier removal and guardrails in the threshold calculation. These methodologies will likely improve stability, but not predictability. We recommend that CMS use previous year Star rating data to develop and publish thresholds prior to the measurement year begins or at least before the measurement year ends. SCAN also recommends that CMS publish the resulting thresholds and impacts of the new methodology using the most recent Star rating data. In the federal registry, CMS uses CY2018 Star rating (2016 measurement year) data for their impact analysis, which is at least two years old.

Substantive Updates to the Specifications of HOS Measures, p. 9045

- CMS Proposal: CMS proposes implementing substantive updates to the specifications of HOS measures (Improving or Maintaining Physical Health measure and Improving or Maintaining Mental Health measure). These include modifying the case-mix adjustment and increasing the minimum required denominator from 30 to 100.

- SCAN Comments: SCAN recommends that CMS perform simulations to evaluate the performance of the new case-mix adjustment methodology (i.e., use complete data set; randomly select records as missing and compare them with the new and existing methodology; and consider whether the missing data is random or not) before implementing.

New Part C Measure to the Star Ratings Program (Transitions of Care), p. 9046

- CMS Proposal: CMS proposes adding two new Part C measures to the Star ratings program (Transitions of Care and Follow-up after Emergency Department Visit for Patients with Multiple Chronic Conditions).

- SCAN Comments: SCAN questions what the new Transition of Care measure means because it is composed of four sub-measures. In the Display measure, CMS uses the average of four sub-measures which is inconsistent with the National Committee for Quality Alliance (NCQA). We disagree that the NCQA changes are non-substantive and recommend that CMS maintain the updated NCQA transition of care measure in Display for another two years before moving to Star rating.

Weight of Patient Experience/Complaints and Access Measures, p. 9049

- CMS Proposal: CMS proposes increasing the weight of patient experience, complaints, and access measures from 2 to 4.

- SCAN Comments: SCAN strongly disagrees with increasing the weights of patient experience, complaints, and access measures from 2 to 4 for a few reasons. The first is that weighing these measures to 4 is higher than the Intermediate Outcome Measures. We believe this sends the wrong message to MA plans, providers, and Medicare beneficiaries that patient experience is more important than outcomes. For example, this increase makes patient experience four times more important than many preventive care measures. However, the literature shows that preventive

screenings, such as colorectal cancer screening, can save lives. SCAN is concerned that this increase would lead to unintended consequences such as MA plans and providers not focusing on these preventive measures or consistently reminding patients about these important screenings.

Another concern is that many patient experience and access measures have small denominators and high variation. Member satisfaction measures are based on the CAHPS survey of 800 members. Based on the sample size and response rate, the lower and upper bound of confidence intervals could cover up to three measure Star ratings. However, survey measures such as member satisfaction based on CAHPS have limitations. Some member satisfaction measure scales assume the response are ratio scale (e.g., "Always" is 4 and "Usually" is 3; however, is "Always" 25% easier or more satisfied than "Usually")? Finally, these weights were recently increased from 1.5 to 2.0 for Star rating 2021. SCAN strongly encourages CMS to evaluate the impact of the proposed weight increase before implementing.

Extreme and Uncontrollable Circumstances Policy *(§§ 422.166(i), 423.186(i))*, p. 9049.

- CMS Proposal: CMS is soliciting comments on current disaster relief policy for treatment of multiple year-affected contracts.

- SCAN Comments: SCAN appreciates that CMS is taking into account the disruption to data collection due to the COVID-19 pandemic and assigning CY2020 scores and Star ratings for HEDIS, CAHPS, and other administrative measures, including the "Extreme and Uncontrollable Circumstances policy." However, we ask that CMS use the final score and Star rating instead of the raw or unadjusted ones.

  Unlike previous "Extreme and Uncontrollable Circumstances Policy" adjustments, which is the higher of current year or prior year scores and Stars, under the current circumstances, CMS will only use the prior year, which is the CY2020 score and Star. Because, as CMS has acknowledged, scores are impacted negatively by major disasters for plans with more than 25% of their members (in our case more than 40%) living in major disaster counties, SCAN requests that the scores be adjusted and based on CY2019 scores and Stars to better reflect a contract's performance. Therefore, we recommend that CMS use the CY2020 final score and Star for the CY2021 Star rating for impacted measures (HEDIS, CAHPS, etc.).

Second "Preferred", Specialty Tier in Part D *(§§ 423.104, 423.560, and 423.578),* p. 9051

- CMS Proposal: CMS proposes establishing a second "preferred" specialty tier at a lower cost-sharing threshold than the current specialty tier. In addition, Part D sponsors would be required to permit tiering exceptions between the two specialty tiers. CMS is also soliciting comments on the potential for permitting the higher cost-sharing specialty tier to exceed the maximum cost sharing currently permitted (25/33%), a maximum allowable cost sharing of 25% without regard to deductible, and whether to set a numeric or other differential in cost sharing between the specialty tiers.

- SCAN Comments: SCAN supports CMS' efforts to allow Part D sponsors flexibility in benefit design and believes that a proposed "preferred" specialty tier has potential for cost savings to beneficiaries and sponsors over time. A second specialty tier would allow plans to negotiate greater discounts from drug manufacturers for preferred status, similar to non-specialty drugs. However, additional changes would be needed for Part D sponsors to take full advantage of this preferred

specialty tier. If CMS adopts a preferred specialty tier, plans should be allowed to have higher cost sharing on the non-preferred specialty tier and have higher cost sharing if there is no deductible.

For the preferred specialty tier to be meaningful to beneficiaries and extract greater discounts from drug manufacturers, the non-preferred specialty tier needs to have higher cost sharing so there is a sufficient differential between the preferred specialty tier and higher specialty tier. If CMS adopts the proposal without allowing changes to cost sharing, plans would not have the necessary leverage to negotiate greater discounts from drug manufacturers. This could result in having fewer plans implement a preferred specialty tier.

In addition, SCAN does not agree with changing the maximum cost sharing of 25% without regard to deductibles. The existing rules allow plans flexibility in benefit design. CMS' should reconsider allowing tier exceptions between the two specialty tiers and a higher cost sharing amount for the higher tier.

Beneficiary Real Time Benefit Tool (RTBT) *(§ 423.128),* p. 9059

- CMS Proposal: CMS proposes that sponsors implement a beneficiary RTBT that would allow enrollees to view information such as formulary and benefit information, cost sharing, formulary alternatives, and utilization management requirements. The information should be available through a patient portal or computer application.

- SCAN Comments: Though the proposal has good intentions, SCAN disagrees with implementing a beneficiary RTBT. Existing tools like Medicare Plan Finder along with formulary and benefit information published on plan websites serve the same purpose. Beneficiaries currently have the tools to determine how much their drugs will cost at their pharmacy of choice, access to formulary and utilization management criteria, and cost sharing of their medications.

  SCAN supports CMS' efforts to promote price transparency, but we believe that the prescriber RTBT would have the greatest impact on lowering beneficiary costs. Providers need to use beneficiary cost sharing information when selecting and initiating treatment. We encourage CMS to implement an incentive program that would allow providers to earn payments for utilizing RTBT while those who do not utilize RTBT are subject to a payment adjustment, similar to the approach used to encourage adoption of electronic prescribing.

Establishing Pharmacy Performance Measure Reporting Requirements *(§ 423.514),* p. 9063

- CMS Proposal: CMS proposes that sponsors disclose to CMS the pharmacy performance measures used to evaluate pharmacy performance. CMS would publish the list of measures to increase public transparency.

- SCAN Comments: SCAN appreciates CMS' interest in public transparency for pharmacy measures. However, we believe that the existing Part D reporting framework is sufficient for this process. We do not believe that having a consensus set of measures for plans to choose from, solely relying on third parties for development of measures, or publishing the list of pharmacy

performance measures publicly for the sake of public transparency, is in the best interest of Medicare beneficiaries.

We also disagree with requirements that only use specific quality measures adopted by CMS or third parties because it often takes years before these quality measures are approved. As a result, this requirement would stifle plan flexibility and innovation. Plans would not be able to measure pharmacies for quality measures that are not in existence today or for clinical quality beyond existing 5-Star measures.

Finally, SCAN does not believe that publishing the list of pharmacy performance measures would result in any meaningful transparency. Currently, many plans can develop their own measures that are specific to their goals, and having this information available publicly would put plans in a competitive disadvantage. Also, plans would have a harder time innovating and differentiating themselves from other plans. SCAN supports CMS collecting pharmacy measures that are being used by plans and to review fairness and improve medication use or outcomes.

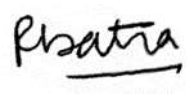
Dismissal and Withdrawal of Medicare Part C Organization Determination and Reconsideration and Part D Coverage Determination and Redetermination Requests *(§§ 422.568, 422.570, 422.582, 422.584, 422.590, 422.592, 422.631, 422.633, 423.568, 423.570, 423.582, 423.584, and 423.600),* p. 9069

- CMS Proposal: CMS proposes establishing processes for the withdrawal or dismissal of: (i) Part C organization determination and reconsideration requests; (ii) Part D coverage determination and redetermination requests; and (iii) Part C and Part D independent review entity (IRE) reconsiderations.

- SCAN Comments: SCAN supports establishing processes that clarify the above proposed guidelines.

Thank you for the opportunity to submit comments on this proposed rule. SCAN truly appreciates your commitment to improving the health of older adults and vulnerable populations. Please do not hesitate to contact me at rbatra@scanhealthplan.com, if you would like additional information.

Sincerely,



Romilla Batra, MD
Chief Medical Officer
SCAN Health Plan

PUBLIC SUBMISSION

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Comment on CMS-2020-0010-0002

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General Comment

See attached file(s)

Attachments

ACAP Comment Letter on 2021_2022 Proposed Rule_Final

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April 6, 2020

Demetrios Kouzoukas
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Centers for Medicare and Medicaid Services
Department of Health and Human Services

Submitted via electronic submission system

Re: Contract Year 2021 and 2022 MA-PD Proposed Rule

The Association for Community Affiliated Plans (ACAP) greatly appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the Contract Year 2021 and 2022 MA-PD Proposed Rule. ACAP is an association of 74 not-for-profit, community-based Safety Net Health Plans located in 29 states. Our member plans provide coverage to over twenty million individuals enrolled in Medicaid, Children's Health Insurance Program (CHIP) and Medicare Advantage Dual-Eligible SNPs. Twenty of our plans are D-SNPs and nationally, ACAP plans serve approximately one out of every four Medicaid managed care enrollees.

We submit the following comments for CMS' consideration.

- ***Star Ratings and Socioeconomic Status***: In order to address the impact of SES on the Star Ratings and to level the playing field for D-SNPs, CMS should evaluate peer grouping the Star Ratings so that D-SNPs are compared to each other in the Star Rating system.

- ***D-SNP Look-Alikes***: ACAP supports CMS' proposal to not renew or enter into new contracts with D-SNP look-alikes. However, the proposed 80 percent threshold is too high, and we suggest CMS lower the threshold.

- ***Special Supplemental Benefits for the Chronically Ill***: We support CMS' proposal to broaden the list of chronic conditions eligible for SSBCI. We also support CMS' proposals to remove the specification that incurred claims are payments to providers for covered services and to permit claims for supplemental benefits to be included in the MLR numerator as Quality Improvement Activities.

- ***SNP Care Coordination Activities***: We would appreciate additional information on the intended benefits to the beneficiary that CMS expects from requiring annual face-to-face encounters beyond what D-SNPs are already providing their members.

- ***ESRD Beneficiaries Enrolling in MA***: We ask CMS to monitor enrollment of beneficiaries with ESRD into D-SNPs and ensure that payments to D-SNPs for their ESRD members are adequate.

Star Ratings

ACAP believes in the need for an accurate quality measurement system for all MA plans, including those who exclusively serve dual-eligible beneficiaries. As CMS is aware, the Star Rating system is currently not a level playing field for D-SNPs, because the ratings do not adjust for the impact of dual-eligible status or other social risk factors. This results in a structural disadvantage for plans serving dual-eligible beneficiaries. As CMS also knows, the December 2016 ASPE Report to Congress found that dual status is a significant predictor of poor-quality ratings, independent of plan or provider performance. However, an effective adjustment has still not been made to the Star Rating system to remove the effect of dual status and other social risk factors on D-SNPs quality scores.

Although the impact of SES on Star Ratings was not addressed in this Proposed Rule, we nevertheless encourage CMS to develop a meaningful, long-term adjustment to the Star Rating system to level the playing field for D-SNPs. Specifically, we are asking CMS to evaluate peer grouping the Star Ratings for D-SNPs as a long-term strategy to address the impact of dual-eligible enrollment on Star Ratings. There is already a precedent for CMS using peer grouping in a quality rating system. The agency currently uses peer grouping in the hospital quality rating system by placing hospitals into quintiles based on their proportion of dual-eligible patients. We ask that CMS maintain consistency in its approach to quality measurement by using peer grouping for D-SNPs in the Star Rating system. We note that for this to occur, Star Ratings will likely have to be reported at the plan level. In addition to peer grouping, we also ask CMS to evaluate using measures that are appropriate for the dual-eligible population. The Star Rating system should incorporate measures that consider the unique needs of dual-eligible beneficiaries with complex health, behavioral, and cognitive conditions and whose care is affected by socioeconomic challenges.

Regarding the proposed changes to the Star Rating system, we do not support increasing the weight of the Patient Experience and Complaints and Access measures from 2 to 4. This change would increase the proportion of these measures to a plan's Star Rating from 37 percent to 53 percent. Although patient experience is an important indicator, we do not believe that members' self-

reported experience should outweigh their actual health outcomes. We also ask CMS to no longer down-weight the responses from dual-eligible beneficiaries on some CAHPs measures.

Regarding CMS' proposed outlier policy, we support the proposal to reduce the influence of outliers on the Star Rating cut points.

D-SNP Look-Alikes

ACAP shares CMS' concern about the proliferation of D-SNP look-alikes and the impact of those plans on enrollment in integrated care programs for dual eligibles. We support CMS' proposal to not renew or enter into new contracts with D-SNP look-alikes. However, the proposed 80 percent threshold to use in identifying D-SNP look-alikes is too high and will result in CMS not identifying all D-SNP look-alikes. Instead, we suggest CMS lower the threshold, such as to 40 or 50 percent. Additionally, we recommend that CMS exclude partial-benefit dual eligibles from the calculation of the threshold in order to enable the identification of a D-SNP look-alike to be based on a plan's enrollment of full-benefit dual eligibles. We also recommend that CMS consider defining D-SNP look-alikes as MA organizations that have a D-SNP and MA-PD under the same contract, with the majority (i.e. 50 percent or more) of dually eligible beneficiaries enrolled in the MA-PD, rather than the D-SNP.

Special Supplemental Benefits for the Chronically Ill

ACAP believes that SSBCI is an important tool for MA plans to tailor extra benefits for their chronically ill members. As such, we support CMS broadening the list of chronic conditions eligible for SSBCI. We also support CMS' proposals to remove the specification that incurred claims are payments to providers for covered services and to permit claims for supplemental benefits to be included in the MLR numerator as Quality Improvement Activities.

SNP Care Coordination Requirements

ACAP believes that care coordination is a key benefit D-SNPs provide their enrollees. Regarding CMS' proposal for all SNPs to conduct an annual face-to-face encounter with each enrollee, we would appreciate additional information on the intended benefits to the beneficiary that CMS expects from this policy beyond what D-SNPs are already providing their members. Additionally, with respect to the requirement that encounters be in-person or through visual, interactive telehealth,

CMS should note that not all dually eligible beneficiaries have access to visual, interactive telehealth technology.

ESRD Beneficiaries Enrolling in MA

With respect to enrollment of individuals with ESRD into MA plans, we note that there may be a higher prevalence of ESRD among the dually eligible population. As such, a disproportionate share of beneficiaries with ESRD could be enrolling in D-SNPs. We ask CMS to monitor enrollment of beneficiaries with ESRD into D-SNPs and ensure that payments to D-SNPs for their ESRD members are adequate.

Conclusion

ACAP is prepared to assist with additional information, if needed. If you have any questions, please do not hesitate to contact Christine Aguiar Lynch at (202) 204-7519 or clynch@communityplans.net.

Sincerely,

Margaret A. Murray
Chief Executive Officer

PUBLIC SUBMISSION

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Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2021 (CMS-4190-P)

Comment On: CMS-2020-0010-0002
Medicare and Medicaid Programs: Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly

Document: CMS-2020-0010-0414
Comment on CMS-2020-0010-0002

Submitter Information

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Organization: Blue Cross Blue Shield Association

General Comment

Thank you for the opportunity to comment. Please see attached for detailed comments from the Blue Cross Blue Shield Association (BCBSA).

Attachments

BCBSA Comment Letter on 2021 MA and Part D Proposed Rule_FINAL_with KH signature

BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

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April 6, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Submitted via the Federal Regulations Web Portal, http://www.regulations.gov

RE: CONTRACT YEAR 2021 AND 2022 POLICY AND TECHNICAL CHANGES TO THE MEDICARE ADVANTAGE PROGRAM, MEDICARE PRESCRIPTION DRUG BENEFIT PROGRAM, MEDICAID PROGRAM, MEDICARE COST PLAN PROGRAM, AND PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PROPOSED RULE; CMS-4190-P)

Dear Administrator Verma:

The Blue Cross Blue Shield Association (BCBSA) appreciates the opportunity to provide comments on the Proposed Rule: Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage (MA) Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly. (85 Fed. Reg 9002)

BCBSA is a national federation of 36 independent, community-based and locally operated Blue Cross and Blue Shield (BCBS) companies (Plans) that collectively provide healthcare coverage for one in three Americans. For more than 90 years, Blue Cross and Blue Shield companies have offered quality healthcare coverage in all markets across America – serving those who purchase coverage on their own as well as those who obtain coverage through an employer, Medicare and Medicaid. Today, BCBS Plans serve millions of Medicare beneficiaries in MA and Part D options.

Overall, we support many of the provisions in the Proposed Rule and thank the Centers for Medicare & Medicaid Services (CMS) for its continued attention to policies that support the successful MA and Part D programs that millions of beneficiaries rely on for their Medicare benefits.

BCBSA and BCBS Plans are supporting beneficiaries and working in partnership with providers across the country during the COVID-19 pandemic. Amid growing concerns about the spread of the virus in communities across the country, Plans are taking steps to ensure enrollees have uninterrupted access to high-quality healthcare during this national emergency.

We applaud the agency for releasing the Interim Final Rule titled “Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health

Emergency." The release empowers local hospitals and healthcare systems to take action to address the crisis and takes important steps to maintain stability for the MA and Part D programs during disruption to the healthcare system. We appreciate all that CMS has done to date to address the impact of COVID-19 on the nation's healthcare systems, and we look forward to working with you throughout this public health emergency.

We would like to highlight several key issues and recommendations, discussed in more detail in the detailed comment letter below.

Key BCBSA recommendations on the Proposed Rule include:

- **Provide Part D sponsors with the flexibility to offer a preferred and non-preferred specialty tier in a way that reduces costs –** We appreciate CMS' proposal to allow for a second, preferred specialty tier. However, we are concerned that the proposal in its current form could lead to higher costs, which will lead to premium increases for beneficiaries. To avoid increases, we recommend that CMS modify the policy to allow plans to increase cost-sharing on the non-preferred specialty tier. This would provide Part D plan sponsors with additional tools to effectively negotiate the lowest prices with manufacturers in order to avoid premium increases and reduce costs for the Medicare program.

- **Strengthen Star Ratings to improve quality –** CMS should continue to focus the Star Ratings program on outcomes-based and objective clinical measures, rather than process measures and subjective non-clinical measures.

- **Broaden "extreme and uncontrollable circumstances" policy in Star Ratings to recognize all disasters that impact plans – I**n order to ensure plans aren't penalized for events completely outside of their control, CMS should expand the definition of "extreme and uncontrollable circumstances" to consider scenarios beyond natural disasters, such as the current COVID-19 pandemic, as well as state public health emergencies, when the Health and Human Services (HHS) Secretary declares a public health emergency, or in the event of a Federal Emergency Management Agency (FEMA) emergency or Fire Management Assistance.

- **Provide more flexibility to improve access in rural areas –** BCBSA strongly supports CMS' new proposals to provide flexibility in network adequacy requirements, especially in rural areas.

- **Assure adequate payments as MA plans prepare for an influx of End Stage Renal Disease (ESRD) beneficiaries–** BCBSA urges CMS to take necessary steps to prepare for 2021, including addressing MA ESRD payment inadequacy. We support CMS' proposals to provide more flexibilities to increase beneficiary access to dialysis as well as adjustment to the Maximum Out-of-Pocket (MOOP) calculation. However, we are concerned that if CMS does not address the inadequacy of MA ESRD benchmarks and expand access to value-based care options for ESRD patients, all MA beneficiaries could be negatively impacted through increased premiums, decreased benefits and fewer plan options.

- **Ensure dually eligible beneficiaries have access to the most appropriate plan –** BCBSA supports efforts to promote integration for beneficiaries eligible for both Medicare and Medicaid and recommends CMS implement any proposal regarding Dual Eligible Special Needs Plan (D-SNP) "look-alikes" in a way that minimizes beneficiary disruption and recognizes state requirements and market dynamics. Specifically, we recommend CMS delay this proposed policy by at least one year, to 2023, and suggest technical changes to ensure the policy is implemented appropriately and targeted to beneficiaries who do not otherwise have access to integrated plans.

Thank you for the opportunity to provide detailed comments and recommendations. We would be pleased to discuss our comments with you at your convenience. Questions regarding these comments may be directed to Sarah.Rayel@bcbsa.com.

Sincerely,



Kris Haltmeyer
Vice President, Legislative & Regulatory Policy
Office of Policy & Representation

DETAILED COMMENTS ON MEDICARE AND MEDICAID PROGRAMS; POLICY AND TECHNICAL CHANGES TO THE MEDICARE ADVANTAGE, MEDICARE PRESCRIPTION DRUG BENEFIT, PROGRAM OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE), MEDICAID FEE-FOR-SERVICE, AND MEDICAID MANAGED CARE PROGRAMS FOR YEARS 2020 AND 2021 (CMS-4185-P)

Section II: Implementation of Certain Provisions of the Bipartisan Budget Act of 2018

Special Supplemental Benefits for the Chronically Ill

Issue #1: Chronic Conditions Eligible for SSBCI

The Bipartisan Budget Act (BBA) of 2018 expanded the type of supplemental benefits that MA plans can offer to include "Special Supplemental Benefits for the Chronically Ill" (SSBCI). These benefits do not have to be primarily health related, and CMS is authorized to waive the uniformity requirements. In this rule, CMS proposes to codify existing guidance from previous Health Plan Management System (HPMS) memos and the 2020 MA and Part D Call Letter and allow plans additional flexibility to target enrollees with conditions beyond those on the Chronic Condition Special Needs Plans (C-SNP) list (outlined in the Medicare Managed Care Manual Chapter 16b).

Recommendation #1:

BCBSA appreciates CMS' implementation of provisions in the BBA that provide plans with more flexibility in their supplemental benefits and encourages CMS to finalize these provisions as proposed.

Rationale #1:

We agree with CMS that the definition of chronically ill in the Medicare Managed Care Manual may not reflect the full universe of beneficiaries who could benefit from SSBCI. This new flexibility will improve the ability of MA plans to target care and effectively manage their members.

Improvements to Care Management Requirements for Special Needs Plans (SNPs)

Issue #1: Implementation of BBA Requirements

The BBA of 2018 modified requirements for C-SNPs related to the interdisciplinary team, requirements for face-to-face encounters and the mandatory model of care (MOC), including its annual evaluation and approval. CMS proposes to implement these requirements and extend them to all SNP types.

Recommendation #1:

BCBSA opposes CMS' proposal to extend the C-SNP requirements enacted in the BBA to Dual Eligible Special Needs Plans (D-SNPs) and Institutional Special Needs Plans (I-SNPs).

Rationale #1:

D-SNPs and I-SNPs provide important, specialized care for high-risk beneficiaries, and these plan types already have significant requirements for care management. We believe extending the BBA requirements specifically designed for C-SNPs to these SNPs would be duplicative and unnecessarily burdensome.

Issue #2: Interdisciplinary Team in Management of Care

CMS proposes to require each MA organization offering a SNP to provide enrollees with an interdisciplinary care management team that includes a team of providers with demonstrated expertise and training and, as applicable, training in a defined role appropriate to their licensure in treating individuals similar to the targeted population of the plan.

CMS specifically requests feedback on how plans can meet the requirements for both demonstrated expertise and training in an applicable specialty.

Recommendation #2:

BCBSA believes there are existing requirements that ensure beneficiaries have access to providers with appropriate expertise and encourage interdisciplinary team management, therefore, additional requirements would be redundant. If CMS proceeds with this proposal, BCBSA recommends that CMS limit documentation requirements related to the composition of the care team and demonstration of expertise and training of providers.

Rationale #2:

BCBSA supports the intent of this provision and agrees with CMS that every enrollee in a C-SNP should have access to an interdisciplinary team in the management of their care. However, we believe existing requirements, such as network adequacy and quality measures, already ensure the expertise and training of providers on an interdisciplinary team and encourage care management.

Issue #3: Face-to-Face Annual Encounters

CMS proposes to require a “face-to-face” encounter between enrollees and a member of the enrollee’s interdisciplinary team or the plan’s case management and coordination staff on at least an annual basis, beginning with the first 12 months of enrollment, and “as feasible” with the individual’s consent. CMS proposes that this “face-to-face” encounter must be either in person or through a visual, real-time interactive telehealth encounter.

Recommendation #3:

BCBSA recommends that CMS expand this requirement to include a visit or encounter with any provider, which could include any provider involved in a beneficiary’s care, not only those on the interdisciplinary team. CMS should also provide additional information to plans about how they intend to measure this requirement, including how they plan to interpret the “as feasible” language. We also support the proposed flexibility that this requirement may be meet via telehealth.

Rationale #3:

Face-to-face encounters are an important part of care coordination, and CMS' policy should ensure it captures all the ways these plans interact with their beneficiaries.

Issue #4: Health Risk Assessments and the SNP Enrollees' Individualized Care Plan

As part of the C-SNP model of care, the results of the initial assessment and annual reassessment (required for each enrollee) must be addressed in the individualized care plan. CMS proposes to extend this requirement to the model of care for all SNPs.

Recommendation #4:

BCBSA supports this proposal. In general, BCBS Plan SNPs already implement this practice, and, therefore, we do not have concerns with the proposal. However, we want to emphasize that individual care plans are member-centric and allow beneficiaries to choose their own goals. As a result, not every issue identified in an assessment becomes part of the care plan. BCBSA encourages CMS to account for this by allowing for as much flexibility as possible and clarifying that the individual care plan is a collaborative document between the beneficiary and his/her care team.

Rationale #4:

A care plan is designed to prioritize a beneficiary's needs, identify the goals that are most important to them, and facilitate interventions where coordination and support might be lacking. As such, not every issue identified in an assessment becomes part of the care plan. For example, a Care Coordinator developing a care plan may see a need for assistance with household tasks, but the beneficiary may have a family member who comes over to help with those tasks and does not want outside assistance. This would not typically be identified as a goal within the care plan, but would be identified in the assessment.

If this requirement is implemented with little flexibility, the care plan is likely to become a less effective tool for patient engagement and care improvement.

Issue #5: SNP Fulfillment of the Previous Year's MOC Goals

CMS proposes, as part of the evaluation and approval of the SNP model of care, that the National Committee for Quality Assurance (NCQA) must evaluate whether goals were fulfilled from the previous model of care. Additionally, plans would need to provide relevant information pertaining to the MOC's goals as well as appropriate data pertaining to the fulfillment of the previous year's MOC's goals. If the SNP model of care did not fulfill the previous year's MOC's goals, the plan must indicate in the MOC submission how it will achieve or revise the goals for the plan's next MOC.

Recommendation #5:

BCBSA supports this proposal with modifications. We ask CMS to recognize that MOC goals are often multi-year and can reflect treating different individuals or populations over time (so

some goals become evergreen as new individuals are engaged). In these cases, plans should not be penalized for failing to meet all goals within a year.

In addition, we recommend that requirements related to fulfillment of MOC goals be distinct from goals for quality performance, which are separate standards for SNPs. If these requirements do overlap, then we suggest that compliance with quality goals would meet the requirements for MOC goals.

Rationale #5:

It is not uncommon for an MOC to include goals that are intended to be achieved across two or more years, and plans shouldn't be penalized for not meeting these goals in a single year.

Issue #6: Establishing a Minimum Benchmark for Each Element of the SNP MOC

Currently, the HHS Secretary establishes a minimum benchmark for each element of the C-SNP model of care, and the MOC can only be approved if each element meets a minimum benchmark. CMS proposes to implement these benchmarks for all SNP MOCs before they can be approved.

Each SNP model of care would be evaluated based on a minimum benchmark for four elements: description of the SNP population, care coordination, SNP provider network, and MOC quality measurement & performance improvement. Currently, each sub-factor of an MOC element is valued at zero to four points with the score of each element based on the number of factors met for that specific element; the aggregate total of all possible points across all elements equals 60, which is then converted to percentage scores based on the number of total points received. CMS proposes that each element of the MOC must meet a minimum benchmark of 50 percent of total points as allotted, and a plan's MOC would only be approved if each element of the model of care meets the applicable minimum benchmark.

Recommendation #6:

BCBSA recommends that CMS release more information to enable more complete recommendations. In the meantime, CMS should delay the implementation of this proposal until 2022 and consider a transition/trial year in which MOCs are scored under both the old and new system so that plans can fully evaluate the impact.

We also urge CMS to consider additional steps to improve consistency of auditor evaluations.

Rationale #6:

BCBSA believes it is difficult to provide a thorough response to this proposal without additional information, particularly about the impact of the 50 percent threshold. This change would increase the importance of the MOC evaluation and approval; therefore, it is critical for plans to be able to fully evaluate and comment on the impacts and for CMS to ensure that auditors use consistent and unbiased criteria in evaluating the MOCs.

We note that BCBS Plans have experienced significant variations across auditors and have even received different scores from different auditors on identical MOCs.

Contracting Standards for Dual Eligible Special Needs Plan (D-SNP) Look-Alikes

Issue #1: Proposals to Address D-SNP "Look-Alikes"

In the Proposed Rule, CMS expresses concerns with D-SNP "look-alikes," which are MA plans that are not SNPs, but have levels of dual eligible enrollment that are "virtually indistinguishable" from SNPs and exceed that of a typical MA plan. CMS proposes that beginning in plan year 2022, the agency will not enter into or renew a contract for a D-SNP look-alike in any state where there is a D-SNP or any other plan authorized by CMS to exclusively enroll dually eligible individuals.

Recommendation #1:

BCBSA supports CMS' efforts to encourage D-SNP integration and recognizes the concerns regarding D-SNP look-alikes. We encourage CMS to implement this proposal in a way that minimizes beneficiary disruption and is informed by the nuances of state D-SNP policies. Specifically, we encourage CMS to allow at least one additional year (beginning in 2023) to implement this policy.

Rationale #1:

BCBSA agrees that advancing integration for individuals dually eligible for Medicare and Medicaid is critically important. This involves a transparent process by which beneficiaries can select plans that best meet their needs. Allowing an additional year for implementation will minimize beneficiary disruption.

Issue #2: Enrollment Threshold to be a D-SNP "Look-Alike"

For the purposes of the policy described above, CMS proposes to not enter into or renew a contract for a D-SNP "look-alike" plan in any state where there is a D-SNP or other plan authorized by CMS to exclusively enroll dually eligible individuals. CMS will treat a plan as a D-SNP "look-alike" if the plan:

- Projects enrollment in its bid that 80 percent or more of its total enrollment are dual eligibles; or
- Has actual enrollment, as determined by CMS using the January enrollment of the current year, consisting of 80 percent or more of dual eligibles, unless the plan has been active for less than one year and has enrollment of 200 or fewer individuals.

Recommendation #2a:

BCBSA recommends that CMS clarify that the 80 percent dual threshold only applies to full-benefit duals rather than full and partial duals. CMS should also clarify what data source the agency will use to determine the percentage of duals in a plan.

Rationale #2a:

Benefit integration between Medicare and Medicaid is important for full benefit duals, who receive benefits under Medicaid and Medicare. While partial benefit duals also benefit from the care coordination provided by all MA plans (SNP and non-SNP), because they only receive premium and/or cost-sharing assistance from Medicaid, not benefits, they have less need for integration with Medicaid benefits. Given the potential disruption to a number of beneficiaries currently in high-performing D-SNP look-alike plans, keeping the threshold at 80 percent and applying it only to full-benefit duals will help ensure that a beneficiary's care is not negatively impacted, beneficiary choice remains and confusion is minimalized.

Recommendation #2b:

We support CMS' exception to this policy in states without a D-SNP or other plan authorized to exclusively enroll dually eligible individuals. However, we recommend that CMS narrow application of this proposed policy from the state to the county level.

Rationale #2b:

Beneficiary access to a D-SNP is at a county level, not a state level – the presence of a D-SNP in some counties within a state does not provide access to coordinated care for dually eligible beneficiaries living in other counties. Plans are aware of several instances where the state may allow for new D-SNPs, but the creation of a D-SNP is restricted at a market or county level.

Therefore, CMS should continue to allow look-alike plans to operate in counties without D-SNPs or other integrated plans.

Issue #3: <u>Timing of Notification</u>

CMS proposes to make the determination of whether an MA organization has a non-SNP MA plan with actual enrollment exceeding the established threshold for D-SNP look-alikes using the plan's enrollment in January of the current year. CMS intends to make these evaluations and issue the necessary information to affected MA organizations early in the coverage year. CMS believes this timing would allow MA organizations the opportunity to make an informed business decision to apply and contract for a new D-SNP, create a new MA plan, or terminate the D-SNP look-alike and not submit a bid for the following contract year.

Recommendation #3:

BCBSA recommends that CMS delay the initial implementation of this policy to contract year 2023, in order to give MA organizations sufficient time to develop new products or apply for a new plan, especially given state requirements for integrated plans. Plans should be notified of their status in early 2021, which provides sufficient time to ensure a smooth transition. The focus should be on beneficiary communications and transitions as needed.

We also recommend affected beneficiaries be directly provided the option to stay with a MA plan that would ensure continued integration of their Medicare and Medicaid benefits.

Rationale #3:

As plans work to enter into agreements with states and stand-up compliant, integrated D-SNP products to transition members into (so as to avoid disruption in care), we do not believe that the timing between the finalization of this rule and the 2022 proposed start date for this policy change will be sufficient in all instances.

Additionally, regarding CMS' proposal to accommodate beneficiaries in terminated look-alike plans, we encourage CMS to consider the implications of this policy where the beneficiary is enrolled in a Medicaid plan that is sponsored by the same organization as the D-SNP look-alike plan. We believe it would be detrimental to make that beneficiary have to choose coverage or be forced to also change their Medicaid carrier as a result of this policy. Such a disruption in ongoing care plans and care teams at the *individual level* is likely to outweigh any additional benefit from the D-SNP integration requirements at the *plan level*.

Section III: Implementation of Several Opioid Provisions of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act

Mandatory Drug Management Programs (DMPs)

Issue #1: Support Act Implementation

The SUPPORT Act made changes to the requirements for Part D DMPs to enhance Part D sponsors' ability to reduce the abuse or misuse of opioids in their prescription drug benefit plans. CMS proposes two corresponding changes to the Part D DMP provisions codified in § 423.153(f):

1. Requiring Part D sponsors to adopt DMPs with respect to a plan year on or after Jan. 1, 2022, as required under section 2004 of the SUPPORT Act.
2. Requiring inclusion of Part D beneficiaries with a history of opioid-related overdose in sponsors' DMPs beginning Jan. 1, 2021.

CMS is also proposing to amend regulatory language to reflect the requirements that no later than 2022, Part D sponsors must have established DMPs.

Recommendation #1:

BCBSA supports CMS' proposal to require Part D sponsors to have established DMPs.

Rationale #1:

CMS' data shows that, since implementation of DMPs became an option in 2019, a large majority of plans (87.2 percent for calendar year 2020) have already adopted these programs to address opioid overutilization among their enrollees.

As CMS takes steps to make DMPs mandatory in 2022, BCBSA requests that the agency provide consistent guidance, particularly around the identification of potentially at-risk

beneficiaries and consistent lookback periods and exemption criteria for beneficiaries receiving long-term or end-of-life care.

Recommendation #1b:

BCBSA recommends that CMS add central nervous system depressants, such as gabapentin, to its list of "frequently abused drugs" so that plans are able to better manage the health and risk of beneficiaries taking them through Part DMPs.

Rationale #1b:

Gabapentin and other central nervous system (CNS) depressants have an elevated risk of abuse, particularly when take concurrently with opioids. Further, the FDA recently warned that abuse of that combination of therapies can lead to death in some cases.[1] Given that, we would like to recommend that CMS consider adding central nervous system depressants to its list of "frequently abused drugs."

We recognize there are potential challenges to this addition, namely that gabapentin and other CNS depressants are not federally controlled substances, one of the criteria for consideration for whether a drug should be included in the DMP, and that gabapentin falls under the list of protected class drugs in Part D. However, there is sufficient evidence to indicate the potential dangers of these drugs under the other two criteria defining a "frequently abused drug" is enough for CMS to consider adding them to the program. Additionally, gabapentin's protected class designation does not appear to interfere with its inclusion, as the management techniques used under the DMP are not intended to encourage beneficiaries to utilize a different product, but instead to ensure their safety and prevent drug abuse and diversion.

Beneficiaries with History of Opioid-Related Overdose Included in Drug Management

Issue #1: <u>Definition of Potential At-Risk Beneficiary</u>

Under section 2006 of the SUPPORT Act, CMS is required to identify Part D beneficiaries with a history of an opioid-related overdose (as defined by the HHS Secretary), and such individuals must be included as potential at-risk beneficiaries (PARBs) for prescription drug abuse under a Part D plan's DMP. In line with this requirement, CMS is proposing to modify the definition of "potential at-risk beneficiary" to include a Part D-eligible individual who is identified as having a history of an opioid-related overdose.

CMS proposes to define a beneficiary with a "history of opioid-related overdose" where a recent claim has been submitted that documents a beneficiary had a principal diagnosis code reflecting an opioid overdose, regardless of the type of opioid, and at least one recently submitted prescription drug event (PDE) for an opioid dispensed to such beneficiary.

[1] "FDA requires new warnings for gabapentinoids about risk of respiratory depression." December 2019. https://www.fda.gov/news-events/fda-brief/fda-brief-fda-requires-new-warnings-gabapentinoids-about-risk-respiratory-depression

CMS proposes to operationalize this proposed definition by using:

1. Diagnoses that include both Part D covered prescriptions and illicit opioid overdoses
2. A12-month lookback period from the end of each Overutilization Management System (OMS) reporting quarter, for record of opioid-related overdose within Medicare fee-for service (FFS) claims and Medicare Advantage Encounter data (excluding those not enrolled in a Part D plan, whether an MA-PD or stand-alone Part D plan (PDP))
3. A six-month lookback period from the end of each OMS reporting quarter, for record of a recent Part D opioid PDE

Recommendation #1:

BCBSA appreciates the intent to modify the definition of "potential at-risk beneficiary" to include a Part D-eligible individual who is identified as having a history of an opioid-related overdose. However, Plans have serious concerns about the feasibility of operationalizing this proposed definition and request that CMS postpones implementation until further details are provided.

Plans are especially concerned about the ability of stand-alone PDPs to identify members based on FFS data. For example, while stand-alone PDPs now have the ability to request a standardized extract of FFS claims data, it is unclear if the timing and contents of this data will be sufficient for these purposes.

BCBSA also seeks additional clarification on CMS' expectations for reviewing the cases of beneficiaries under this classification, as well as additional guidance on aligned exemptions, timeframes and qualifying criteria if such reviews are implemented as a requirement.

Rationale #1:

Stand-alone PDPs have the ability to request standardized extracts of FFS Medicare claims data on their members. However, this process is optional, and there is a significant time lag in the data.

Clarification on CMS' expectations for reviewing beneficiaries' cases is needed because beneficiaries with an overdose history should be regularly reviewed, and such a review is part of most plans' ongoing efforts. As such, including these reviews in the DMP process could be duplicative.

Information on the Safe Disposal of Prescription Drugs

Issue #1: <u>Information Provided During In-Home Health Risk Assessments</u>

MA plans are required to provide information on the safe disposal of prescription drugs when furnishing an in-home health risk assessment. CMS proposes to revise regulations to add a provision requiring MA plans that furnish an in-home health risk assessment on or after Jan.1, 2021, to include both verbal (when possible) and written information on the safe disposal of prescription drugs that are controlled substances in such assessments. CMS proposes specific information that must be included, such as information on drug takeback programs, safe in-

home disposal methods, and a web link to HHS' website identifying methods for the safe disposal of drugs.

Recommendation #1:

BCBSA requests that CMS provide additional clarity about what must be included in the health risk assessment to be complaint with this requirement. We recommend CMS provide sample language that plans can use. This sample language should contain information that recommends beneficiaries remove or conceal personal information prior to disposal. Additionally, we request CMS provide in the model language, or allow MA plans to provide, links to state and/or national websites that list current takeback sites, rather than requiring plans to include information on the hours and locations of takeback sites, which change frequently.

CMS should also consider alternate mechanisms for beneficiaries to receive this information, such as in their evidence of coverage (EOC) document, their annual notice of changes (ANOC) and/or a section in their version of the Medicare and You handbook. BCBSA also recommends CMS require the same notices to be communicated to FFS Medicare beneficiaries by prescribers and pharmacies.

Rationale #1:

BCBSA agrees with CMS on the importance of informing beneficiaries about safe disposal of prescription drugs, especially opioids. We believe that providing model language will assist plans with compliance with this requirement. Additionally, requiring prescribers and pharmacies to provide similar information will increase opportunities to inform beneficiaries about safe disposal of opioids.

Beneficiaries' Education on Opioid Risks and Alternative Treatments

Issue #1: <u>Information Provided to Beneficiaries</u>

Currently, all Part D sponsors disclose certain information about the risks of prolonged opioid use to all enrollees. In addition to this information, with respect to the treatment of pain, MA-PD sponsors must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans. CMS proposes to amend requirements for Part D sponsors to disclose opioid risks and alternative treatment options to only a subset of plan enrollees, such as enrollees who have been prescribed an opioid in the previous two-year period, rather than disclosing the information to each plan enrollee.

Recommendation/Rationale #1:

BCBSA supports this proposal and appreciates the flexibility on how to identify the appropriate enrollees. We request that CMS provide more specific guidance on the information plans will be required to provide to each enrollee annually.

Eligibility for Medication Therapy Management Programs (MTMPs)

Issue #1: <u>Eligibility for MTM Programs</u>

CMS proposes to amend Part D Medication Therapy Management Program (MTMP) requirements to conform to the relevant SUPPORT Act provisions by expanding the population of beneficiaries targeted for MTMP enrollment ("targeted beneficiaries") to include at-risk beneficiaries (ARBs), and by adding a new service component requirement for all targeted beneficiaries. Under this proposal, Part D sponsors would be required to automatically enroll all at-risk beneficiaries in their MTMPs on an opt-out only basis. In addition, Part D sponsors would be required to offer each at-risk beneficiary to be enrolled in the MTMP the same minimum level of MTM services that sponsors currently are required for beneficiaries enrolled in their current MTMP. This means, in addition to interventions for both beneficiaries and prescribers, sponsors must offer ARBs an annual comprehensive medication review (CMR). The CMR must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider.

Recommendation #1:

BCBSA recognizes that this expansion in targeted enrollment for MTMPs is required by the SUPPORT Act. However, we are concerned about the impact of these expanded new enrollments in Part D MTMPs. BCBSA recommends CMS not wholly import all ARBs into MTMPs, but rather enable plans to incorporate ARB status as a factor (in conjunction with other criteria) to better target MTMPs.

Rationale #1:

BCBSA is concerned the expanded enrollment could overwhelm current MTMP resources, require additional administrative complexity, and potentially lead to beneficiary confusion.

MTMPs provide demonstrated value to beneficiaries who have multiple chronic conditions, are on multiple medications, and are expected to incur high prescription drug costs for the year. While at-risk beneficiaries may benefit from some MTMP elements (many already qualify under existing criteria), many beneficiaries are distinctly different from the current MTMP population.

The bifurcation of the MTMPs into two targeted groups of enrollees would have negative effects on plans, initially requiring them to make substantial updates to support readiness for Jan. 1, 2021, as current system logic and processes do not incorporate the ARB population into MTMP activities. Plans would also need immediate guidance to address any changes to MA bids. Finally, BCBSA is concerned that the addition of ARBs into the MTMP population will have unknown performance impact on the MTMP Completion Rate for CMRs Star Ratings measure. If CMS moves ahead with this proposal, the agency should proactively implement safeguards in the scoring of this measure in order to ensure that plans with a high population of ARBs are not adversely and unintentionally affected.

Issue #2: <u>Information about the Safe Disposal of Drugs</u>

Section 6103 of the SUPPORT Act added a new requirement that Part D sponsors provide beneficiaries enrolled in their MTMP with information about the safe disposal of prescription drugs that are controlled substances, including information on drug takeback programs, in-home disposal and cost-effective means for safe disposal of such drugs. To implement this new requirement, CMS proposes that Part D sponsors would be required to provide this information

to all beneficiaries enrolled in their MTMPs at least annually, as part of the CMR or through the quarterly targeted medication reviews (TMR), or follow-up.

Like MA plans, Part D plans would retain the flexibility to refine their educational materials based on updated information and/or on beneficiary feedback, so long as the materials meet the proposed criteria. Part D plans would have the discretion to furnish safe disposal information to the beneficiary during the CMR, a TMR, or another follow up service, depending upon the circumstances, as long as the required information is shared with each MTMP enrollee at least once per year.

Recommendation/Rationale #2:

BCBSA supports this proposal and appreciates the continued flexibility from CMS.

Automatic Escalation to External Review under a Medicare Part D Drug Management Program (DMP) for At-Risk Beneficiaries

Issue #1: Automatic Escalation to External Review

Under existing Part D appeals procedures, there is no automatic escalation to external review for adverse appeal decisions; instead, the enrollee (or prescriber, on behalf of the enrollee) must request review by the Part D independent outside review entity (IRE). Under the existing process, cases are auto-forwarded to the IRE only when the plan fails to issue a coverage determination within the applicable timeframe. While the HHS Secretary has discretion under statute to provide for automatic escalation of drug management program appeals to external review, CMS declined to exercise that discretion in previous rule-making.

Section 2007 of the SUPPORT Act requires that, if on reconsideration a Part D sponsor affirms its denial of a DMP appeal, in whole or in part, the case shall be automatically forwarded to the IRE. CMS proposes rules to codify this provision.

Recommendation #1:

BCBSA recommends modifications to the timeframes that would be required to meet this standard. We request that CMS continue to allow 72 hours for review of new information, then after the 72-hour timeframe, additional time to forward to the IRE. In addition, we disagree that providing the appeal notification on the first notice adds value to the beneficiary, since the first notice has a 30-day window to gain additional information, if necessary, before a final decision is made to implement a lock-in or POS edits. BCBSA recommends that appeal language is included only on second notices.

Rationale #1:

BCBSA is concerned that the proposed timeframes are operationally problematic and place an unnecessary burden on plans.

Section IV: Implementation of Certain Provisions of the 21st Century Cures Act

MA Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries

Issue #1: Plan Options for ESRD Beneficiaries

CMS proposes to implement changes in the 21st Century Cures Act, which remove the prohibition for beneficiaries with ESRD from enrolling in an MA plan, effective for plan years on or after Jan. 1, 2021.

On the recent CMS stakeholder call, CMS stated that there are currently 131,000 beneficiaries in MA in 2020 with ESRD, and CMS is projecting roughly 83,000 additional beneficiaries with ESRD will enroll in MA over the next five years, with half in the first year (2021). On the Advance Notice stakeholder call, CMS discussed that they used plan and academic studies to develop these estimates.

Recommendation #1:

As discussed in detail in our comment letter on the 2021 MA and Part D Advance Notice (submitted to CMS on March 6, 2020), BCBSA recommends that CMS take necessary steps to ensure effective implementation of the provisions in the 21st Century Cures Act impacting MA plans as to this new enrollment. CMS should update MA ESRD benchmarks to more accurately reflect the actual costs of ESRD patients. It is critically important that CMS consider steps to improve ESRD payment adequacy, both related to benchmark calculations and ESRD risk adjustment, particularly as we look to 2021, and full integration of ESRD individuals into MA.

Specifically, we recommend:

- ESRD benchmarks: BCBSA continues to urge CMS to revise the current ESRD payment methodology, including exploring recommendations BCBSA offered in our issue paper, such as updating the ESRD ratebook methodology, carving out the dialysis bundle from MA ESRD payment, or anchoring ESRD payment within the MA ESRD ratebook methodology. We look forward to continuing to work with CMS to address these concerns.

- ESRD Growth Rate: To improve accuracy of the dialysis-only ESRD growth rate (United States per capita cost (USPCC)) and better align with the non-ESRD FFS USPCC, we encourage CMS to modify the methodology for the ESRD growth percentage to use five years of FFS claims data, rather than just one year. Such a change would more closely align the methodologies for the FFS and ESRD growth percentages and would reduce volatility in ESRD payment rates, which is critical as more ESRD beneficiaries are able to join MA in 2021. Additionally, in line with the non-ESRD FFS USPCC, BCBSA requests that CMS release more data and be more transparent about the specific data and trends, underlying methodology and other variables impacting growth updates. We appreciate inclusion of the dialysis-only ESRD USPCC in this year's 2021 Early Preview.

- Automatically move ESRD enrollees: In an effort to support the probable increase in ESRD MA enrollment levels, we ask CMS to move enrollees with a current chronic dialysis diagnosis into the MA ESRD payment and risk adjustment segment

automatically. The current process requires an extensive documentation process that adds significant administrative burden to members, providers and health plans. We request that CMS track ESRD enrollment during the open enrollment period (OEP) and pay MA plans the ESRD reimbursement amounts as of the first month of these new enrollments.

Rationale #1:

The MA program will see an influx of new ESRD patients in 2021, and CMS should take steps to assure that inadequate payments do not create new financial risks for plans, especially smaller plans. The payment methodology must account for the intersection of dialysis provider concentration and network adequacy requirements, which can undermine the ability for plans to negotiate reasonable reimbursement rates for dialysis services. This, among other factors, can mean that ESRD rates are not adequate to pay for the true costs of caring for these complex, high-cost patients. Inadequate payment for complex patients negatively impacts beneficiary care and inhibits the ability of plans to improve care coordination, reduce cost and innovate ways to improve beneficiary outcomes. By not addressing the chronic shortfall in revenue for ESRD members through a material increase in state benchmark calculations, CMS is creating the possibility of plans reducing benefits for all of their MA beneficiaries as well as raising the maximum out of pocket and inpatient (IP) benefit limits. When Congress moved to open up MA plans for ESRD members, they did not address payment issues and the fact that an influx of new ESRD members could have a significant impact on a plan's existing membership by raising their cost-sharing amounts and/or lowering their supplemental benefits, such as cost-sharing reductions, in order to achieve financial stability.

Though some variation is expected in growth rates year to year, we have concerns with how volatile the dialysis-only ESRD estimates have been, which make it difficult for Plans to model revenues and prepare bids. For example, the final update for 2021 was 9.81 percent, and the final update for 2020 was -0.48 percent. Currently, the ESRD growth percentage is developed based on the most recent calendar year of data available, trended to the upcoming year, leading to large swings and volatility in ESRD payment. The FFS growth percentage is developed based on the most recently available five years of data repriced based on the upcoming year's Medicare fee schedule, which provides more data to facilitate more consistent rates year over year.

In addition, consistent with the Administration's Advancing American Kidney Health initiative, CMS should provide MAOs with the option of participating in the CMMI kidney models to improve the dissemination of best practices in kidney care. With a focus on care coordination and whole-person health, BCBS Plans are well-positioned to participate in, and achieve the goals of, improving chronic kidney disease management, lowering the incidents of patients progressing to ESRD, increasing ESRD home care, and increasing kidney transplant opportunities through value-based payment arrangements.

Medicare Fee-for-Service (FFS) Coverage of Costs for Kidney Acquisitions for MA Beneficiaries

Issue #1: <u>Coverage of Costs for Kidney Acquisitions</u>

CMS proposes to implement changes made by the 21st Century Cures Act, which exclude organ acquisitions for kidney transplants from the list of items or services an MA plan is required to cover and, instead, mandates that these costs will be covered under FFS.

Recommendation/Rationale #1:

BCBSA supports this change and provides comments below.

Exclusion of Kidney Acquisition Costs from MA Benchmarks

Issue #1: Calculation of MA Benchmarks

Starting in 2021, the 21st Century Cures Act directs CMS to exclude kidney acquisition costs, which are the standardized costs for payments for organ acquisitions for kidney transplants, from the FFS county benchmarks. Therefore, starting in 2021 the specified amount, which is the benchmark using the post-ACA formula, is as follows: Specified amount = (2021 FFS cost minus (IME phase-out amount + kidney acquisition costs)) × (applicable percentage + applicable percentage quality increase). CMS released 2021 Preliminary Kidney Acquisition Cost Carve-out Factors and Applicable percentages.

CMS laid out a nine-step process to comply with Section 17006(b) of the 21st Century Cures Act, which directs CMS to exclude the agency's estimate of the standardized cost elements for payments for organ acquisition for kidney transplants from MA benchmarks starting in 2021. CMS states the impact of excluding kidney acquisition costs will vary by county, with a FFS enrollment-weighted average impact of approximately $4 PMPM for the MA (i.e., non-PACE) non-ESRD county rates and a FFS enrollment-weighted average impact of about $36 PMPM for the MA (i.e., non-PACE) ESRD state rates. For the 2021 MA (i.e., non-PACE) county rates, the largest impact is estimated to be about $20 PMPM, and for the 2021 MA (i.e., non-PACE) ESRD state rates, the largest impact is estimated to be about $75 PMPM. CMS is releasing the preliminary 2021 kidney acquisition cost carve-out factors for MA plans by county and state.

Recommendation #1:

BCBSA wants to ensure the kidney acquisition costs accurately reflect the true costs for organ acquisitions for kidney transplants to ensure CMS is not reducing the benchmarks inappropriately. To this end, we recommend the following:

- Counties with transplant centers: BCBSA has concerns that the calculation disadvantages counties with a transplant center in or near them, and we recommend adjusting accordingly. It appears CMS is assuming that within a transplant facility, the percentage of kidney transplant discharges of total discharges by patient or county is equal. However, 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. This assumption has the unintended negative consequence of allocating higher or excessive costs to the counties that have transplant centers.

- Acquisition cases by provider: We suggest that CMS explore using the number of acquisition cases by provider and county rather than allocating using the total patient cases by county to produce a more reasonable allocation.

- Phase-in: We suggest that CMS consider phasing in the kidney acquisition cost benchmark adjustment similar to how the agency phased in the graduate medical education (GME) and indirect medical education (IME) adjustments.

- Consider MAO experience data: We ask that CMS consider MAOs' data and actual experience with kidney acquisition costs, which Plans estimate to vary by state and are substantially lower than $4 PMPM. This may be influenced by our interpretation of CMS' calculation of these costs, which reinforces the need for specific detail and further guidance in this area. The discrepancy may also reflect the volatility of the costs of care for this patient population. Because CMS' FFS data includes a greater proportion of kidney transplant patients compared to individual MAOs, we are concerned about the disproportionate impact the $4 PMPM reduction in benchmarks will have with minimal or no claims reductions to offset this revenue loss. CMS' consideration of specific MA data and experience, and disclosure of key methodological steps the agency used to develop the proposed benchmark reduction, will help ensure the accurate and appropriate exclusion of kidney acquisition costs from the benchmark.

- Release CMS data elements included in the carve out and other data: We request that CMS release more data to support its 2021 Preliminary Kidney Acquisition Cost Carve-out Factors and Applicable percentages, including all the elements included in the carve out and underlying data. In particular, it would be helpful if CMS could identify 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 provide a quantitative example of the calculation discussed in Step 5. The regulatory impact section of the recently Proposed Rule, "Policy and Technical Changes to the Medicare Advantage and Part D Programs for CY 2021," states that the costs for these services are expected to be lower than the amount that is expected to be excluded from the MA benchmarks.

Rationale #1:

BCBSA has concerns that the preliminary adjustments proposed by CMS are excessive and do not reflect current kidney acquisition costs in MA. If CMS excludes costs that are artificially high, it will exacerbate the current issues of underpayment in MA for ESRD.

Section V: Enhancements to the Part C and D Programs

Reinsurance Exceptions

Issue #1: Reinsurance Exceptions

In general, MA organizations are required to assume full financial risk for the provision of basic benefits furnished to enrollees. However an exception at section 1855(b)(1) allows MA

organizations to obtain reinsurance above a per-enrollee aggregate level established by the Secretary.

CMS proposes to implement the statutory exception in regulation because of concerns that there was legal uncertainty regarding the permitted use of reinsurance in the MA program. CMS proposes that an MA organization may obtain reinsurance or make other arrangements for the cost of providing basic benefits if the aggregate value of such an arrangement exceeds a $10,000 aggregate per individual (or the first-dollar equivalent).

Recommendation #1:

BCBSA appreciates CMS' concern that overly generous reinsurance could lead to moral hazard. However, we believe the Proposed Rule does not accommodate the different uses of reinsurance or explicitly grant exceptions where the reinsurer and MAO are owned by a common parent. We, instead, recommend a minimum standard of 10 percent risk assumption where the MAO obtains reinsurance from an affiliate and/or a joint venture or alliance partner.

We also appreciate the flexibility CMS is extending by not requiring plans to purchase reinsurance and, instead, leaving the choice up to the plans.

Rationale #1:

While BCBSA appreciates CMS' desire to balance risk-assumption with potential moral hazards, we would like to make the Administration aware of situations where reinsurance is used for the purpose of allocating risk among participants in an MA venture or alliance. For example, a local plan may wish to pair its market knowledge with the operational expertise of a larger player. The two organizations take on the joint responsibility to administer the product and use a reinsurance agreement as a mechanism to allocate the proportional profits/losses of the venture or alliance – related to the stake in the venture or alliance.

These types of arrangements can lead to better products for members that are fiscally sound, higher-quality, have lower administrative costs, and are more tailored to local demands than either participant could do independently. To this end, we believe CMS' proposal is overly broad in its application to reinsurance and would have unintended consequences by eliminating arrangements designed as profit-share distribution mechanisms between participants in the venture or alliance.

In order to accommodate the multiple uses of reinsurance in the business of MA, we propose adopting an alternative standard: An MA organization may obtain insurance, reinsurance or make other arrangements for the cost of providing basic benefits to an individual enrollee that either the aggregate value of which exceeds an aggregate level that is greater than or equal to $10,000 during a contract year or through quota share reinsurance on a first dollar proportional basis, where the MA organization or an affiliate of the MA organization retains a minimum 10 percent quota share percentage of the risks being transferred.

We urge CMS to make accommodations in its Proposed Rule for situations where an MAO obtains reinsurance from an affiliate and/or a joint venture or alliance partner. As noted earlier, because reinsurance is a useful means by which to share profits/losses in joint ventures and

alliances, an entity may choose to allocate its risk to a reinsurer that is an affiliate of the MAO and to another joint venture or alliance partner. Again, such arrangements are not about the abdication of risk, but rather serve as a mechanism to facilitate the allocation of profits/losses under a joint venture or alliance.

Issue #2: Definition of Parent Company

CMS is also proposing to broaden its interpretation of MA organization for purposes of this statute to include the MA parent organization.

Recommendation #2:

BCBSA supports evaluation of compliance with section 1855(b) at the parent organization level. CMS should consider a parent organization to be part of an MA organization for purposes of section 1855(b) of the Act.

Rationale #2:

Reinsurance between wholly-owned subsidiaries and the parent organization is a common and long standing market practice for both commercial health insurers and MA organizations, and the practice serves to reduce financial exposure to changes in healthcare costs, helps effectively manage capital requirements, and allows healthcare insurers to grow enrollment, particularly in rural underserved counties.

Out-of-Network Telehealth at Plan Option

Issue #1: Out-of-Network Telehealth

The BBA of 2018 authorized MA plans to offer additional telehealth benefits (ATBs) to enrollees starting in plan year 2020 and to treat ATBs as basic benefits. In rule-making last year, CMS finalized a requirement that MA plans furnishing ATBs only do so using contracted providers – any benefits furnished by a non-contracted provider through electronic exchange could only be covered by an MA plan as a supplemental benefit.

At the time, CMS believed this limitation on providers was needed to ensure oversight of providers' performance. CMS is now considering whether this requirement unnecessarily limits the ability of MA plans to offer ATBs. Therefore, CMS is considering whether to revise §422.135 to permit ATBs to be provided by non-contracted providers in cases whether the non-contracted providers satisfy ATB requirements set forth in the April 2019 Final Rule.

Recommendation #1:

BCBSA supports this proposal, which will help increase access to telehealth for beneficiaries

Rationale #1:

This proposal will give plans more flexibility to offer additional telehealth benefits and help accelerate the growth of telehealth to improve beneficiary choice and access to care.

Referral/Finder's Fees

Issue #1: Referral/Finder's Fees

Under existing rules regarding agent and broker compensation, compensation for initial enrollments is limited to Fair Market Value (FMV), and compensation for renewal enrollments is limited to 50 percent of fair market value. CMS does not believe the limits on referral fees are necessary, since total compensation, of which referral fees are a component, are also subject to limits. Therefore, CMS proposes to eliminate the current specific limit on finder or referral fees codified in regulation.

Recommendation #1:

BCBSA views referrals and enrollment as different activities, and, thus, we recommend CMS consider payment for these activities separately. Therefore, instead of bundling referral fees within the definition of FMV, we propose the agency allow for reasonable referral and enrollment fees separate and apart from FMV.

Rationale #1:

CMS seeks to clarify that compensation is on a per-enrollment basis. Since referral fees are part of compensation, organizations may not pay independent agents more than regulatory limits. Because referral fees are already incorporated into compensation, CMS believes limiting the amount of a referral fee has no impact on the statutory requirement of an agent enrolling a beneficiary in the plan that best meets their healthcare needs. However, in some Plans' experience the referring agent is often different than the agent or broker who enrolls the beneficiary. Therefore, we request the ability to handle the referral and enrollment fees separately.

MA and Part D Prescription Drug Program Quality Rating System

Issue #1: Overarching Recommendations to Improve the Stars Rating Program

Recommendation/Rationale #1:
BCBSA would like to offer several recommendations to improve the reliability and effectiveness of the MA and Part D Quality Star Ratings System. Specifically, we request that CMS:

- Restore prospective cut points and more transparency. Although we appreciate the great strides CMS has made in providing more transparency in the federal rule-making process with required notice and comment on the Star Ratings, BCBSA strongly recommends that CMS restore the process of making the measure cut points prospective for both Parts C and D measures. This change is needed to better support the ability of plans and providers to engage in value-based contracts that incentivize higher quality. Additionally, CMS should provide comprehensive analysis regarding the cut-point guardrails in place for non-CAHPs measures beginning for 2022 Star Ratings, and CMS should consider a cap of less than 5 percent.

- Only apply the Categorical Adjustment Index (CAI) if it positively impacts a plan's ratings. BCBSA has supported CMS' continued efforts to address the impact of socio-

economic and disability status on Stars ratings and appreciates CMS' attention to stakeholder feedback on this issue. However, in our experience, the CAI is insufficient to address this important problem and we look forward to working with CMS to reach a long-term solution.

- Create, publicize and follow a set of methodological criteria that specify minimum levels of reliability for all measures, including, but not limited to, the health outcomes survey (HOS) and Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures. Adopting and abiding by such minimum reliability thresholds at the measure-contract level (since reliabilities can vary across contracts, even for the same measure) would clarify CMS' intent in implementing the Star Ratings program, set lower bounds on the degree of arbitrariness in distributing financial rewards and penalties, and help CMS and its contractors proactively identify and avoid any future inclusion of measures with unacceptably low reliabilities in the Star Ratings program.

Issue #2: Definition of New MA Plan

CMS proposes to amend and clarify the definition of a "new MA plan." Currently, a "new MA plan" is defined as an MA contract offered by a parent organization that has not had another MA contract in the previous three years. CMS proposes to modify this definition and, instead, define a "new MA plan" that is:

1) Offered under a new MA contract
2) Offered under an MA contract that is held by a parent organization that has not had an MA contract in the prior three years

Recommendation/Rationale #2:

BCBSA supports this change and appreciates clarity on this issue.

Issue #3: Methodology for Removal of Outliers

In previous rule-making, CMS has considered options for removal of outliers in the methodology to calculate Stars scores for non-CAHPs measures, but did not finalize an approach. In this Proposed Rule, CMS discusses two options to address the direct removal of outliers and proposes to apply the Tukey outlier fence deletion methodology, rather than a trimming methodology.

CMS believes that the Tukey outlier fence deletion is preferable to the alternative because trimming would remove all scores below the 1st percentile or above the 99th percentile, which could delete scores that are not true outliers and retain scores that are outliers.

CMS estimates that this change alone would reduce plan payments by over $800 million in 2024 and up to $1.4 billion in 2030. Combined with other proposals and accounting for the impact of ordinary inflation, CMS estimates a net reduction of nearly $5 billion over 10 years.

Recommendation #3:

BCBSA is concerned that this outlier methodology would dramatically decrease payments to plans by reducing Star Ratings for most plans. CMS should not finalize this proposal and should consider other policies to remove outliers that would not have such a dramatic impact on plan payments.

Furthermore, it is difficult for plans to evaluate these proposals without full information about the impact of the proposal on their plan-specific Stars Ratings. BCBSA recommends that CMS consider publishing a display version of cut points with and without the proposed outlier deletion so that plans can fully evaluate the impact.

Rationale #3:

CMS estimates that if the Tukey fence outlier deletion and a five percent guardrail had been implemented for the 2018 Star Ratings, 2 percent of MA-PD contracts would have seen their Star Ratings increase by half a Star, while 16 percent would have decreased by half a Star and one contract would be reduced by a full Star. For PDP contracts, 2 percent would have increased by half a Star and 18 percent would have decreased by half a Star.

These large decreases go beyond the scope of a policy aiming to address outliers, especially when Plan-specific impacts are difficult to analyze and prepare for. To ensure stability in the Stars system, CMS should not finalize the policy as proposed and work with stakeholders to develop a less disruptive policy that addresses outliers.

Issue #4: Contract Consolidations

CMS proposes several changes to regulations on how contract consolidations are treated in calculating Star Ratings. CMS proposes two new policies effective for contract consolidations approved on or after Jan. 1, 2021:

- In cases where a measure score is missing from the consumed or surviving contract(s) due to a data integrity issue, CMS proposes to assign a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score.
- For appeals measures, CMS proposes to combine the Timeliness Monitoring Project (TMP) or audit data for the consumed and surviving contracts before applying their existing methodology for reducing a contract's measure for IRE data.

Recommendation #4:

BCBSA supports this proposal**.**

Rationale #4:

We agree that this will help to clarify the issue of assigning Stars to consolidated contracts.

Issue #5: Proposed Measure Removal

CMS proposes to remove the Rheumatoid Arthritis Management measure from the Part C Star Ratings for the 2021 measurement year and the 2023 Star Ratings since NCQA is retiring this measure.

Recommendation #5:

BCBSA agrees with this proposal.

Rationale #5:

We agree with CMS' rationale for removing this measure from Part C Star Ratings.

Issue #6: Proposed Measure Updates: HOS Measures

CMS proposes two changes to the Improving or Maintaining Physical Health (PCS) Measure and Improving or Maintaining Mental Health (MCS) Measure from the HOS.

First, CMS proposes to change the way the case-mix adjustment address missing variables. Currently, if any of the case-mix variables in a group are missing for a beneficiary, none of the variables in the group are used. CMS proposes to replace this "all-or-nothing" approach with one in which they replace a missing adjuster with the mean value for that adjuster for other beneficiaries in the same contract.

Second, CMS proposes to increase the minimum required denominator from 30 to 100 for the two measures. The proposed increase to the minimum denominator would bring these measures into alignment with the denominator requirements for the HEDIS measures that come from the HOS survey and increase the reliability for these measures compared to the current reporting threshold of 30.

Recommendation #6a:

We applaud CMS' decision in the recently released Interim Final Rule to postpone until late summer (and maybe later) this year's HOS survey, administered by NCQA in partnership with CMS, which was scheduled to be from April through July 2020. This survey administration has been postponed to late summer, and CMS will continue to monitor the situation to see if any further adjustments are needed.

Rationale #6a:

It is appropriate to reduce burden while the healthcare system rises to face the COVID-19 pandemic. Additionally, beneficiaries should not be asked to complete surveys at a time when they are facing this crisis.

Recommendation #6b:

Moving forward beyond this pandemic, BCBSA appreciates the changes CMS proposes to improve the comparability and reliability of the Improving or Maintaining Physical and Mental Health measures, but we do not believe these adjustments go far enough to address our concerns about the reliability and validity of these measures. We do not believe the Improving or Maintaining Physical Health and Improving or Maintaining Mental Health measures should

continue to be part of the Star Ratings unless modifications produce year-over-year consistency and reliability.

Rationale #6b:

BCBSA would like to reiterate our comments from the 2021 Advance Notice, in which we expressed concerns about the reliability of measures derived from the HOS instrument in differentiating quality performance across MAOs is low. BCBSA has shared with CMS our summary of the findings of a 2017 RAND research report as well as an internal analysis conducted with five years (2015-2019) of HOS performance scores, which found that there was significant volatility year-over-year in MAOs' HOS performance. As a result of these findings, and in conjunction with the other BCBS Plans, we request CMS: (1) conduct an independent study to confirm and address reliability and validity concerns; (2) define standards for reliability and publish the reliability for all Star measures in line with or exceeding the National Quality Forum standards; and (3) work with stakeholders to determine the best ways to measure outcomes and how plans can influence them.

Recommendation #6c:

BCBSA generally supports the proposed changes to case mix adjustments but requests that CMS publish reliability data under the old case mix methodology and new case mix methodology.

Rationale #6c:

In the 2019 Final Rule CMS set out guiding principles used in making enhancements and updates to Star Ratings. One of these principles is that "data are complete, accurate, and reliable."

Multiple studies validate the reliability of the core components of the two current Outcomes Measures (VR-12 PCS and MCS). However, there is less research on the Performance Measures used in the Stars Program (Improving or Maintaining Physical Health, and Improving or Maintaining Mental Health). One such study[2] (focused on individuals with chronic conditions) was conducted by RAND, and its conclusion was that the VR-12 PCS and the VR-12 MCS "point-in-time" measures are reliable, but the measures used to gauge change in those components over time have very low reliability. While the study's focus was not on the entire beneficiary population, its conclusions are still concerning, and indicates possible reliability concerns with the two Star Outcomes Measures. We request that CMS publish the reliability of the outcomes measures to respond to this concern.

Our concern for reliability is rooted in trends we have observed in industrywide performance in the two Outcomes measures. Data indicate that plans lack the ability to influence the outcomes measures, possibly due to the reliability concerns. While plans are able to maintain consistent

[2] Kazis, Lewis E., William H. Rogers, James Rothendler, Shirley Qian, Alfredo Selim, Maria Orlando Edelen, Brian D. Stucky, Adam J. Rose, and Emily Butcher, Outcome Performance Measure Development for Persons with Multiple Chronic Conditions. Santa Monica, CA: RAND Corporation, 2017. https://www.rand.org/pubs/research_reports/RR1844.html.

levels of performance in Star measures from HEDIS, CAHPS and other data sources, plans are less able to maintain performance levels in the outcomes measures obtained from HOS.

Recommendation #6d:

BCBSA directionally supports CMS' proposed expansion of the minimum required denominator from 30 to 100. However, we still believe the HOS survey size is extremely small and may not be truly representative, especially for larger plans. We recommend CMS further expand the minimum required denominator as well as the overall sample size that CMS selects for survey distribution.

Rationale #6d:

A larger minimum required denominator and overall sample size will improve the representativeness of the HOS survey.

Issue #7: Proposed Measure Updates: Statin Use in Persons with Diabetes (SUPD) (Part D)

Based on commenter feedback from the 2020 Draft Call Letter, CMS proposes to modify the classification of the SUPD measure category from an intermediate outcome classification to a process measure, starting with the 2023 Star Ratings.

Recommendation #7:

BCBSA supports CMS' proposal to modify the classification of this measure and agrees it is a process, not an outcome measure.

However, we would like to reiterate our comments from the 2021 Advance Notice, in which we requested that CMS keep this measure at a weight of 1 for CY 2019, 2020 and beyond. This is consistent with CMS' language in the 2020 Final Rate Notice, where the agency stated, "For the 2020 Star Ratings, we will keep this measure's weight at 1 as a new measure while we further review this measure's category and consider if CMS should propose to change the technical specifications to reclassify it in the future."

Rationale #7:

BCBSA agrees with CMS that the SUPD measure is a process measure, not an outcome measure, because it requires only a single fill of a statin. In order for a medication to truly contribute to an outcome, it should require measured adherence over a course of treatment. Reclassifying the SUPD measure on an earlier timeline is appropriate given that CMS has proposed returning SUPD to a process measure, and the measure has not changed in any way that would warrant retaining its classification as an interim outcome measure weighted at three.

Issue #8: Proposed Measure Addition: Transitions of Care

CMS proposes two new HEDIS measures for addition in the Part C Star Ratings program for measurement in 2021 (2023 Star Ratings). The first is Transitions of Care, which is the percent of discharges for members 18 years or older who have each of the four indicators during the

measurement year: (1) notification of inpatient admission and discharge; (2) receipt of discharge information; (3) patient engagement after inpatient discharge; and (4) medication reconciliation post discharge. Based on stakeholder input, NCQA is considering several non-substantive measure specification changes, such as broadening the form of communications and changing the timing of notifications and receipts.

Recommendation #8:

BCBSA has significant concerns with this measure, as described in detail in our comments on the 2021 Advance Notice, and does not support it be finalized as proposed.

It is also unclear to BCBSA whether the proposed Transitions of Care measure was actually on display for the 2020 Star Year. The measure described in the Proposed Rule does not exactly match the specifications of any of the Transitions of Care measures currently on the display page. We request that if this actually represents new measure specifications, the measure should remain on display for 2021 before being considered for 2023 Star Ratings at the earliest.

Rationale #8:

We are concerned that the measure in its current form is counter-productive to improving the quality of care of transitions from the inpatient setting to the home. We encourage CMS to ensure the measure indicators include all providers who can appropriately support a beneficiary during a care transition, support transition programs that do not require that a member have a Primary Care Provider visit, and provide measure flexibility due to privacy and administrative limitations.

Additionally, we believe that performance in this measure is largely a function of process and technology on the part of hospitals, and that introduction of this measure would disadvantage plans that manage the care of beneficiaries, especially in rural areas. This furthers the case for extending the time this measure should be on display, because more time is necessary to make the proper investments.

Issue #9: <u>Proposed Measure Addition: Follow-up After Emergency Department (ED) Visit for Patients with Multiple Chronic Conditions</u>

CMS also proposes to add the "Follow-up After Emergency Department (ED) Visit for Patients with Multiple Chronic Conditions" measure in 2021 (for 2023 Star Ratings). This measure is the percentage of ED visits for members 18 years and older who are high-risk multiple chronic conditions who had a follow-up service within seven days of the ED visit. To be eligible for the measure, beneficiaries must have two or more conditions from a specified list. CMS proposes that follow-up services should include: an outpatient visit (with or without telehealth modifier); a behavioral health visit; a telephone visit; transitional care management services; case management visits; and complex care management.

Recommendation #9:

BCBSA does not support CMS' proposal to include this measure in the Stars program. The seven-day timeframe for follow-ups is too short for MA plans to take action, especially since

beneficiaries can go to out-of-network emergency departments, and notification of these visits can be delayed. We encourage CMS to remove or delay this measure and consider whether this measure is better suited as a hospital quality measure.

Rationale #9:

BCBSA supports CMS' goals of ensuring all beneficiaries receive appropriate follow-up care after an ED visit, and we recognize that this measure, in particular, will target the most vulnerable beneficiaries. However, the timeframe proposed in this measure is unworkable for plans, which may not even know that their members have been to an ED within 7 days of that visit. The fact that no prior authorization is required for ED visits means that insurers generally would become aware of ED visits only when claims are submitted. This submission - including the timing - is under the sole influence of facilities indicating varying degrees of claim submission lags e.g., plans may only receive claims well after that one week period has elapsed.

Furthermore, the fact that beneficiaries have equal access to out-of-network EDs as in-network EDs limits plans' abilities to partner with facilities to address this issue. In contrast to the Medication Reconciliation Post Discharge measure, or other Transitions of Care measures where plans are able to effectively manage the measures because the transition of care is done almost exclusively within the confines of a managed care network (i.e., plans working with the providers with whom they contract directly), this is not the case with ED visits. Beneficiaries have the ability to visit all EDs wherever they are located, limiting the influence of MAOs to work with those facilities to address this measure (e.g., if a member visits an out-of-network ED, their plan is unlikely to have had the ability to work with that facility to address this care). This would limit plans' ability to address this important beneficiary need.

Issue #10: <u>Measure Weights</u>

CMS proposes to increase the weight of patient experience/complaints and access measures from two to four. These measures include the patient experience of care measures collected through the CAHPS survey, Members Choosing to Leave the Plan, Appeals, Call Center, and Complaints Measure. CMS estimates that this change would increase overall payments to MA plans by $391.4 million in 2024 and $1.8 billion over 2024-2030. This would somewhat offset the reduction in payments expected from the proposed Tukey outlier deletion methodology.

Recommendation #10:

BCBSA recommends that CMS withdraw the proposal to increase the weights of these measures from two to four.

Rationale #10:

BCBSA shares CMS' goals of empowering patients and recognizes the importance of capturing members' experience, but we respectfully oppose CMS' proposal to increase the weight of patient experience and complaint measures to four, well above the weight of clinical outcome measures. We are concerned about an unprecedented shift away from the objective clinical Star Ratings measures. In particular, Plans raised the following concerns:

- **CAHPs:** As CMS knows, CAHPS measures reflect "member perception of their experience." Changing members' *perceptions* takes significant amount of time and lift by a health plan (this is backed by multiple studies on individual health behavior change). The agency's proposal to increase the weights of member experience measures from two to four represents a significant weight change in an incredibly short period of time. While health plans can mobilize quickly to enact changes with the goal of improving the member experience, it often takes members more than one year to *perceive* an improved experience.

  In addition, for the CAHPs survey, an inherent contract-level rating volatility exists mainly due to the 'last-minute' and 'point-in-time' nature of CAHPS survey questions relative to the contract-year. MA plans already struggle with this volatility and a measure-weight increase will further exacerbate this challenge. Increasing the weight of patient experience measures would make CAHPS a very significant portion of the overall Star Rating. If CMS insists that the weights must be increased, then we would recommend changes to the methodology to ease some of that volatility, allowing plans to be more effective in providing and improving beneficiaries' experiences in a fluid manner.

- **Members Choosing to Leave the Plan:** This area is extremely volatile and can be impacted by many factors beyond a member's experience with their health plan, including job loss/movement, changes in individual finances, provider changing plans, relocations and changes in member needs, among other issues.

  In addition, for this measure, plans are currently penalized even in instances where beneficiaries choose to stay with the same parent organization, but switch contracts that better suit their evolving needs. A weight increase in this measure will hurt MAO Star Ratings further despite continuously striving to offer innovations in their products. The presence of a new innovative product offering does not necessarily indicate the older products are inferior. Rather, new plans are added to accommodate the wide and evolving range of beneficiary needs, where one plan may be optimal for some, but not for others.

Any change regarding the weight of these measures should be preceded by a critical evaluation of the CAHPS and HOS surveys given concerns about decreasing response rates, and the accuracy and reliability of survey results. We encourage CMS to continue to base the Star Ratings on a comprehensive, objective, quality review system. While we appreciate the importance of ensuring patients have a positive experience, and appropriate access to care, we encourage a slower and more thoughtful transition to increasing the weight of patient experience and complaint measures.

Finally, we request clarification from CMS on the definition of the "Call Center." It is unclear if this encompasses the Star measure for prospective members or if this is in reference to the member Customer Service call center.

Issue #11: <u>Extreme and Uncontrollable Circumstances</u>

In previous rule-making, CMS finalized a policy, beginning with the 2022 Star Ratings, for contracts with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas that were affected by disasters that began in one year and were also affected by disasters that began in the previous year. These multiple year-affected contracts will receive the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure. Those policies also included a provision to address when an affected contract has missing data and specified that, for an affected contract with missing data in the current or previous year, the final measure rating comes from the current year unless an exemption described elsewhere in the regulation applies.

In this rule, CMS proposes to modify and add new text to clarify that missing data includes data where there is a data integrity issue. Under this proposal, when there is a data integrity issue in the current or previous year, the final measure rating comes from the current year.

Recommendation #11a:

BCBSA appreciates CMS' clarification regarding missing data, but continues to recommend that CMS further clarify and/or expand the definition of "extreme and uncontrollable circumstances" to consider scenarios beyond natural disasters, such as fires or floods or unique circumstances outside the current definitions used for this policy, such as epidemics. We request that CMS expand eligibility for the policy in the event of a state or local public health emergency, when the HHS Secretary declares a public health emergency, or in the event of a FEMA emergency or Fire Management Assistance Grant (FMAG) declaration for which public or individual assistance is available.

Rationale #11a:

We appreciate the changes CMS released in the Interim Final Rule related to COVID-19. In the long-term, we encourage CMS to analyze the impact of this pandemic and relief policies on Star Rating to develop an industrywide standard that appropriately measures quality during this type of pandemic and provides all plans with the opportunity to earn a quality bonus payment. It will also be important to understand how the relief policies may have negatively impacted some plans and make adjustments in future rule-making to ensure stability and fairness in the Star Ratings program.

Recommendation #11b:

We continue to recommend that CMS lower the threshold from 25 percent to 20 percent of members impacted by extreme and uncontrollable circumstances and holistically assess the impact of natural disasters on the quality performance of contracts.

Rationale #11b:

While we appreciate CMS' attention to extreme and uncontrollable circumstances that may impact MA and Part D contract performance on Star Rating measures and/or measure level data, we are concerned requiring contracts to have 25 percent of enrollees residing in a FEMA-designated individual assistance area at the time of the extreme and uncontrollable

circumstance is setting the threshold too high. Instead, we encourage CMS to lower the threshold when 20 percent of enrollees are impacted by uncontrollable circumstances, because at this lower percentage, Star Ratings are materially affected.

Recommendation #11c:

BCBSA encourages CMS to look at disasters in aggregate, rather than per incident. We also request clarification on how to calculate the relative percentages of enrollees impacted by the extreme and uncontrollable circumstances policy.

Rationale #11c:

Some BCBS Plans experienced multiple natural disasters in 2019. When the beneficiaries impacted by the disasters are analyzed in aggregate, greater than 25 percent of beneficiaries were impacted. However, the current policy requires that at least 25 percent of enrollees must reside in a FEMA-designated Individual Assistance area at the time of the incident. We encourage CMS to clarify its methodology to look at the aggregate impact of all natural disasters affecting a plan, rather than solely at each incident. Currently, it is unclear how the proposed policy impacts a contract with different members affected by different disasters at different time periods. For example, a group retiree contract with members across the country may not qualify for relief because members experience different disasters in a given year that do not individually meet the 25 percent threshold.

Recommendation #11d:

CMS should reevaluate the application of the extreme and uncontrollable circumstances policy and its applicability to contracts impacted across multiple years and to hold beneficiaries harmless through the improvement measures

Rationale #11d:

Currently, when a contract is impacted across three years, CMS will not grandfather in more than the prior year relief, rather than the prior two years of relief. Additionally, if the plan's Star Ratings are the same, CMS applies the more recent rating, even if the underlying measure scores are not the same. Moving forward, CMS should account for every year the contract experienced an extreme and uncontrollable circumstance. In addition, if a contract gets the same Star Rating in both years, CMS should take the higher of the two years' measure scores in order to ensure that plans and beneficiaries are truly held harmless in the event of a disaster.

Permitting a Second, "Preferred", Specialty Tier in Part D

Issue #1: <u>Permitting Plans to Establish Two Specialty Tiers</u>

Beginning in 2021, CMS proposes to allow Part D plan sponsors to establish up to two specialty tiers.

Recommendation #1:

BCBSA appreciates CMS' proposal to allow plan sponsors to establish up to two specialty tiers. However, as discussed in more detail below, we are concerned that the proposal to retain maximum coinsurance at current levels will lead to higher plan costs, which, in turn, will increase premiums for beneficiaries. BCBSA also notes that due to timing of formulary development and the bid process, even if this proposal is finalized, some plans may not be able to operationalize these changes for 2021.

Rationale #1:

BCBSA appreciates CMS' proposal to establish a second, preferred specialty tier and agrees with CMS that it could improve plans' ability to negotiate with manufacturers, leading to lower costs for beneficiaries. Recent research from actuarial firm Oliver Wyman found that the ability to offer a second specialty tier would increase payer pressure on manufacturers for price concessions, potentially leading to lower direct subsidy payments and savings to the federal government.[3]

Issue #2: Tiering Exceptions

Currently, Part D sponsors may exempt drugs on the specialty tier from their tiering exceptions process.

CMS proposes that if a plan sponsor offers two specialty tiers, they would be required to permit tiering exceptions from the higher cost-sharing specialty tier to the preferred specialty tier if tiering exceptions requirements are met (e.g. when an enrollee cannot take a therapeutic alternative).

Further, consistent with current policy, CMS proposes to specify that if a sponsor offers up to two specialty tiers, the Part D sponsor may design its exception process so that drugs on the specialty tier(s) are not eligible for a tiering exception to non-specialty tiers.

Recommendation #2:

BCBSA supports CMS' proposal to permit Part D plan sponsors to design their exception processes so that drugs on the specialty tier(s) are not eligible for a tiering exception to non-specialty tiers.

If CMS allows exceptions between the two specialty tiers, the agency must balance the potential for beneficiary cost-savings against potential confusion.

Rationale #2:

BCBSA agrees with CMS that maintaining the current policy of exempting specialty tier drugs from tiering exceptions will allow Part D sponsors to negotiate better rebates, ultimately leading to lower costs for beneficiaries and the federal government.

[3] Conway, Brooks and Armstrong, Steven. Evaluating the CMS Proposed Rule to Permit Two Specialty Tiers in Part D. Oliver Wyman. 2020. https://www.oliverwyman.com/content/dam/oliver-wyman/v2/publications/2020/March/OW_CMS_PartD_Specialty_Tiering_Proposal.pdf

Tiering exceptions within the two specialty tiers may be relatively rare and could leave beneficiaries facing complex comparison of different coinsurance rates for drugs with very different prices (as opposed to tiering exceptions in non-specialty tiers where, under many plans, a beneficiary simply sees a lower copayment rate).

Overall, we continue to believe that drug selection should be based on the pricing and positioning on the formulary to maintain transparency to consumers and allow for meaningful negotiations with manufacturers.

Issue #3: Maximum Allowable Cost-Sharing

CMS proposes to codify existing policy, such that the maximum allowable cost-sharing for a specialty tier (or in the case of a plan with two specialty tiers, the higher cost-sharing specialty tier) is 25 percent for plans with the full deductible under the standard benefit, 33 percent for plans with no deductible, and a sliding scale between 25 and 33 percent for plans with a deductible of greater than $0 and less than the defined standard.

CMS also proposes that a plans' second specialty tier (if applicable) must have a maximum allowable cost-sharing that is less than the maximum allowable cost-sharing of the higher cost-sharing specialty tier. However, CMS is not proposing to require a minimum difference between the cost-sharing levels of the two specialty tiers.

Recommendation #3:

BCBSA recommends CMS give Part D plan sponsors more flexibility to set appropriate coinsurance for the two specialty tiers, including the ability to set the non-preferred tier cost-sharing above 25/33 percent.

We support CMS' decision not to propose a minimum difference between the cost-sharing levels of the two specialty tiers and recommend CMS continue to allow plans this flexibility in designing their benefits.

Rationale #3:

As with many Part D policies, we recognize CMS must balance concerns over actuarial equivalence and discriminatory benefit designs in order to strike an appropriate balance between plan flexibility and beneficiary access. However, we are concerned that a reduction in cost-sharing for the preferred specialty tier without the ability to increase cost-sharing for the non-preferred, absent offsetting increases in rebates, could lead to increased costs in premiums or non-specialty coinsurance. We note that the Medicare Payment Advisory Commission (MedPAC) shares these concerns and also recommends CMS provide additional flexibility to set appropriate coinsurance.[4] BCBSA agrees with CMS that ultimately the flexibility to offer two specialty tiers will strengthen the negotiating plan and Pharmacy Benefit Manager (PBM) negotiations with manufacturers in order to drive down prices, but we believe flexibility in setting cost-sharing is critical to the success of this policy.

[4] http://medpac.gov/docs/default-source/comment-letters/04032020_ma_partd_comment_v2_sec.pdf?sfvrsn=0

Issue #4: Tier Composition

CMS does not propose to prescribe which drugs (e.g. generics and biosimilars versus brands and biologics) should be placed on either specialty tier, but notes that placement will be subject to the formulary review and approval process.

Recommendation #4:

BCBSA supports CMS' proposal to maintain flexibility for plans to decide which specialty tier to place drugs on, without prescribing one tier for generics and biosimilars only.

Rationale #4:

Providing plans with flexibility to determine which drugs should be placed on either tier will maximize plans' leverage in negotiations with drug manufacturers and ensure beneficiaries have access to the lowest cost drugs. As we have noted in our comments on the 2021 Advance Notice in response to a potential Star measure related to biosimilar utilization, plans make formulary decisions based on the net cost of a product, which is often, but not always, the generic or biosimilar. Sometimes, when rebates and other price concessions are factored in, the branded biologic may have a net cost to the beneficiary that is lower than the biosimilar drug. In addition, as more pharmaceutical companies pursue an authorized generic strategy, generic drugs may be priced more like brand drugs. Any restrictions on the placement of drugs on the two specialty tiers could have unintended consequences of increasing, rather than decreasing, beneficiary costs.

Issue #5: Codifying the Specialty-Tier Cost Threshold Methodology

CMS proposes to codify, with some modifications, the methodology for determining the specialty cost threshold. Currently, the methodology identifies the top 1 percent of 30-day equivalent PDEs, based on negotiated price. Since 2017, the specialty-tier threshold has been $670.

CMS proposes to codify this methodology, but use the 30-day equivalent ingredient cost instead of negotiated prices. They note that the ingredient cost has fewer variables than the negotiated price and, therefore, represents the most transparent, least complex and most predictable of all the components of negotiated price on which to base threshold determination. CMS does not expect this change to significantly affect the number of Part D drugs meeting the threshold.

Additionally, to maintain stability year-to-year, CMS proposes to undertake an analysis yearly and increase the specialty-tier threshold for a plan year only if CMS determines that no less than a 10 percent increase in the threshold, before rounding to the nearest $10 increment, is needed to reestablish the specialty-tier cost threshold that represents the top 1 percent of 30-day equivalent ingredient costs.

Using the methodology in this Proposed Rule and 2019 PDE data to date, CMS estimates that the specialty-tier threshold for contract year 2021 would be $780 as a 30-day equivalent ingredient cost.

Recommendation #5:

BCBSA supports this proposal.

Rationale #5:

BCBSA agrees with CMS that the ingredient cost is a more transparent and predictable factor than negotiated price.

Beneficiary Real Time Benefit Tool (RTBT)

Issue #1: Requirement to Implement a Beneficiary RTBT

CMS proposes to require Part D sponsors to implement a beneficiary RTBT that would allow enrollees to view accurate, timely and clinically appropriate, patient-specific, real-time formulary and benefit information, effective Jan. 1, 2022.

Recommendation #1:

BCBSA supports CMS' goals of providing out-of-pocket (OOP) drug cost and coverage information to beneficiaries. We recommend CMS delay this requirement by at least one year, to no earlier than Jan. 1, 2023.

Rationale #1:

A delay in effective date will allow plans to incorporate lessons learned from implementation of the prescriber RTBT and provide additional time for the development, testing and wider implementation of an industry standard. Further, CMS should consider lessons learned from the implementation of the changes to the Medicare Plan Finder in terms of the types of information on drug costs that beneficiaries found most useful when selecting a plan, and whether any of those findings are applicable to a beneficiary RTBT.

Issue #2: RTBT Required Elements

The RTBT would be required to include:

- Real-time values for the patient's cost-sharing
- Clinically appropriate formulary alternatives (where appropriate)
- Formulary status of clinically appropriate formulary alternatives, including any utilization management requirements

Recommendation #2:

BCBSA has serious concerns with the requirement for the beneficiary RTBT to include clinically appropriate formulary substitutions and recommends CMS eliminate this requirement.

Rationale #2:

Plans' experience in implementing a prescriber RTBT has identified challenges in providing reliable information on therapeutic alternatives. Specifically, because the categories in the U.S. Pharmacopeia (USP) and other classification systems are not sufficiently granular, the "potential

substitute" suggestions may be meaningless. For example, if a plan uses the USP classification system, drugs to treat diabetes fall under one therapeutic category – Blood Glucose Regulators – which have three therapeutic classes: Antidiabetic agents, Insulins, and Glycemic agents. Within a class, there may be drugs that do not work by the same mechanism of action and are not therapeutically substitutable (e.g. Trulicity® and glipizide within the "Antidiabetic agents" class). It would be misleading to a beneficiary to recommend glipizide as an alternative to Trulicity® despite both agents being used to treat diabetes.

We believe there is value in prescribers having reliable information on therapeutic alternatives given the complexity of identifying appropriate pharmaceutical treatment options. However, this information would not be meaningful for beneficiaries in conversations with their providers, and is more likely to lead to confusion or frustration than help beneficiaries truly identify lower-cost therapeutic alternatives.

Issue #3: Information Not Required

CMS is not proposing to require that beneficiary RTBTs include pharmacy-specific information.

CMS encourages plans to show each drug's negotiated price in addition to the out-of-pocket costs, but does not require this. If the beneficiary RTBT does not show the negotiated price, CMS encourages plans to provide additional cost data comparing the beneficiary and plan cost comparison for each drug and its alternatives.

Recommendation #3:

BCBSA agrees with CMS' proposal not to require that beneficiary RTBTs include pharmacy-specific information or negotiated prices.

Rationale #3:

Providing pharmacy-specific information would be unduly complex. We also agree with CMS that consumers are generally most interested in knowing what they actually need to pay, and terms like "negotiated price" could be unnecessarily confusing.

Issue #4: Rewards and Incentives

CMS proposes to allow plans to offer rewards and incentive (RI) to their enrollees who use the tool. For the purposes of permitted RI, CMS proposes to define "use" as logging into either the portal or application or calling the plan's call center to ask for this information, without regard to whether the enrollee engages in a discussion with his or her prescriber or obtains or switches to any medication in response to such use.

Recommendation #4:

BCBSA supports this proposal.

Rationale #4:

We appreciate the flexibility provided to plans in offering rewards and incentives.

Establishing Pharmacy Performance Measure Reporting Requirements

Issue #1: Disclosure of Pharmacy Performance Measures

CMS proposes to establish a requirement for Part D sponsors to disclose to CMS the pharmacy performance measures they use to evaluate pharmacy performance, as established in their network pharmacy agreement.

CMS believes that this information will allow CMS to better understand the extent to which measures are applied to different pharmacy types, explain pharmacy performance problems, and bring transparency to the process and confirm or dispel the idea that many of the measures may not provide appropriate metrics across all types of pharmacies.

CMS encourages the industry to work together on developing a set of pharmacy performance measures through a consensus process and Part D sponsors to adopt such measures to ensure standardization, transparency and fairness.

Recommendation #1:

BCBSA supports CMS efforts and recognizes the potential value of increased transparency around pharmacy performance measures, but note this should be balanced with the protection of competitive information and acknowledgement of diverse plan, market and pharmacy characteristics that may make standardization challenging.

Rationale #1:

BCBSA appreciates CMS' efforts to ensure beneficiaries have access to high-quality pharmacies that incentivize lower costs and improve health outcomes, and some BCBS Plans are involved in efforts to develop consensus-based pharmacy performance measures through the Pharmacy Quality Alliance (PQA).

Pharmacies play an important role in the health of beneficiaries – especially for those with chronic conditions – and plans use pharmacy performance measures to ensure they can provide high-quality pharmacy networks to their beneficiaries.

We appreciate the role CMS plays in creating alignment between the Part D sponsors, pharmacy retail networks, and medical providers to support better health outcomes and cost reductions. Furthermore, we understand the need for greater consensus among Part D plan sponsors regarding measurement as consistent public reporting supports transparency and fairness among all pharmacies and PBMs. We are encouraged that CMS proposes to continue to rely on the ongoing process being undertaken by PQA and others, prior to issuing any additional data collection guidance. This will help ensure a robust collection of industry accepted, tested, and validated measures.

Medical Loss Ratio (MLR)

Issue #1: Regulatory Changes to Incurred Claims

Under current regulations, the "incurred claims" component of the MLR numerator includes direct claims that the MA organization pays to providers (including under capitation contracts) for covered services (defined as basic benefits, mandatory supplemental benefits, and optional supplemental benefits) that are provided to all enrollees under the contract.

CMS proposes to amend the regulation to remove the specification that incurred claims are payments to providers for covered services. CMS also proposes to remove the specification that incurred claims include payments under capitation contracts with physicians. Finally, CMS proposes to replace the phrase "direct claims," which customarily refers to billing invoices providers submit to payers for reimbursement, with the general term "amounts."

Recommendation #1:

BCBSA supports this proposal. Many BCBS Plans offer supplemental benefits for the chronically ill (SSBCI) that are not delivered by medical providers. Therefore, we appreciate CMS' acknowledgement that SSBCI should be included in the numerator as expenses plans incur to deliver important new flexible supplemental benefits that help address social drivers of health. In addition, given the COVID-19 public health emergency, we encourage CMS to make the same accommodation for costs related to combating the outbreak. It's important that all resources are brought to bear to prevent vulnerable MA beneficiaries from contracting the virus.

Rationale #1:

BCBSA agrees with CMS' assertion that this change will reduce confusion over where spending on supplemental benefits that meet the "primarily health related standard" as well as on "non-primarily health related" supplemental benefits should be counted within the MLR numerator.

Dismissal and Withdrawal of Medicare Part C Organization Determination and Reconsideration and Part D Coverage Determination and Redetermination Requests

Issue #1: Proposed Requirements

Based on inquires, CMS is proposing rules that would apply for withdrawal and dismissal of Parts C organization determinations and reconsiderations and Part D coverage determinations and redeterminations. Specifically, CMS is proposing to permit a plan to dismiss requests when: (1) the individual or entity making the request is not permitted to make the request; (2) the plan determines that the individual or entity making the request failed to make a valid request; (3) the enrollee dies while the request is pending and the enrollee's spouse or estate has no remaining financial interest in the case and no other individual or entity with a financial interest in the case wishes to pursue the request; or (4) the individual or entity who requested the review submits a timely written request for withdrawal of their request with the plan. CMS is also proposing an avenue to appeal a plan dismissal decision through an IRE.

Recommendation #1:

BCBSA does not believe the proposed definitions provide sufficient clarity around these issues. We are concerned that these definitions address situations where the request for

determination/redetermination was invalid to begin with. In these cases, CMS should consider a new, separate classification that would not imply the request was initially valid.

CMS is proposing to permit a plan to dismiss a request for the initial plan-level coverage determination when the individual or entity who requested the review submits a timely written request for withdrawal. Currently, plans use the withdrawal process, which is a different decision type than a dismissal. We recommend CMS follow the withdrawal process in this scenario, not the dismissal process. In addition, when a beneficiary dies during the request process, we recommend CMS follow the withdrawal process rather than the dismissal process.

In addition, while currently CMS allows parties to withdraw preservice and appeal requests verbally or in writing, this proposal would only allow withdrawals in writing. BCBSA recommends continuing to allow verbal withdrawals because they are more efficient and faster for members, representatives and plans and furthers CMS' "People over Paperwork" initiative.

Rationale #1:

BCBSA does not believe the proposed definitions in this section should address requests that were invalid to begin with.

Furthermore, the agency also seeks comment on whether the proposed rules would create inconsistencies with any state-specific Medicaid procedures pertaining to dismissals or withdrawals. Medicare determination and coverage processes may be different than Medicaid, therefore, if medical care or services are not covered by Medicare, but are covered by Medicaid, withdrawing the appeal is an effective way to minimize the administrative burden of appeals.

We encourage CMS to provide more clarity around the circumstances under which a dismissal process is followed versus a withdraw process and the different expectations associated with these two processes

Section VI: Codifying Existing Part C and D Program Policy

Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services

Issue #1: Codifying MOOP Limits

All MA plans (including Employer Group Waiver Plans and SNPs) are required to establish limits on enrollee out-of-pocket cost-sharing for Parts A&B services that do not exceed the annual limits established by CMS.

CMS proposes to codify the current practice of setting the MOOP limits based on a percentile of projected Medicare FFS beneficiary out-of-pocket spending. In addition, beginning in 2022, CMS proposes a new “intermediate” MOOP limit, so that there would be up to three MOOP levels:

- Lower MOOP limit – Any dollar limit that is between zero dollars and up to and including the lower MOOP limit

- Intermediate MOOP limit – Any dollar limit that is above the lower MOOP limit and at or below the intermediate MOOP limit
- Mandatory MOOP limit – Any dollar limit above the intermediate MOOP and at or below the mandatory MOOP limit

The MOOP limit would be rounded to the nearest whole $50 increment.

Recommendation #1:

BCBSA supports the establishment of a third MOOP or voluntary intermediate MOOP limit.

Rationale #1:

The introduction of an intermediate MOOP limit will provide plans with the option of offering more flexible benefit designs to deliver more high-value plan options to beneficiaries. This flexibility is increasingly important as CMS has allowed sponsors to develop specialized plans that are better tailored to beneficiaries' chronic conditions.

Issue #2: ESRD Cost Transition

CMS proposes a multi-year transition from their current practice of excluding costs of beneficiaries with ESRD to including all related costs in the FFS data that is used to set MOOP.

The ESRD cost differential is defined as the difference between projected OOP costs for beneficiaries using Medicare FFS data excluding the costs incurred by beneficiaries with ESRD diagnoses for contract year 2021 (95th percentile = $7,175; 85th percentile = $3,360), and the projected OOP costs for all beneficiaries using Medicare FFS data (including costs incurred by beneficiaries with ESRD)

- For 2022 – CMS factors in 60 percent of the ESRD cost differential
- For 2023 or the next year of the ESRD cost transition – CMS factors in 80 percent of the ESRD cost differential
- For 2024 or the final year of the ESRD cost transition and beyond – CMS uses complete Medicare FFS data that includes the OOP costs incurred by beneficiaries with and without diagnoses of ESRD

Recommendation #2:

BCBSA supports the multi-year transition for including the costs of beneficiaries with ESRD in setting the maximum allowable MOOP. In our comment letter on the 2021 Part C Benefits Review and Evaluation memorandum, BCBSA recommended an increase of $3 PMPM to $39 PMPM for the TBC change threshold for 2021. We recommend that CMS consider increases to TBC change thresholds for 2022 and beyond to accommodate the increase in MOOPs.

Rationale #2:

The maximum allowable MOOP increase will provide flexibility to plans to adjust to the costs of covering ESRD beneficiaries. However, since the ESRD payment rates are inadequate, other

MA beneficiaries will be subsidizing the additional cost due to ESRD beneficiaries through additional cost-sharing or increased premiums. The transition schedule will allow for a more gradual implementation of higher MOOPs and provide some limits on the impacts to beneficiaries.

Plan Crosswalks for MA Plans and Cost Plans

Issue #1: Codifying Existing Policy

CMS proposes to codify the current process and conditions under which MA organizations and 1876 cost plans can transfer their enrollees into the same plan or plan type from year to year when no other election has been made (known as a "plan crosswalk").

CMS also codifies the requirements that protect a beneficiary's right to choose a plan and specifies when a MA organization or cost plans can transfer their enrollees to other plans of a different type offered by the same MA organization or cost plan (referred to as a "crosswalk exception).

CMS is proposing to codify existing policy regarding plan crosswalks, implement rules to protect a beneficiary's right to choose a plan, and describe allowable circumstances under which MA organizations may transfer beneficiaries from one of its plans into another, or a cost contract may transfer beneficiaries from one of its plans into another.

Recommendation/Rationale #1:

BCSBA supports CMS' proposal to codify crosswalk and crosswalk exception processes and conditions. However, we request CMS provide clarification as to whether two different ANOCs would be required in situations in which a plan crosswalks beneficiaries into two different plans.

MA Change of Ownership Limited to the Medicare Book of Business

Issue #1: Change of Ownership

Under existing practice and contracting regulations, when an MA organization changes ownership, the execution of a novation agreement is required for a transfer of ownership to a new entity. CMS states that it has been its long-standing practice to only permit such MA contract novation for transfers involving the organization's entire line of MA business.

CMS proposes to codify explicitly that CMS will not recognize or allow a sale or transfer that consists solely of the sale of transfer of individual beneficiaries, groups of beneficiaries enrolled in a plan benefit package, or one MA contract if the organization holds more than one MA contract.

CMS will not recognize the sale or transfer of just one MA contract because it states that it could have a negative effect on beneficiary election rights.

Recommendation #1:

BCBSA recognizes that this is a long-standing policy, but notes that some BCBS Plans believe this rule is overly restrictive and limits an MAO's ability to ensure a smooth transition for enrollees if the plan decides to exit a contract.

Rationale #1:

CMS' proposal would remove a viable option for a plan to transfer a contract with minimal disruption to enrollees, especially because the enrollee would move within the contract, and, ideally, the move would be invisible to the enrollee. This limitation would require a plan to retain a contract that is not working and force them to exit the MA market entirely in order to close an underperforming contract.

MA and Cost Plan Network Adequacy

Issue #1: Codifying Existing Network Adequacy Standards

CMS proposes to codify existing network adequacy standards to provide MA organizations with a greater understanding of how CMS measures and assesses network adequacy.

CMS proposes to codify the list of provider and facility specialty types subject to network adequacy reviews, county type designations and ratios, maximum time and distance standards, and minimum number requirements and exceptions.

Recommendation #1:

BCBSA supports CMS' proposed flexibilities to the MA network adequacy requirements, as described in detail below.

Rationale #1:

CMS' proposed approach reflects the challenges associated with establishing a network in some geographies and would improve beneficiaries' access to plan options in rural areas and access to telehealth innovations to close care gaps.

Issue #2: New Network Adequacy Provisions

While the majority of the provisions proposed here would codify existing guidance and current practices, CMS proposes several new provisions, primarily intended to increase access to MA in rural areas.

- Percentage of Beneficiaries Residing Within Maximum Time and Distance Standards. CMS has historically required that, in order to meet the time and distance standards, at least 90 percent of beneficiaries must have access to at least one provider and facility of each specialty type within the county. CMS proposes to reduce this percentage to 85 percent in Micro, Rural and Counties with Extreme Access Considerations (CEAC) counties.
- Bonus for Coverage of Telehealth Services: CMS proposes to give an MA plan a 10 percentage point credit towards the percentage of beneficiaries residing within the applicable time and distance standards for certain provider specialty types when the plan contracts with

telehealth providers. This telehealth credit would be applied only to specific provider specialty types: dermatology, psychiatry, neurology, otolaryngology and cardiology.

- Bonus for Beneficiaries Affected by State Certificate of Need (CON) Laws: CMS proposes to give an MA plan a 10 percentage point credit towards the percentage of beneficiaries residing within applicable time and distance standards for affected provider and facility types in states that have CON laws, or other state imposed competitive restrictions, that limit the number of providers or facilities in a county or state.

Recommendation #2:

Overall, BCBSA believes that a revision of the health service deliver (HSD) tables are needed and network adequacy should be based more on type of care than numeric tables. BCBSA supports CMS' new proposals to provide flexibility in network adequacy requirements, especially in rural areas. Regarding telehealth, we continue to encourage CMS to allow diagnoses and other encounter data from telehealth services to be used for the purposes of risk adjustment, especially as we see how quickly non-emergent care can be moved to the remote space such as what we are seeing during the COVID-19 crisis. BCSBA recommends that CMS expand the proposed list of provider specialty types eligible for the telehealth network adequacy credit to include other behavioral health specialties (in addition to psychiatry), internal medicine, pediatrics, family practice, obstetrics and gynecology, and endocrinology.

We understand the types of eligible providers have been expanded during the current national emergency, and we request CMS consider such an expansion of eligible providers after the end of the current national emergency.

Rationale #2:

This new flexibility acknowledges the challenges with establishing a network in some geographies and would improve beneficiaries' access to plan options and access to telehealth innovations to close care gaps. Given the challenges associated with the COVID-19 outbreak, we appreciate that CMS has proposed flexibilities when plans contract with telehealth providers.

General practitioners are the main provider groups helping to triage and reduce unnecessary ED utilization by providing virtual visits to their patients. In addition, many Medicare beneficiaries frequently see endocrinologists due to diabetes and other complications. Expanding telehealth credits to these provider groups can improve access to care for Medicare beneficiaries and help them better manage their chronic conditions.

Issue #3: Options to Improve Access to Dialysis Services

CMS is also considering options to improve access to dialysis services, and solicits comments on:

> (1) Whether outpatient dialysis should be removed from the list of facility types subject to time and distance standards.
>
> (2) Allowing plans to attest to providing medically necessary dialysis services in its contract application (as is current practice for DME, home health and transplant

services) instead of requiring time and distance standards for providers of these services be met.

(3) Allowing exceptions to time and distance standards if a plan is covering home dialysis for all enrollees who need these services.

(4) Customizing time and distance standards for dialysis facilities.

Recommendation #3: Given the expected increase in ESRD beneficiary enrollment in MA, BCBSA recommends removal of outpatient dialysis from the list of facility types for which MA plans must meet time and distance standards and allowing plans to attest to providing medically necessary dialysis services in contract applications.

Rationale #3:

These flexibilities will encourage competition, bring down high reimbursement costs, and drive patient-centered innovation in dialysis treatment. We understand that these facilities and the services they provide are critical to the members that need them, but we believe that removing these facilities from the necessary time and distance standards is one way to address their skewed market power, as is allowing plans to attest to providing the services in their contract applications.

Supplemental Benefit Requirements

Issue #1: Definition of Supplemental Benefits

CMS proposes to codify existing guidance related to supplemental benefits, its recent reinterpretation of benefits that are primarily health-related and its recent reinterpretation of uniformity requirements.

Recommendation #1:

BCBSA agrees with these provisions and recommends they be adopted as proposed. We request that CMS allow geographic flexibility to offer supplemental benefits at a county level within a multi-county service area plan.

Rationale #1:

Many of the organizations that a health plan would partner with to offer supplemental benefits are community based and do not have capacity to provide benefits to a multi-county service area. This means that plans have to partner with larger, national organizations rather than the community organizations that may be better suited to address the needs of the beneficiaries in the region and better able to target interventions.

Issue #2: Uniformity Flexibility

CMS also proposes to codify in §422.100(d)(2)(ii) its reinterpretation of uniformity flexibility that permits MA plans to meet uniformity flexibility requirements by providing supplemental benefits

(such as specific reductions in cost-sharing or additional services or items) that are tied to disease state or health status in a manner that ensures that similarly situated individuals are treated uniformly. The Proposed Rule would state that and would require that there be a nexus between the health status or disease state and the specific benefit package designed for enrollees meeting that health status or disease state.

Recommendation #2:

BCBSA supports CMS' reinterpretation of uniform flexibility and codifying it in regulation.

Rationale #2:

CMS' reinterpretation of uniform flexibility provides plans with necessary tools to design benefits that best meet the needs of their beneficiaries.

Rewards and Incentives Program Regulations for Part C Enrollees

Issue #1: Proposed Changes to Rewards and Incentives Programs

CMS proposes several changes to Reward and Incentive (R&I) programs in response to many questions the agency has received over the years. First, CMS proposes rewards must be provided to an enrollee in the same contract year as the rewardable activity. Second, CMS proposes to limit mid-year R&I program changes.

Recommendation #1a:

BCBSA does not believe CMS should finalize its proposal to cap utilization of rewards within the contract year.

Rationale #1a:

BCBSA appreciates CMS' emphasis on MA beneficiary experience with R&I programs by ensuring plans provide reward item to enrollees in the same contract year. However, there are concerns with regards to instances where members complete rewardable activities towards the end of a contract year. Delay in plan notification and general end-of-year claims data lag could create operational complications for plan R&I programs to be entirely compliant.

Recommendation #1b:

BCBSA does not believe CMS should finalize its proposal to limit mid-year R&I program changes. CMS should continue to allow these changes so that programs can cater to evolving member needs throughout a program year.

Recommendation #1b:

We also recommend CMS continue mid-year changes to MA plan R&I programs to allow MA plans to drive quality in clinical outcomes and ensure care and motivation for beneficiaries to get appropriate preventative screenings.

Rationale #1b:

Disallowing changes during the contract year could limit plans' ability to provide adequate incentives for members to get preventative screenings and manage certain medical conditions. Furthermore, taking away flexibility of changing R&I programs within a contract year would also limit plans' ability to offer rewards that may help members respond in a timely manner to activities promoting improved heath in response to public health crises e.g., COVID-19.

Requirements for Medicare Communications and Marketing

Issue #1: Codifying Guidance

CMS is proposing to codify and further define the sub-regulatory guidance in the Medicare Communications & Marketing Guidelines (MCMG). The reorganization of existing regulations is not intended to change the policies contained therein.

CMS notes that the MCMG prohibits plans from sending unsolicited materials that call out the opportunity afforded by the OEP, using mailing lists or other anecdotal information to target individuals who made enrollment requests during the annual coordinated enrollment period or leveraging agent/broker activities that target the OEP as a way to make further sales.

Recommendation #1:

BCBSA has the following recommendations and questions regarding the proposals at 42 C.F.R. § 422:

- 422.2262(b)(1)(iv). CMS should clarify what it means by "use of a previous post?" It is unclear what types of social media ads would be considered product endorsements or testimonials.
- 422.2262(c)(1)(i). CMS should clarify whether the MCMG or this regulation would control? Here, CMS includes the requirement to add the hours of operation to any customer service number, but in the MCMG for 2019, CMS removed this requirement to include the hours of operation.
- 422.2266(b). The sentence should be revised to say ". . . including but not limited to," rather than ". . . including, are not limited to . . .".
- 422.2267(e). This sentence should be revised to say ". . . must be provided to current and/or prospective enrollees," rather than ". . . must be provided to current and or perspective enrollees . . ."
- 422.2267(e)(30)(ii).
    - CMS should consider including, as an exception, envelopes, ID cards and call scripts, as allowed per the MCMG.
    - CMS should consider including these exceptions for all disclaimers, rather than only for the Federal Contracting Statement, as allowed per the MCMG.

BCBSA has the following recommendations and questions regarding the proposals at 42 C.F.R. § 423:

- 423.2262(b)(1)(iv). CMS should clarify what it means by "use of a previous post?" It is unclear what types of social media ads would be considered product endorsements or testimonials.

- 423.2262(c)(1)(i). CMS should clarify whether the MCMG or this regulation would control? Here, CMS includes the requirement to add the hours of operation to any customer service number, but in the MCMG for 2019, CMS removed this requirement to include the hours of operation.
- 423.2267(e). This sentence should be revised to say ". . . must be provided to current and/or prospective enrollees," rather than ". . . must be provided to current and or perspective enrollees . . .".
- 423.2267(e)(32)(ii).
    - CMS should consider including, as an exception, envelopes, ID cards and call scripts, as allowed per the MCMG.
    - CMS should consider including these exceptions for all disclaimers, rather than only for the Federal Contracting Statement, as allowed per the MCMG.

Rationale #1:

These recommended edits and clarifications will help ensure BCBS plans can remain compliant with all CMS communications and marketing requirements.

Past Performance

Issue #1: Codifying Guidance

CMS proposes to adopt an updated past performance methodology that uses a three-pronged test as basis for denying an MA or Part D application: (1) the imposition of civil money penalties (CMPs) or intermediate sanctions; (2) failure to achieve at least a three-star Part C or Part D summary rating in the set of Star Ratings CMS issued during the 12-month review period; and (3) failure to maintain a fiscally sound operation.

Recommendation #1:

BCBSA appreciates CMS' efforts to clarify and simplify the past performance methodology; however, we are concerned that this proposal would be overly restrictive in its application. We encourage CMS to consider the factors in combination, as well as the size of the identified contract. Additionally, we believe CMS should use at least two years of Star Ratings performance to allow for improvement efforts to be measured and reported. Finally, given the narrow time frame CMS proposes for review, BCBSA requests that plans should be provided a remediation opportunity and an appeals process should the plan quickly address the identified issues.

Rationale #1:

BCBSA understands the need to restrict the ability of poor performing plans to expand, particularly for plans with a history of poor performance under the current past performance standards. However, we do not believe the proposed methodology sufficiently takes into account the nature and context of performance issues over a sufficient period of time and, thus, would inadvertently limit new high-quality plan offerings.

With low Star Ratings, for example, if a large organization acquires a struggling MA plan with the goals of improving its performance; it would be reasonable for that organization to focus on

improving the contract in that geography, but unduly restrictive to stop that organization from applying for any new contracts across the country. To address this issue, we would ask CMS to consider at least two years (and preferably three years) of Star Ratings performance to allow for improvement efforts to be measured and reported.

CMS notes that the agency intends to exclude intermediate sanctions imposed on D-SNPs (2021 through 2025) as a basis for denying a MA or Part D application. We appreciate CMS' acknowledgement that given the new requirements of the BBA 2018, more intermediate sanctions may not be tied to overall contract performance.

Call Center Requirements

Issue #1: General

MAOs and Part D sponsors are required to have in place a toll-free customer service call center. CMS proposes changes to existing call center requirements to add specificity.

Recommendation #1:

Our interpretation of the proposed requirements for call center hours is that CMS is putting into regulation the existing requirements that exist in section 80.2 of the current Medicare Communications and Marketing Guidelines. CMS should clearly reflect that this is existing policy in the final regulation.

Rationale #1:

BCBSA appreciates CMS' efforts to provide explicit performance standards for MA and Part D customer service call centers and ensure protections for beneficiaries.

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Docket: CMS-2020-0010
Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2021 (CMS-4190-P)

Comment On: CMS-2020-0010-0002
Medicare and Medicaid Programs: Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly

Document: CMS-2020-0010-0481
Comment on CMS-2020-0010-0002

Submitter Information

Name: Amanda Hurley
Organization: Anthem

General Comment

Dear Administrator Verma:

Anthem, Inc. ("Anthem") appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') "Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly," proposed rule.

I have attached Anthem's comment letter. As a committed participant in the Medicare Advantage and Part D programs, we look forward to continuing to work with CMS on these important issues. Should you have any questions or wish to discuss our comments further, please contact us.

Attachments

2020.04.06_Anthem Comments on MA-PD Regulation for 2021 and 2022

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Submitted via Federal e-Rulemaking Portal: https://www.regulations.gov

April 6, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4190-P
P.O. Box 8013
Baltimore, MD 21244–8013

Re: CMS-4190-P

Dear Administrator Verma:

Anthem, Inc. ("Anthem") appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') "Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly," proposed rule, published on February 5, 2020.

Anthem shares CMS' commitment to preserve and strengthen the Medicare Advantage (MA) and Part D programs. We deliver high quality services to improve beneficiaries' health and well-being by working with CMS to offer affordable and patient-centered coverage options. We commend CMS for proposing a number of streamlining and clarifying guidance that support these goals. We are also concerned with certain CMS proposals that would negatively impact beneficiaries and the operation of the MA and Part D programs. Below are Anthem's recommendations on key issues at a high level followed by our detailed comments and recommendations.

Executive Summary

1. Provide Clear and Timely Guidance during Public Health Emergency

The health and well-being of our beneficiaries is of the utmost importance. We are closely monitoring the 2019 Novel Coronavirus (COVID-19) pandemic developments and instituting policies to ensure our beneficiaries continue to have access to high quality, affordable healthcare during this rapidly evolving public health emergency. We have taken steps to eliminate the burden of additional costs for our beneficiaries by providing coverage of the coronavirus screening test and treatment at no out-of-pocket-cost, and ensuring prior authorization is not required for diagnostic services related to COVID-19 testing. We have also relaxed early prescription refill limits for beneficiaries, and we will waive any cost-sharing for telehealth visits, including visits for mental health providers, for 90-days to help prevent the virus from spreading further.

We recognize the Administration is actively working to respond to COVID-19 by recently releasing an interim final rule, and issuing guidance to inform Medicare Advantage Organizations (MAOs) and Part D Sponsors of obligations and flexibilities. As plans prepare coverage offerings for 2021, we encourage CMS to consider the impact of COVID-19 on the strength of the MA program.

Clear and timely guidance is needed on how CMS will account for the impact of COVID-19 on plan bids, benchmarks, potential mid-year rate adjustments, risk adjustment, and Star Ratings to ensure the availability of adequate resources to care for all beneficiaries, including those vulnerable to this infectious disease. As plans develop benefit packages for 2021 we encourage CMS to take the following actions to ensure the stability of the MA and Part D programs:

- Bid timeline: Provide clear guidance on COVID-19 and the impacts of the virus on rates, bids, and benchmarks. Given the already tight timeframe, we do not support extending the bid timeline, and instead recommend CMS relax documentation requirements for bid development such as waiving the requirement to file End Stage Renal Disease (ESRD) bids, providing plans with assumptions around Fee-for-Service (FFS) Medicare cost trends, and waiving desk review if a plan freezes 2021 benefits at 2020 levels.

- Risk adjustment: We recommend CMS allow telehealth visits as valid encounters for the documentation of diagnosis codes used for the calculation of MA risk scores during the public health emergency. Such guidance is consistent with CMS' decision that face-to-face visits can be furnished via telehealth in FFS for payment purposes due to COVID-19 in the interim final rule, and the recommendation that older Americans remain home and avoid seeking any non-urgent healthcare. We also ask CMS to leverage previous data that supports the diagnosis of a chronic condition that cannot be cured to avoid burdening providers with requests for medical records. In addition, we would recommend the 2020 final payment period be held open until January 2022, instead of the typical timeframe of January 2021 to reduce the burden on providers working to stop the spread of this virus.

- Program flexibilities: We request additional guidance and flexibilities on drug quantity limits that may be effective in treating COVID-19 to avoid shortages. CMS should also issue guidance giving plans the option to exceed supplemental benefit limits to provide additional food to beneficiaries, expand access to currently approved transportation assistance if public transportation has been suspended, and provide additional over-the-counter benefits for health related items beneficiaries may need to shelter in place such as blood pressure cuffs. In addition, we encourage CMS to expand the use of home health beyond the FFS benefit to help prevent beneficiaries from leaving their homes and potentially spreading the virus further.

- Enforcement Standards: We appreciate CMS' guidance delaying auditing and monitoring activities. We encourage the agency to continue clarifying how such activities will be impacted moving forward to enable plans to focus resources on the COVID-19 response.

2. Modify Star Ratings in 2021 and 2022 Beyond Extreme and Uncontrollable Circumstances Policies to Accurately Account for Impact of COVID-19

Anthem is committed to providing beneficiaries with access to high quality care and support services during the COVID-19 pandemic. As CMS and states have quickly adapted to provide care during the public health emergency, we encourage the agency to make necessary changes to the 2021 and 2022

Star Ratings to enable plans to fully shift their focus and attention to improving beneficiary care under these unique circumstances, and redeploy trusted resources to help members remain safely in their homes to help avoid the further spread of the virus.

While we appreciate CMS' proposals in the interim final rule to modify the calculation of the 2021 and 2022 Part C and D Star Ratings to address the disruption to data collection and measure scores, we are concerned the agencies proposal does not fully account for the impact of the COVID-19 public health emergency on Star Ratings.

In the short-term, CMS and MAOs should ensure Star Ratings activities do not require efforts counterproductive to the work of providers to combat the virus, or to the health and safety of beneficiaries. The Star Ratings should not require plans to submit requests to providers for medical records, or encourage beneficiaries' to seek non-emergent care during the public health emergency.

In the long-term, we encourage CMS to develop an industry-wide standard that appropriately measures quality during this pandemic. This approach – which could be operationalized using the agency's demonstration authority – should carry forward the Quality Bonus Payments (QBPs) for 4 and 5-Star plans, and provide plans with 3.5 or 3 Star Ratings the opportunity to earn a QBP for contract years 2022 and 2023 (2021 and 2022 Star Ratings) of at least 3.5 percent.

If CMS does not update the Star Ratings program to fully account for COVID-19, then, at a minimum, the agency should expand the extreme and uncontrollable circumstances policy to account for the pandemic and use data from the most recent unaffected year.

Currently, the potential for relief through the "extreme and uncontrollable circumstances" policy is limited to areas where Federal Emergency Management Agency (FEMA) major disasters have been declared and individual disaster assistance has been approved. CMS should expand eligibility for the policy to recognize federal, state, and local public health, emergency and disaster declarations. Expanding the current policy will ensure that beneficiaries are not unfairly penalized by fewer plan benefit options when quality thresholds are impacted by extreme and uncontrollable circumstances.

Specifically, we ask CMS to expand eligibility for the policy in the event of a state or local public health emergency, if the Secretary of Health and Human Services (HHS) declares a public health emergency, or in the event of a FEMA emergency or Fire Management Assistance Grant (FMAG) declaration for which public or individual assistance is available. Expanding CMS' recognition of these declarations and providing relief across multiple years will ensure quality measures are fairly applied across the country.

3. Proceed Cautiously on Curtailing Dual Eligible Special Needs Plan (D-SNP) Look-Alikes to Minimize Disruption to Beneficiaries

Anthem is committed to the enrollment of full-benefit dual eligible beneficiaries into D-SNPs that meet new integration requirements, and we appreciate the flexibility CMS has provided to implement these requirements in the most appropriate way for each state. However, we are concerned that if CMS moves forward with its proposal to curtail D-SNP look-alikes, the agency could disrupt beneficiary services and benefits.

We encourage CMS to implement any proposal regarding D-SNP look-alikes with sensitivity towards both continuity of care and the nuances of state requirements and market dynamics that conflict with

CMS' proposal. Specifically, we support CMS' proposal to allow D-SNP look-alike plans in states where D-SNPs or other integrated plans currently do not operate—in these states, look-alike plans provide valuable extra benefits to dual eligible beneficiaries that would not be available in a traditional MA benefit design.

We also request CMS extend this exception to counties or local markets where D-SNPs do not exist, since we are aware of instances where the state may allow for new D-SNPs, but the creation of a D-SNP is restricted at the market or county level, such as in California.

We believe that CMS' proposed definition of look-alikes as MA plans with at least 80 percent dual eligible membership is an appropriate threshold, assuming it applies only to full-benefit dual eligible beneficiaries. Given the potential disruption in care to a number of beneficiaries currently in high-performing four or five star plans even under this definition, we do not think the threshold should be any lower (since a lower threshold would negatively impact even more beneficiaries currently in high-performing plans), nor should it include partial duals (for which look-alike plans can provide benefit choice that better meets beneficiaries' needs).

If this proposal is finalized, we also encourage CMS to delay implementation by at least one year, until 2023 or later, to allow MAOs the opportunity to file bids and align with CMS' goals to avoid disruption in beneficiaries' care as they transition into other plans. Given the current COVID-19 crisis, states will also likely need additional time to approve new D-SNPs and help coordinate the transition process. This will ensure that beneficiaries are not negatively impacted, choice remains, and confusion is minimalized.

4. Enhance Care for ESRD Beneficiaries in MA by Improving Benchmark Accuracy and Expanding Access to Value-Based Care

In 2021, as directed by the 21st Century Cures Act, all ESRD patients will be eligible to enroll in MA. This new policy will lower Out-of-Pocket (OOP) costs for ESRD beneficiaries and expand access to new supplemental benefits to address drivers of health, including care coordination services not available in FFS.

In addition, the Administration's Advancing Kidney Health in America initiative creates new opportunities to improve the lives of Americans suffering from kidney disease. We support the goals of this initiative, as well as the changes of the 21st Century Cures Act as we have experience managing the specialized care associated with ESRD patients.

Given this significant change in policy, and our collective desire for successful implementation, we encourage CMS to address the inadequacy of the MA benchmarks and expand access to value-based care options for ESRD patients. We are concerned all MA beneficiaries could be negatively impacted through increased premiums, decreased benefits, and fewer plan options due to the higher costs associated with caring for beneficiaries with ESRD.

We appreciate that CMS acknowledges current ESRD reimbursement is not sufficient to prevent premium increases to accommodate the higher costs of ESRD beneficiaries in MA, particularly given that MA plans have a mandatory Maximum Out-of-Pocket (MOOP) limit that most, if not all, beneficiaries

with ESRD will surpass. In fact, applying the MOOP to ESRD beneficiary spending increases MA costs by an estimated 8 to 9 percent on average compared to FFS spending.[1]

To account for this inadequacy, CMS proposes to enable MA plans to increase MOOP limits. However, this change does not go far enough to mitigate the costs of ESRD beneficiaries, and a higher MOOP would increase OOP costs for all MA beneficiaries.

MA plans have a mandatory MOOP, while ESRD payments are based on FFS that does not have a MOOP. Plans will have to cover the increased costs of caring for ESRD beneficiaries by raising premiums by as much as $18 Per Member Per Month (PMPM), cutting benefits, or limiting plan options for all beneficiaries if CMS does not account for the value of the MOOP in setting MA ESRD benchmarks.[2] These long-standing policy concerns were raised to CMS by two of the sponsors of the 21st Century Cures Act that expanded ESRD patients' access to MA, Representatives Jason Smith (R-MO) and Gus Bilirakis (R-FL).[3]

Anthem is also concerned CMS' estimate of kidney acquisition costs is inflated. We encourage CMS to re-evaluate the estimate of kidney acquisition costs and make the underlying cost and discharge data more transparent, while considering MA plans' data and actual experience before removing $4 PMPM from the benchmark.

In order to ensure the continuation of low OOP costs, expanded supplemental benefits, including special supplemental benefits for the chronically ill, and care coordination services, CMS should directly address the payment inadequacies for ESRD beneficiaries in MA by updating the benchmarks.

In addition, to expand beneficiaries' access to value-based models of care, we encourage the Administration to allow MA plans to participate in the Center for Medicare & Medicaid Innovation (CMMI) kidney models, expand the list of Chronic Condition Special Needs Plans (C-SNPs) conditions to include patients with Chronic Kidney Disease (CKD), and provide flexibilities in network standards for dialysis services.

5. Update Past Performance Methodology to Account for Persistent Performance Issues

While Anthem appreciates CMS' efforts to clarify and simplify the past performance methodology, we are concerned the proposal would be overly restrictive in its application. We do not believe the proposed methodology sufficiently takes into account the nature and context of performance issues over a long enough period of time, and would inadvertently limit new high-quality plan offerings for beneficiaries.

Given the negative impact COVID-19 will have on Star Ratings, we recommend that CMS does not consider low Star Ratings as a determining factor to deny new contract and service area expansions. At a

[1] Health Management Associates. "End-Stage Renal Disease and Medicare Advantage." February 12, 2019. https://www.healthmanagement.com/wp-content/uploads/Health-Management-Associates-ESRD-and-Medicare-Advantage-White-Paper.pdf.

[2] Wakely. "2021 Medicare Advantage Advance Notice." March 4, 2020. https://www.ahip.org/wp-content/uploads/CY2021-Advance-Notice-Summary-and-Analysis-03-04-2020.pdf.

[3] Representatives Jason Smith (R-MO) and Gus Bilirakis (R-FL). January 13, 2020. https://share.antheminc.com/teams/PublicPolicy/Resource/Bilirakis-Smith_CMS_Ltr_ESRD_Choice_Act_Implementation(2020-1-13).pdf#search=Bilirakis.

minimum, we encourage the agency to consider two to three years of Star Ratings performance to allow for improvement efforts to be measured and reported.

Additionally, given the narrow timeframe CMS proposes for review, we encourage the agency to provide plans with a remediation opportunity and an appeals process should the plan quickly address identified issues.

Lastly, we recommend CMS exclude plans from the past performance review which have been, or will be non-renewed prior to the following contract year. Such a policy would enable plans to refocus efforts on ensuring existing Medicare contract performance remains at an acceptable level, and expanding high-quality plan choices to beneficiaries' in new service areas.

While we have concerns with the proposed methodology updates, we appreciate CMS' acknowledgement that given the new requirements of the Bipartisan Budget Act of 2018 (BBA) for D-SNPs, more intermediate sanctions should not be tied to overall contract performance.

6. Ensure Foundation of Star Ratings Continues to be Based on Objective Clinical Measures

Anthem opposes increasing the weight of patient experience and complaint measures to 4, well above the weight of clinical outcome measures. Any change regarding the weight of these measures should be preceded by a critical evaluation of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey and the Health Outcomes Survey (HOS) given concerns about decreasing response rates, and the accuracy and reliability of survey results.

While we appreciate the importance of ensuring patients have a positive experience and appropriate access to care, we encourage a slower and more thoughtful approach to changes to ensure the Star Ratings, which beneficiaries use to make plan choices, take a balanced approach to patient experience, and objective clinical outcomes.

7. Retain a Weight of 1 for the Statin Use in Persons with Diabetes (SUPD) Improvement Measure

While Anthem supports the goal of ensuring quality care for patients with diabetes, we believe the SUPD measure is more appropriately categorized as a process improvement measure. In addition, we encourage CMS to allow for clinically appropriate exclusions to improve the accuracy of the measure.

We are concerned that CMS is proposing to classify the SUPD measure as an intermediate outcome measure with a weight of 3 in the 2021 and 2022 Star Ratings Improvement Measures. Implementing the SUPD measure with a weight of 1 for the 2020 Star Ratings, reclassifying the measure and increasing the weight to 3 for 2021 and 2022, and then again reclassifying the measure and reducing the weight to 1 for 2023 is inconsistent and does not align with the guidance of expert measure developers.

We encourage CMS to make a technical correction to existing regulations to keep the SUPD measure at a weight of 1. This would align with both the Pharmacy Quality Alliance's (PQA's) classification of the SUPD measure as a process measure as well as the National Quality Forum's (NQF's) definition of a process measure.[4] Furthermore, in the 2020 Final Notice, CMS expressed agreement with stakeholder

[4] PQA. "Statin Use in Persons with Diabetes." Accessed February 25, 2020. https://www.pqaalliance.org/measures-overview#supd.

comments that the SUPD measure should retain a weight of 1 as a process measure, rather than a weight of 3 as an outcome measure.

In addition to our concerns around the measure classification and increased weighting, the COVID-19 public health emergency could impact beneficiaries' adherence, negatively impacting the accuracy of the measure. Furthermore, the measure does not allow for clinically appropriate exclusions to acknowledge certain demographic groups are more likely to be predisposed to statin intolerance.[5]

8. Account for Social Drivers of Health (SDOH) and COVID-19 in the Medical Loss Ratio (MLR)

This proposed rule change would establish the leadership of this Administration as the first to incorporate SDOH into the MLR framework. Anthem supports enabling social investments to be included in the MLR numerator, and appreciates CMS' proposed change to the definition of incurred claims to allow for an accurate accounting of SSBCI benefits.

Given the public health emergency, we also encourage CMS to allow investments in combating COVID-19 to be considered as incurred costs, thereby allowing such investments to be applied to the numerator of the MLR.

Including investments associated with SDOH, such as SSBCI benefits, and combating COVID-19 in the MLR numerator would further strengthen the MA program and support whole person health.

9. Implement Network Adequacy Flexibilities to Improve Beneficiaries' Access to Care

Anthem supports CMS' proposed flexibilities to the MA network adequacy requirements. CMS' approach reflects the challenges associated with establishing a network in some geographies and would improve beneficiaries' access to plan options in rural areas, as well as access to telehealth innovations to close care gaps.

Given the expected increase in ESRD beneficiary enrollment in MA, we support CMS' proposal to remove outpatient dialysis from the list of facility types for which MA plans must meet time and distance standards, and instead allow plans to attest to providing medically necessary dialysis services in contract applications. These flexibilities will encourage competition and drive patient-centered innovation in dialysis treatment.

Given the challenges associated with the COVID-19 outbreak, we also appreciate that CMS has proposed flexibilities when plans contract with telehealth providers. We request further clarification on how health plans can expand coverage of telehealth services beyond those approved by CMS.

10. Require Submission of Pharmacy Claims and Allow Attestations to Improve Patient Safety and the Accuracy of Star Ratings

Anthem is concerned patient safety and Star Ratings accuracy are compromised when a beneficiary obtains a medication without utilizing their prescription drug benefit, and their pharmacist does not file a claim.

[5] Zahid Ahmad, MD. "Statin Intolerance." May 2014. https://www.ajconline.org/article/S0002-9149(14)00725-5/pdf.

Safety issues arise when a plan does not know a beneficiary has obtained a prescription medication. In these situations, plans are unable to appropriately monitor safety issues such as dangerous drug interactions, opioid use, or duplicate therapies. It is critical that plans are able to conduct concurrent drug utilization reviews to ensure patient safety.

We ask CMS to require a pharmacy claim submission process for cash payments, and permit plans to submit attestations to show the beneficiary received their medication for purposes of calculating Star Ratings measures. This will address situations in which beneficiaries have extended gaps in their fill histories, while other supplemental data shows they received their medication.

Moving forward, we encourage CMS to develop a repository with pharmacy records so plans can better monitor prescribing and dispending patterns. These policy changes will improve patient safety and the accuracy of medication adherence measures in the Star Ratings program.

11. Account for Volatility in Specialty Drug Prices in the Medicare Plan Finder (MPF) Star Ratings Measure to Improve Accuracy of Drug Prices for Beneficiaries

Since drug prices are volatile due to manufacturers' ability to change prices at any time without warning or constraint, Anthem is concerned the MPF can exhibit inaccurate information to the consumer as compared to the cost at the Point-of-Sale (POS).

We are also concerned that it can take two to four weeks to update pricing changes submitted by any Pharmacy Benefit Manager to the MPF leading to higher dollar discrepancies for beneficiaries at the pharmacy counter.

Therefore, we request that CMS allow for the correction of specialty drug prices during the Star Ratings plan preview window to improve the accuracy of high-priced drug costs for beneficiaries. We would also like to work with CMS to increase the efficiency of the process for updating drug prices on the MPF.

Given that challenges ensuring the accuracy of prescription drug costs on the MPF are expected to persist, we request CMS consider an exceptions process to hold plan Star Ratings harmless with proof a drug price has changed significantly over a two-week period.

Detailed Comments on Provisions in the Proposed Regulation

A. Implementation of Certain Provisions of the Bipartisan Budget Act of 2018

Special Supplemental Benefits for the Chronically Ill (SSBCI) (§ 422.102)

Recommendation Summary: Anthem strongly supports CMS' proposal to give plan sponsors more flexibility in the delivery of supplemental benefits for chronically ill beneficiaries. We appreciate additional flexibility in the definition of eligible populations because MA plans are in the best position to coordinate care for beneficiaries with chronic conditions for whom SSBCI would have the largest benefit.

We encourage CMS to implement this flexibility within existing administrative reporting requirements so innovations can be implemented without new or conflicting administrative burdens. We also encourage CMS to test ways to provide more flexibility in targeting supplemental benefits to address social risk factors like homelessness. Furthermore, we would like to work with CMS to identify ways beneficiaries can be better educated about SSBCI benefits within the MPF.

Recommendation Detail: Anthem has embraced the new flexibility provided by CMS through SSBCI benefits, as well as the expanded definition of primarily health related supplemental benefits. We are also testing prescribed nutrition programs, respite care, pain management, and an outreach support program to address loneliness and isolation. Specifically, in 2020, beneficiaries in our MA plans may have access to the following:

1) Pest Control: Quarterly preventive treatments to regulate or eliminate the intrusion of household pests that may impact a chronic condition;
2) Healthy Nutrition: Based on qualifying clinical criteria, access to eight sessions per year with a dietitian who can provide nutritional education support as well as monthly delivery of pantry staples (nonperishable items) to help make dietary changes;
3) Health and Fitness Tracker: The beneficiary is provided a fitness tracker device as well as membership in programs to promote improved physical and mind fitness;
4) Service Dog Support: Up to $500 annual allowance to help pay for items used to care for a member's service dog, such as leashes and vests;
5) Healthy Food Deliveries: Up to 16 delivered meals four times each calendar year (64 total) to support beneficiaries who are either discharged from an overnight stay at a hospital, have a Body Mass Index (BMI) more than 25 or less than 18, or have an A1C level more than 9.0;
6) Transportation: Up to 60 trips per year to health-related appointments or to obtain a service covered by the health plan;
7) Personal Home Helper: Up to 124 hours of an in-home personal care aide for assistance with activities of daily living such as dressing, grooming, & bathing;
8) Assistive Devices: Up to a $500 allowance for safety devices such as Americans with Disabilities Act (ADA) compliant toilet seats, shower stools, hand-held shower heads, and reaching devices;
9) Day Center Visits: One visit per week for adult day center services, in order to help older adults who need supervision and assistance; and
10) Alternative Medicine: Up to 24 acupuncture and/or therapeutic massage visits each calendar year.

We support CMS' proposal to allow for the identification of beneficiaries beyond the current list of chronic conditions as long as they meet the standards of chronically ill as defined by the statute. To this

end, while CMS works to roll out this new flexibility, we encourage the agency to seek feedback from plans on how to report eligibility criteria consistently so that innovations can be implemented without new or conflicting administrative burdens.

We recommend CMS provide plans with more flexibility in targeting supplemental benefits to address social risk factors. Today supplemental benefits can address SDOH as long as they maintain or improve health function, and don't solely address social factors. SDOH alone cannot be used to determine SSBCI eligibility. We encourage CMS to work with CMMI to test benefits targeted at SDOH challenges, such as homelessness.

Specifically, we encourage CMS to pilot a Special Needs Plan (SNP) addressing homelessness to test the effectiveness of this model of care for people experiencing homelessness or housing instability, with the goal of achieving better clinical outcomes, a lower rate of homelessness, and lower overall system costs. This strategy could be particularly effective for patients whose homelessness is associated with mental health conditions, substance use disorders, and/or other debilitating medical conditions. Benefit flexibility would be a critical component of the homeless SNP pilot program to establish appropriate solutions to reduce the number of homeless individuals in Medicare.[6]

Furthermore, while Anthem has embraced the inclusion of SSBCI benefits into our plan designs for 2020, we believe CMS could do more to help educate beneficiaries about their plan and benefit options through tools such as the MPF. Currently, the MPF only displays a subset of the supplemental benefits in the overview page and requires the beneficiary to click on plan details for a full list of the supplemental benefits. We are concerned this extra step could prevent a beneficiary from learning about all of their supplemental benefit options and fully evaluating plan choices. CMS currently publishes OOPC estimates on the MPF, but CMS has shared that the costs for optional supplemental benefits are not included in the calculation of OOPCs. Therefore, the current OOPC model does not accurately capture the actuarial impact for the beneficiary.

SSBCI benefits are included in plan designs alongside other traditional supplemental benefits—and plans must make choices of what mix of the two to include. However, we are concerned that in the MPF, plans are ordered, and therefore penalized based on cost. To ensure beneficiaries can consider the full spectrum of health plan offerings, we recommend CMS increase the visibility of new supplemental benefit offerings and incorporate the value of supplemental benefits into the OOPC model calculations.

Improvements to Care Management Requirements for Special Needs Plans (SNPs) (§422.101)

Recommendation Summary: Anthem supports CMS' desire to ensure that beneficiaries in C-SNPs, and the providers that care for them, are engaged in the care plan. However, we do not believe the proposed implementation of the BBA's C-SNP requirements provide either enough flexibility or specificity to meet beneficiaries' needs while still reaching Model of Care (MOC) benchmarks.

Anthem also does not support extending these C-SNP requirements to D-SNPs and Institutional-SNPs (I-SNPs) since such a policy would result in duplicative and inconsistent requirements, given the many existing related requirements already in place.

[6] JAMA. "Homeless Special Needs Plans for People Experiencing Homelessness." February 13, 2020. https://jamanetwork.com/journals/jama/fullarticle/2761555.

Recommendation Detail: CMS proposes to update its regulations to extend the BBA's C-SNP requirements to other SNP care management and MOC submissions. We have the following comments on the implementation of the elements of the new requirements:

- Interdisciplinary Team (IDT): The BBA requires that the interdisciplinary team include a team of providers with demonstrated expertise. We recommend that CMS implement requirements related to the documentation of the care team—rather than implement prescriptive requirements for the composition of a care team. This approach provides beneficiaries with choice regarding caregivers and thus the greatest chance for success in meeting CMS' MOC goals.

  Anthem undergoes a rigorous credentialing process to ensure that its network providers have the expertise and training to care for MA beneficiaries that enroll in our plans. Additionally, Anthem fully complies with network adequacy requirements to ensure our networks have all necessary providers overall and within proximity to beneficiaries. Because of the rigor of these current requirements, we believe that MA plans' networks already have providers to care for any set or subset of beneficiaries that may enroll.

  For I-SNPs and D-SNPs, this requirement is not appropriate. For I-SNPs, the institutional settings in which many beneficiaries reside already have staffing and physician supervision requirements that CMS believes are necessary for quality long-term care. Adding additional IDT requirements will increase the burden on long-term care facilities and may require some patients to be managed to different standards than others, which should not be necessary since plans already promote the identification of providers from disciplines that are most relevant to the beneficiary's needs.

  For D-SNPs, given the diverse needs of this population (some of whom are not chronically ill), we believe the credentialing and network adequacy standards that are in place ensure appropriate access to high-quality providers. We note that many states already include additional provider network requirements for specific sub-populations that could vary from and conflict with these C-SNP requirements.

- Face-to-Face Annual Encounters: The BBA requires that C-SNPs provide face-to-face encounters with beneficiaries not less frequently than on an annual basis. We encourage CMS to allow for any face-to-face encounter with a provider to meet this requirement. For example, if a beneficiary chooses to engage through their primary care physician, then that interaction should be counted. For I-SNPs, given the existing requirements related to patients in long-term care, such a requirement would be duplicative. For D-SNPs, certain sub-populations of D-SNP beneficiaries would benefit from annual face-to-face encounters; however, we believe the better place to standardize this process is through specific types of SNPs, such as Highly Integrated Dual Eligible SNPs (HIDE-SNPs) and Fully Integrated Dual Eligible SNPs(FIDE-SNPs), rather than as part of broad MOC requirements. While the vast majority of beneficiaries in SNPs are receiving ongoing, regular care from a multidisciplinary team, there are a subset who chose not to obtain routine medical care. Even though Anthem strongly encourages annual wellness visits at a minimum for these individuals, it is ultimately the choice of the beneficiary to engage in the health care system.

Additionally, we would encourage CMS align all evaluation and documentation requirements to the calendar year in order to align these processes with benefits such as the annual wellness visit.

- Health Risk Assessments (HRAs) and the SNP Beneficiary's Individualized Care Plan: The BBA requires that as part of the mandatory MOC, the results of the initial assessment and annual reassessment required for each beneficiary be addressed in the individual's individualized care plan. We recommend that CMS allow for as much flexibility as possible and clarify that the care plan is a collaborative document between the beneficiary and their care team. A care plan is designed to prioritize the beneficiary's needs and facilitate interventions where coordination and support may be lacking. As such, not every issue identified in an HRA becomes part of the care plan (for example, a beneficiary may report in an HRA something that is not relevant to the care plan or is not a covered benefit), and conversely a care plan may address additional issues not part of an HRA. If this requirement is implemented too rigidly, then the care plan will become a less effective tool for patient engagement and care improvement.

- SNP Fulfillment of the Previous Year's MOC Goals: The BBA requires that as part of the annual evaluation and approval of the MOC, CMS take into account whether the plan fulfilled the previous year's goals. Anthem supports the ongoing tracking and reporting of MOC goals; however, we recommend CMS recognize that MOC goals are multi-year and often reflect treating different individuals or populations over time (so some goals become evergreen as new individuals are engaged). We also ask that requirements related to fulfillment of MOC goals are distinct from goals for quality performance, which are separate standards for SNPs. If these requirements do overlap, then we suggest that compliance with quality goals would meet the requirements for MOC goals.

- Establishing a Minimum Benchmark for Each Element of the SNP MOC: The BBA requires that CMS establish a minimum benchmark for each element of the MOC and only approve a C-SNP's MOC if each element of the model of care meets such minimum benchmark. Anthem encourages a standardized and transparent process related to the evaluation of MOCs; in particular, we would appreciate more clarity regarding how separate scoring of the four elements would be conducted, in contrast to the current system, before providing feedback as to whether the 50 percent minimum is an appropriate threshold. We request additional guidance from CMS, along with a comment period on that guidance, before a minimum benchmark percentage is finalized. CMS should also ensure that inter-rater-reliability meets the standards of other CMS programs and that plans are provided resources to understand any negative compliance decisions.

Contracting Standards for Dual Eligible Special Needs Plan (D-SNP) Look-Alikes (§ 422.514)

Recommendation Summary: Anthem supports the enrollment of full-benefit dual eligible beneficiaries into D-SNPs that meet new integration requirements. However, if CMS moves forward with its proposal to curtail D-SNP look-alikes, we encourage this policy change be implemented in such a way that minimizes beneficiary disruption and is informed by the nuances of state D-SNP policies.

Recommendation Detail: CMS states that it is concerned with D-SNP look-alike plans not meeting standards for meaningful integration, particularly in light of additional requirements for D-SNPs starting in 2021 that are designed to ensure coordinated care between Medicare and Medicaid. As a result of

this concern, CMS is proposing, starting in 2022, not to enter into or renew contracts for an MA plan for an upcoming plan year when that plan is identified as exceeding a specific enrollment threshold (80 percent) for dually eligible individuals. MA organizations with plans identified as exceeding the enrollment threshold that also have approved D-SNPs for the following plan year, would be permitted to transition dually eligible beneficiaries from D-SNP look-alikes to D-SNPs for which the individuals are eligible. Given the significant impact this proposal would have on beneficiaries and plans, as outlined below, we request CMS finalize this policy well before bids are due.

Anthem supports CMS' efforts to encourage D-SNP integration, including the flexibility it has provided states to implement these requirements in ways that are most appropriate for each state. We encourage CMS to implement its proposal regarding D-SNP look-alikes with similar sensitivity to the nuances of different state requirements and market dynamics. Specifically, we support CMS' proposal to continue to allow D-SNP look-alike plans in states where D-SNPs or other integrated plans currently do not operate—in these states, D-SNP look-alikes provide valuable extra benefits to dual eligible beneficiaries that would not be available under a traditional MA benefit design.

We also request CMS not just allow for look-alike plans in states where D-SNPs do not operate, but also in counties or local markets where D-SNPs do not exist. We are aware of several instances where the state may allow for new D-SNPs, but the creation of a D-SNP is restricted at the market or county level (for example, we currently do not know which plans will be allowed to offer D-SNPs in certain California markets for 2021), and we do not believe CMS should close plans where either state or county policies prohibit that plan sponsor from creating a D-SNP that meets the necessary integration requirements. Therefore, we request CMS provide exemptions when state or local requirements are contradictory to its proposal.

Regarding CMS' proposed exception to its look-alike policy for new plans (plans that have been active for less than one year) with low enrollment, we encourage CMS to raise the enrollment minimum from 200 enrollees to 500 enrollees. This would better align with the enrollment levels already required for plan viability for Prescription Drug Plans (PDPs). Aligning these standards would create policy consistency and reduce administrative burden.

We also request CMS clarify that its 80 percent threshold applies only to full-benefit duals. As partial benefit duals do not receive full Medicaid benefits, and thus have less of a need for integrated benefits and services (and are rarely the target of states' integration efforts), we do not believe the enrollment of these individuals in D-SNP look-alikes is detrimental. In fact, the presence of D-SNP look-alikes may provide additional benefit choices that better meet beneficiaries' needs. And given the potential disruption to a number of beneficiaries currently in high-performing, five star look-alike plans that contain over 80 percent dual eligibles, we believe that keeping the threshold at 80 percent (or higher) and applying it only to full-benefit dual eligibles will help ensure that beneficiaries' care is not negatively impacted, choice remains, and confusion is minimalized (since a lower threshold would negatively impact even more beneficiaries currently in high-performing plans).

Regarding CMS' proposal to accommodate beneficiaries in terminated look-alike plans by transitioning their enrollment to a D-SNP or another zero-premium plan offered by the MA organization, the agency seeks comment on whether additional criteria for the plans accepting beneficiaries from terminated plans are necessary. We recommend CMS allow for an opt-out process for impacted beneficiaries to preserve beneficiary choice. Also, for terminated beneficiaries, we encourage CMS to consider the implications of this transition policy where the beneficiary is enrolled in a Medicaid plan that is

sponsored by the same organization as the D-SNP look-alike plan. We believe it would be detrimental to make that beneficiary have to choose unaligned coverage or be forced to also change their Medicaid carrier as a result of this policy. Such a disruption in ongoing care plans and care teams at the *individual level* is likely to outweigh any additional benefit from the D-SNP integration requirements at the *plan level*. Thus, we recommend that affected beneficiaries be permitted to stay with a MA plan or MAO, ensuring continued integration of their Medicare and Medicaid benefits.

Additionally, we encourage CMS to allow at least an additional year (until 2023) to implement this transition policy if finalized. As plans work to enter into agreements with states and implement compliant integrated D-SNP products to transition beneficiaries into (so as to avoid disruption in their care), we do not believe the timing between the finalization of this rule and the 2022 proposed start date for this policy change will be sufficient in all instances. If plans have not already submitted an application for a D-SNP, they will not be able to transition impacted beneficiaries for 2021, as required under this proposal. Additionally, as stated above, some states have not yet clarified which plans will be allowed to offer D-SNPs in specific markets for 2021. And since all D-SNPs currently must have executed contracts with applicable state Medicaid agencies, we request CMS also allow for subcontracts through a directly contracted entity in order to ease transitions for beneficiaries into the most integrated plan possible. If CMS will not allow at least an additional year for implementation, we ask CMS to allow for continuation of certain plans for the 2022 plan year where the MAO can demonstrate a good faith effort to apply for and implement a compliant D-SNP product.

We also request CMS clarify what data source it will use to determine the percentage of dual eligible beneficiaries in a plan, since plans would subsequently need to ensure these beneficiaries are eligible for a D-SNP (as well as what type of D-SNPs, such as a FIDE-SNP or HIDE-SNP). After plans have determined beneficiaries' dual status level, we would need to develop Annual Notice of Changes (ANOCs) that clearly explain to the beneficiary both how and why they are transitioning to a new plan—therefore, we also request CMS assist in providing guidance for providers and beneficiaries as to why this transition is occurring to prevent confusion.

B. Implementation of Several Opioid Provisions of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act

Mandatory Drug Management Programs (DMPs) (§ 423.153)

Recommendation Summary: Anthem supports CMS' efforts to implement DMPs across Part D. We have successfully implemented our program, and believe these programs are effective tools to prevent and reduce beneficiary harm. We request guidance that provides clarity around the identification of potentially at-risk beneficiaries and consistent lookback periods and exemption criteria for beneficiaries receiving long-term or end-of-life care.

Recommendation Detail: The SUPPORT Act made changes to the requirements for Part D DMPs intending to enhance Part D sponsors' ability to reduce the abuse or misuse of opioid medications in prescription drug benefit plans. CMS is proposing to require Part D sponsors to adopt DMPs starting on or after January 1, 2022.

Anthem was an early adopter of the DMP program requirements, having implemented a successful program in2019. We believe these programs are an important and necessary tool to combat the opioid epidemic. As CMS takes steps to make these programs mandatory starting in 2022, we ask that the

agency provide more clarity and guidance around the requirements of the DMPs, particularly related to the specific criteria for identifying potentially at-risk beneficiaries.

Consistent measure criteria across programs, including the alignment of the Opioid Drug Management Program (ODMP) definitions, are needed to achieve positive outcomes. For example, CMS typically requires a 6-month lookback to define a beneficiary with a history of an opioid-related overdose. However, in the Advance Notice CMS proposed no lookback period for the Initial Opioid Prescribing (IOP) Measures for Part D.[7] Such inconsistencies negatively impact the implementation of the ODMP. In addition, exemptions should consistently include beneficiaries residing in long-term care setting or receiving palliative/end-of-life care, consistent with the DMPs.

Furthermore, with the addition of beneficiaries at-risk of opioid abuse to Medication Therapy Management Programs (MTMPs), we ask CMS to confirm expectations around At-Risk Beneficiaries (ARBs) in annual reporting. We would appreciate further harmonization of the clarification of potential modifications to reporting elements moving forward.

Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.100)

Recommendation Summary: Anthem supports the inclusion of beneficiaries with history of an opioid-related overdose in plan DMPs. CMS should ensure alignment with the ODMP definitions, timelines, and exemptions as it implements this requirement.

Recommendation Detail: CMS is proposing to modify the definition of a potential at-risk beneficiary to include a Part D eligible individual who is identified as having a "history of an opioid-related overdose"—defined as a beneficiary with a recent claim containing the principal diagnosis code for an opioid overdose, regardless of the type of opioid, and at least one recent Prescription Drug Event (PDE) for an opioid dispensed to the beneficiary. Specifically, CMS proposes the following criteria:

- Diagnoses that include both prescription and illicit opioid overdoses;
- A 12-month lookback period from the end of each Overutilization Monitoring System (OMS) reporting quarter, for record of an opioid-related overdose within FFS claims and MA encounter data (excluding those not enrolled in a Part D plan, whether an MA-PD or standalone PDP plan); and,
- A 6-month lookback period from the end of each OMS reporting quarter, for record of a recent Part D opioid PDE.

Anthem recommends that CMS make every effort to align the inclusion criteria used to identify those with a history of opioid-related overdose with the standardized reporting of ODMP. For example, reconciling the definitions of negative opioid history versus someone who is opioid naïve. Without this alignment, conflicting definitions will inhibit reliable outcomes.

[7] CMS. "Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter." April 1, 2019. https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.

We also seek additional clarification on CMS' expectations for reviewing the cases of beneficiaries under this classification. Anthem believes someone with an overdose history should be regularly reviewed, and such a review is already part of our ongoing efforts. As such, we do not think a review needs to be part of the DMP process as it would be duplicative to existing efforts. We seek additional guidance on aligned exemptions, timeframes, and qualifying criteria, if such reviews are implemented as a requirement.

We appreciate CMS' acknowledgment that providers are integral to the process of communicating potential safety concerns to beneficiaries with a history of an opioid-related overdose. In addition to providing updated model notices, we encourage the agency to help communicate these changes to providers and beneficiaries to improve education and understanding around DMP changes.

Information on the Safe Disposal of Prescription Drugs (§ 422.111)

Recommendation Summary: Anthem appreciates the need to provide information to beneficiaries regarding the safe disposal of prescription drugs and encourages CMS to require the same notices to be communicated to Medicare beneficiaries by prescribers and pharmacies.

Recommendation Detail: The SUPPORT Act requires CMS to establish criteria for the information provided to an individual during an in-home HRA to ensure that each individual is sufficiently educated on the safe disposal of prescription drugs that are controlled substances. Anthem appreciates the need for CMS to implement this statutory requirement, and we are prepared to provide this information to our beneficiaries as part of our in-home HRAs.

We also believe this information could be effectively delivered to the beneficiary at the point they are given the prescription and/or when they fill the prescription. At these times, information on safe disposal is more likely to be understood, and the drugs are more likely to be disposed of safely as part of the beneficiary's care routine (e.g., expired medications can be disposed of at or near the same location where a new prescription is filled).

In model materials, CMS should include ways to identify local resources for disposing of unused/ unwanted drugs. For example, the Food and Drug Administration (FDA) provides consumer-friendly instructions on the safe disposal of unused medicines.[8] In addition, the U.S. Department of Justice provides a database to search controlled substance public disposal locations by zip code, city, or state.[9] Plans, prescribers, and pharmacists should provide information on resources to help beneficiaries identify locations to safely dispose of prescription drugs.

Beneficiaries' Education on Opioid Risks and Alternative Treatments (§ 423.128)

Recommendation Summary: Anthem supports the proposed flexibility for plan sponsors to target a subset of beneficiaries who would benefit most from information on opioid risks and alternative

[8] FDA. "Disposal of Unused Medicines: What You Should Know." Accessed March 18, 2020. https://www.fda.gov/drugs/safe-disposal-medicines/disposal-unused-medicines-what-you-should-know.

[9] U.S. Department of Justice. "Controlled Substance Public Disposal Locations - Search Utility." Accessed March 18, 2020. https://apps2.deadiversion.usdoj.gov/pubdispsearch/spring/main;jsessionid=lcHVs66J-ZlxHw0aFkA2BrLCEWm0o7cLJBWEKJNY.web2?execution=e1s1.

treatments. We request more specific guidance on the information Part D sponsors of MA-PDs will be required to provide to each beneficiary annually.

Recommendation Detail: Starting in 2021, the SUPPORT Act requires Part D sponsors to disclose to each beneficiary information about the risks of prolonged opioid use when used for the treatment of pain. In addition to this information, MA-PD sponsors must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans. Sponsors of standalone PDPs must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans and under Medicare Parts A and B. The SUPPORT Act also permits Part D sponsors of MA-PDs to disclose opioid risk and alternative treatment coverage information to only a subset of plan beneficiaries.

Anthem appreciates the proposed flexibility CMS has suggested for implementation of this provision; we also appreciate the additional information CMS provided in the proposed rule regarding possible subsets of beneficiaries plan sponsors could target. Finally, we appreciate the ability to provide this information as a separate, distinct beneficiary outreach mailing as this will reduce the burden of having to modify other standard materials or issue the standard materials in multiple versions.

We request more information about what must be provided to each beneficiary annually. While CMS has many helpful resources on the pain management website, each beneficiary must receive information in a standardized form for the treatment of pain, the risks associated with prolonged opioid use, and coverage of alternative therapies. We support the dissemination of clear model materials and/or examples to help Part D sponsors of MA-PDs comply with the new requirement.

Eligibility for Medication Therapy Management Programs (MTMPs) (§ 423.153)

Recommendation Summary: MTMPs provide demonstrated value to beneficiaries who have multiple chronic conditions, are on numerous medications, and are expected to incur high prescription drug costs for the year. While ARBs, or beneficiaries' determined to be at-risk for misuse or abuse frequently abused drugs, may benefit from some MTMP elements (many already qualify under existing criteria), still many other ARBs are distinctly different from the current MTMP population. Thus, we recommend CMS not require the inclusion of all ARBs into MTMPs, but rather enable plans to incorporate ARB status as a factor (in conjunction with other criteria) to target MTMPs better.

Recommendation Detail: The SUPPORT Act modifies MTMP requirements for Medicare Part D plans beginning January 1, 2021, by expanding the population of beneficiaries who are targeted for MTMP enrollment to include ARBs, and by adding a new service component requirement for all targeted recipients. We are concerned that COVID-19 will make the numerous proposed changes to the MTMP challenging to implement. In an environment where resources, time, and expertise are directed to support the COVID-19 public health crisis, we encourage CMS to delay implementation of the new requirements.

First, Anthem agrees with CMS that for many ARBs, Part D MTMPs can provide another tool to address opioid misuse. While DMPs primarily involve a prescriber-centric approach through case management to promote safer use of opioids and benzodiazepines, MTMPs leverage a beneficiary-centric approach to improve a beneficiary's medication use and reduce the risk of adverse events involving all medications (including opioids and other Frequently Abused Drugs). MTMPS and DMPs require different elements in order to produce positive outcomes for members, including case management and member engagement. Each program should be designed to serve a tailored population in order to best address

members' needs. While the programs create different approaches to mitigate misuse, we are concerned that without added clinical benefits, i.e. official medical reviews, DMPs and MTMPs will create duplicative efforts that may obstruct the intended solutions. We encourage CMS to enable MAOs to define ARBs to provide benefits beyond current DMP efforts to ensure at-risk beneficiaries are not overlooked.

Second, under existing criteria, many ARBs are already being targeted for MTMPs, but instead of requiring all ARBs to be targeted for inclusion for MTMPs, we ask that CMS allow plans to use ARB status as one factor, among others, to determine targeting for an MTMP. This flexibility will enable the industry, in partnership with CMS, to properly update all of the necessary standard materials and operationalize processes, including allowing MAOs to study the impact of MTMP services and create innovative programs to define clinical outcome goals better. Additionally, Anthem has other programs in place that are specific to ARBs outside of the DMP process.

Third, CMS inquires about the value of encouraging Part D MTM providers to use Fast Healthcare Interoperability Resources-enabled platforms when providing MTM to Part D beneficiaries to facilitate the integration of the service elements into prescribers' Electronic Health Records (EHRs). While Anthem understands the long-term potential of this approach, we see current deficiencies in EHR standardization and interoperability that create barriers to implementation. We would appreciate a standardized data exchange, within the proposed standardized format to further streamline data exchanges. Because Anthem is investing in these types of technologies and capabilities, we welcome continued opportunities to provide technical feedback on this type of approach as policy proposals move forward.

Fourth, regarding CMS' proposal to provide safe disposal information through MTM programs, we would reiterate our comments above: that while Anthem is capable of providing this information and more communication around safe disposal sites is valuable, prescribers and pharmacies are also in a position to provide beneficiaries with information that is relevant and more likely to be acted upon given providers' knowledge of local resources. We encourage CMS to leverage model language in the MTM welcome letter to ensure beneficiaries have access to more specific, localized resources to dispose of drugs safely.

Finally, we note that CMS is proposing a new standardized format for the Comprehensive Medication Review (CMR) as the completion rate is critical for Star Ratings, CMS should account for the operational challenges of implementing this change. CMS should also study the effects of CMR completion rates on MTMPs. We have noted diminishing returns as more beneficiaries have received reviews. While Anthem supports the updating of these materials, we are concerned about the timing of these requirements in conjunction with the new proposed requirements related to ARBs. We ask CMS to provide MAOs with more time to implement and test proposed changes by implementing the proposals in 2022.

Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2)

Inappropriate Prescribing of Opioids

Recommendation Summary: We recommend CMS align this definition with existing regulations and guidance, including exclusions for long-term care, palliative care, and end-of-life care.

Recommendation Detail: To implement SUPPORT Act requirements around communication on over-prescribers, CMS proposes a definition for inappropriate prescribing. We encourage CMS to work to align this definition with existing regulations and guidance, including those related to PDMPs. Specifically, this would include exceptions for situations such as long-term care, palliative care, and end-of-life care, and other alignments as appropriate.

C. Implementation of Certain Provisions of the 21st Century Cures Act

Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110)

Recommendation Summary: In 2021, as directed by the 21st Century Cures Act, all ESRD patients will be eligible to enroll in MA. This new policy will lower OOP costs for ESRD beneficiaries and expand access to new supplemental benefits to address drivers of health, including care coordination services not available in FFS. Additionally, the Administration's Advancing Kidney Health in America initiative creates new opportunities to improve the lives of Americans suffering from kidney disease. We are prepared to support the goals of this initiative, as well as the changes of the 21st Century Cures Act, by managing the specialized care associated with ESRD patients.

Given the significant changes brought about by the 21st Century Cures Act, and our collective desire for successful implementation, it is important that CMS address several long-standing policy concerns associated with expanding access to MA for individuals with ESRD. These concerns include improving MA ESRD payment accuracy by adjusting the benchmarks to account for the MOOP limit required in MA and moving away from a statewide benchmark for payment.

Furthermore, we recommend that the Administration allow MA plans to participate in the CMMI kidney models and expand the list of C-SNP conditions to include patients with CKD, to expand ESRD beneficiaries' access to value-based plan designs.

Recommendation Detail: We are eager to collaborate with CMS to increase high-quality plan options for ESRD beneficiaries in 2021. However, if concerns around benchmark accuracy and barriers to care are not addressed, all MA beneficiaries, not only those with ESRD, would face increased premiums, reduced benefits, and fewer plan options.

Benchmark Accuracy and Bid Process

The ESRD benchmarks in MA are based on Medicare Parts A and B FFS costs. For beneficiaries with ESRD, MA plans are required to cover the same services offered in FFS, but currently MA beneficiaries' OOP costs cannot exceed more than $6,700 a year. This makes OOP financial protection in MA different from FFS, where there is no OOP limit. This is a crucial difference, given that today, the average FFS annual OOP responsibility for individuals with ESRD is $13,000.[10]

[10] Health Management Associates. "End-Stage Renal Disease and Medicare Advantage." February 12, 2019. https://www.healthmanagement.com/wp-content/uploads/Health-Management-Associates-ESRD-and-Medicare-Advantage-White-Paper.pdf.

The MA ESRD benchmarks do not take into consideration the cost of the mandatory MOOP limit in MA. As a result, these benchmarks do not accurately anticipate the costs of treating ESRD patients. The mandatory MOOP will increase MA costs by approximately 8-9 percent compared to FFS spending (and benchmarks).[11] As a result, to make up for this payment shortfall for ESRD beneficiaries, analysis shows beneficiary premiums in MA could increase by as much as $18, or benefits could be cut by a similar magnitude if CMS does not address payment inadequacies for beneficiaries with ESRD.[12] Therefore, CMS should incorporate the $6,300 difference between the FFS OOP spending and the MA MOOP as part of its estimates in the MA benchmarks.[13]

While CMS has proposed adjusting the methodology for setting the MOOP limits to take into account the removal of restrictions on beneficiaries with ESRD allowed to enroll in MA plans beginning in 2021, we are concerned the proposal does not do enough to keep program costs low for beneficiaries'. CMS' proposal would create a new third MOOP limit – referred to in the Proposed Rule as the "intermediate" MOOP limit – set in-between the existing mandatory MOOP limit and the "lower" (or "voluntary") MOOP limit. In addition, CMS would phase-in additional costs incurred by beneficiaries with ESRD into the MOOP limit calculation over time. Therefore, the agencies proposal would increase costs for all beneficiaries'.

In addition, we encourage CMS to consider the significant variation in spending that exists for ESRD patients across metropolitan areas in a single state. CMS pays MA plans a statewide benchmark for ESRD beneficiaries, based on FFS costs. However, data from California, Florida, Ohio, and Texas reveal that metropolitan areas in the same state can be significantly above or below the overall state average. These metropolitan areas also show significant volatility in their averages over a three-year period.[14] CMS should model the implications of setting ESRD rates at the metropolitan level, rather than the state level, and allow stakeholder comment on a new approach to setting ESRD benchmarks at a smaller geographic level to achieve more accurate payment for ESRD beneficiaries.

Improve Prevention and Address Clinical Barriers

Studies have found that C-SNPs achieve better outcomes by providing targeted care to address beneficiaries' chronic conditions.[15, 16] Today, while C-SNPs serve ESRD patients, they are not able to serve patients with CKD who have not yet progressed to ESRD. The care coordination offered by MA plans could help patients with CKD better manage their disease and delay, or even avoid the progression

[11] Health Management Associates. "End-Stage Renal Disease and Medicare Advantage." February 12, 2019. https://www.healthmanagement.com/wp-content/uploads/Health-Management-Associates-ESRD-and-Medicare-Advantage-White-Paper.pdf.

[12] Wakely. "2021 Medicare Advantage Advance Notice." March 4, 2020. https://www.ahip.org/wp-content/uploads/CY2021-Advance-Notice-Summary-and-Analysis-03-04-2020.pdf.

[13] $6,300 was determined based on subtracting the MA's MOOP of $6,700 from the average OOP cost for a FFS ESRD beneficiary of $13,000.

[14] Health Management Associates. "End-Stage Renal Disease and Medicare Advantage." February 12, 2019. https://www.healthmanagement.com/wp-content/uploads/Health-Management-Associates-ESRD-and-Medicare-Advantage-White-Paper.pdf.

[15] Avalere Health. "Effects of Chronic Condition Special Needs Plan Enrollment on Outcomes for Medicare Beneficiaries with Diabetes." October 2017. https://www.antheminc.com/cs/groups/wellpoint/documents/wlp_assets/d19n/mziw/~edisp/pw_g320739.pdf.

[16] Health Affairs. "Medicare Advantage Chronic Special Needs Plan Boosted Primary Care, Reduced Hospital Use among Diabetes Patients." January 2012. https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2011.0998.

of their condition to ESRD. Therefore, we encourage CMS to expand the list of C-SNP conditions to include patients with CKD.

In addition, consistent with the Administration's Advancing American Kidney Health initiative, CMS should provide MAOs with the option of participating in the CMMI kidney models to improve the dissemination of best practices in kidney care. With a focus on care coordination and whole person health, Anthem is well-positioned to participate in these programs and achieve the goals of improving CKD management, lowering the incidence of patients progressing to ESRD, increasing ESRD home care, and increasing kidney transplant opportunities through value-based payment arrangements.

Medicare Fee-for-Service (FFS) Coverage of Costs for Kidney Acquisitions for Medicare Advantage (MA) Beneficiaries (§ 422.322) and Exclusion of Kidney Acquisition Costs from Medicare Advantage (MA) Benchmarks (§§ 422.258 and 422.306)

Recommendation Summary: Anthem is concerned CMS' estimate of kidney acquisition costs does not accurately reflect the costs for MAOs. As additional analysis has shown, CMS' current estimate appears to be inflated.[17] We encourage CMS to re-evaluate the estimate of kidney acquisition costs and make the methodology to estimate the kidney acquisition costs more transparent, while considering MAOs' data and actual experience before removing $4 PMPM from the MA benchmarks.

Recommendation Detail: Anthem is concerned about payment accuracy for ESRD beneficiaries in MA, particularly with regard to CMS' estimate of kidney acquisition costs. Beginning in 2021, the 21st Century Cures Act allows all ESRD beneficiaries to join MA and excludes organ acquisition costs for kidney transplants for MA beneficiaries from payment benchmarks, with such costs covered by FFS. CMS estimates a weighted average reduction of about $4 PMPM from the MA ESRD state rates. Based on Anthem's internal analysis, we are concerned CMS is overestimating the impact of excluding kidney acquisition costs from the benchmark, since we interpret the new rule as requiring MAOs to continue to be responsible for the costs associated with the transplant procedure and subsequent medical care.

While CMS provides helpful detail regarding the steps it will take to exclude kidney acquisition costs from MA benchmarks, we ask the agency to release the underlying cost and discharge data to make the methodology more transparent. We are concerned 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. This misalignment may be inflating the total estimated organ acquisition costs.

In addition, we ask that CMS consider MAOs' data and actual experience with kidney acquisition costs, which Anthem estimates to vary by state, and be substantially lower than $4 PMPM. This may be influenced by our interpretation of CMS' calculation of these costs, which reinforces the need for specific detail and further guidance. The discrepancy may also reflect the volatility of the costs of care for this patient population. Because CMS' FFS data includes a greater proportion of kidney transplant patients compared to individual MAOs, we are concerned about the disproportionate impact the $4 PMPM reduction will have on benefits with minimal or no claims reductions to offset this revenue loss.

[17] Wakely. "2021 Medicare Advantage Advance Notice." March 4, 2020. https://www.ahip.org/wp-content/uploads/CY2021-Advance-Notice-Summary-and-Analysis-03-04-2020.pdf.

D. Enhancements to the Part C and D Programs

Reinsurance Exceptions (§ 422.3)

Recommendation Summary: Anthem appreciates CMS' concern that overly generous reinsurance can lead to moral hazard; however, we believe the proposed rule does not accommodate the different uses of reinsurance, or explicitly grant exceptions where the reinsurer and MAO are owned by a common parent. We instead recommend a minimum standard of 10 percent risk assumption where the MAO obtains reinsurance from an affiliate and/or a joint venture or alliance partner.

Recommendation Detail: CMS proposes that an MAO may obtain reinsurance or make other arrangements for the cost of providing basic benefits if the aggregate value of such an arrangement exceeds a $10,000 aggregate per individual (or the first-dollar equivalent).

While Anthem appreciates CMS' desire to balance risk-assumption with potential moral hazard, we would like to make the Administration aware of situations where reinsurance is used for the purpose of allocating risk among participants in an MA venture or alliance. For example, a local plan may wish to pair its market knowledge with the operational expertise of a larger player. The two organizations take on the joint responsibility to administer the product, and use a reinsurance agreement as a mechanism to allocate the proportional profits/losses of the venture or alliance – related to the stake in the venture or alliance.

These types of arrangements can lead to better products for beneficiaries that are higher-quality, have lower administrative costs, and are more tailored to local demands than either participant could do independently. To this end, we believe CMS' proposal is overly broad in its application to reinsurance, and would have unintended consequences by eliminating arrangements designed as profit share distribution mechanisms between participants in the venture or alliance.

In order to accommodate the multiple uses of reinsurance in the business of MA, we propose adopting an alternative standard: an MAO may obtain insurance, reinsurance or make other arrangements for the cost of providing basic benefits to an individual beneficiary that either the aggregate value of which exceeds an aggregate level that is greater than or equal to $10,000 during a contract year or through quota share reinsurance on a first dollar proportional basis, where the MA organization or an affiliate of the MA organization retains a minimum 10 percent quota share percentage of the risks being transferred.

We urge CMS to make accommodations in its proposed regulation for situations where an MAO obtains reinsurance from an affiliate and/or a joint venture or alliance partner. As noted earlier, because reinsurance is a useful means by which to share profits/losses in joint ventures and alliances, an entity may choose to allocate its risk to a reinsurer that is an affiliate of the MAO, and to another joint venture or alliance partner. Again, such arrangements are not about the abdication of risk, but rather serve as a mechanism to facilitate the allocation of profits/losses under the joint venture or alliance.

Out-of-Network Telehealth at Plan Option

Recommendation Summary: Anthem supports CMS' proposal to expand the use of out-of-network telehealth which would allow these services to be covered as a basic benefit.

Recommendation Detail: CMS is considering permitting Additional Telehealth Benefits (ATBs) to be provided by non-contracted providers as a basic benefit in cases where the non-contracted providers satisfy ATB requirements set forth in previously finalized MA regulations.

Anthem supports this flexibility because we believe that out-of-network providers will be able to meet the existing requirements and having telehealth access to more providers in the basic benefit will create additional resources for beneficiaries to get timely and appropriate care. This could be especially valuable where there is a strain on local health care resources resulting from a spike in COVID-19 across a community.

Referral/Finder's Fees (§§ 422.2274 and 423.2274)

Recommendation Summary: Anthem views referrals and enrollment as different activities and thus we recommend CMS consider payment for these activities separately. Therefore, instead of bundling referral fees within the definition of Fair Market Value (FMV), we propose the agency allow for reasonable referral and enrollment fees separate and apart from FMV.

Recommendation Detail: CMS seeks to clarify that compensation is on a per-enrollment basis. Since referral fees are part of compensation, organizations may not pay independent agents more than regulatory limits. Because referral fees are already incorporated into compensation, CMS believes limiting the amount of a referral fee has no impact on the statutory requirement of an agent enrolling a beneficiary in the plan that best meets their healthcare needs. However, in our experience the referring agent is often different than the agent or broker who enrolls the beneficiary. Therefore, we would like to handle the referral and enrollment fees separately, and recommend CMS address payment for these activities separately

Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186)

As detailed below, Anthem has specific recommendations related to 1) measure-level star ratings, 2) adding, updating and removing measures, 3) measure weights, and 4) extreme and uncontrollable circumstances. Overarching all of our comments is a request for flexibility and accommodations related to the ramifications of the ongoing COVID-19 pandemic.

Necessary changes in how we provide beneficiaries with access to care during this time—as well as in requests to our provider partners—will require changes to the Star Ratings program in response. For instance, in the short-term, we encourage CMS to ensure health plans are not encouraging beneficiaries or providers to conduct activities counterproductive to combating COVID-19 such as chart collection, calling to encourage beneficiaries to seek preventive care, and delivery of routine care or non-emergency related screening. At the same time, plans and providers should be encouraging beneficiaries to use telehealth for non-emergency consultation with a provider. As a result, and given that the duration of the public health emergency remains uncertain, larger policy changes and

modifications to the Star Ratings will be necessary as quality measures will be incomplete for 2021 Star Ratings (HEDIS and CAHPS) and 2022 Star Ratings (all measures).

Measure-Level Star Ratings (§§ 422.166(a), 423.186(a))

Recommendation Summary: Instead of removing outliers, Anthem strongly recommends that CMS restore the predetermined thresholds as they provide valuable stability and enable plans to track and achieve known targets over time.

Recommendation Detail: CMS is proposing to remove outlier values via the Tukey outer fence methodology. While Anthem appreciates CMS' focus on providing more stability to the cut points from year-to-year, we believe the best approach to achieve that goal is to return to the previous CMS policy of predetermined thresholds.

Given the significance of the Star Ratings on beneficiary enrollment decisions and plan payment, Anthem continues to believe that sponsors need better information to benchmark performance and focus improvement efforts. Specifically, we recommend that CMS reinstate predetermined 4-Star thresholds. We valued the stability that predetermined thresholds provided and used them as benchmarks to track achievement. We also found the thresholds helpful in setting quality expectations and performance targets jointly with providers to track improvements and design value-based payment arrangements.

If CMS chooses not to reinstate the predetermined 4-Star thresholds, we have concerns with CMS' proposed outlier removal approach. Removing outliers is a statistical approach that is typically employed where there is reason to believe that the outlier values are somehow invalid—for example data entry errors, sampling problems, or measurement issues. Our understanding is that current integrity monitoring should account for these types of issues, so that outliers in the existing star ratings reflect natural variation. We are concerned the approach could further cluster cut points, inaccurately pulling cut points down. Furthermore, one study found it was not possible to replicate CMS' cut point calculations because the agency excludes some contracts' Stars measure data from the published data set. If the goal is to create more cut point stability then using fixed thresholds is a simpler and more transparent approach.[18]

Adding, Updating and Removing Measures (§§ 422.164, 423.184)

Recommendation Summary: Anthem's recommendations on adding, updating, and removing the proposed Star Ratings measures are as follows:

- Rheumatoid Arthritis Management Measure: We support the removal of the Rheumatoid Arthritis Management measure.
- SUPD Measure: We support the categorization of the SUPD measure as a process measure with clinically appropriate exclusions, retaining a weight of 1 for the Star Ratings and Improvement Measures.
- HOS Measures: We encourage CMS not to field the HOS due to COVID-19 as we are concerned beneficiaries should not be asked to respond to surveys at this time. CMS should recognize that the HOS baseline will be significantly impacted by the pandemic, and results should be rated

[18] Wakely. "Proposed Rule Changes to the Medicare Star Rating Program." March 20, 2020.

N/A through at least 2023. In addition, we do not believe the Improving or Maintaining Physical Health (PCS) measure and Improving or Maintaining Mental Health (MCS) measures should continue to be part of the Star Ratings unless modifications produce year-over-year consistency and reliability.

- HEDIS Transitions of Care Measure: We are concerned the Transitions of Care measure in its current form is counter-productive to improving the quality of care transitions from the inpatient setting to the home. We encourage CMS to ensure the measure indicators include all providers who can appropriately support a beneficiary during a care transition, support transition programs that do not require that a beneficiary have a Primary Care Provider (PCP) visit, and provide measure flexibility due to privacy and administrative limitations.
- Emergency Department (ED) Follow-up Measure: We encourage CMS to delay the inclusion of the Follow-up after ED Visits for Patients with Multiple Chronic Conditions measure for an additional two years in order to improve the measure accuracy regarding the transition to home, particularly given the challenges related to the increase in ED visits for COVID-19.
- SNP Care Management Measure: We ask that CMS modify the SNP Care Management measure calculation to better align with compliance standards.

Recommendation Detail:

- Rheumatoid Arthritis (RA) Management Measure: We support CMS' proposal to remove the Rheumatoid Arthritis Management measure from the Part C Star Ratings for the 2021 measurement year and the 2023 Star Ratings. This measure assesses whether patients 18 years and older with a diagnosis of RA were dispensed at least one Disease-Modifying Antirheumatic Drug (DMARD) during the measurement year.

  While we support the goal of aggressively treating RA to achieve clinical remission, minimize irreversible joint damage, preserve function, and improve long-term outcomes, this measure has low reliability. The measure denominator currently includes RA patients in remission without the use of DMARDs, patients who cannot tolerate DMARDs, and patients in clinical trials receiving sample medications. Furthermore, some patients can manage their RA through other medications, and the measure could force the unnecessary use of biologic disease modifying Antirheumatic drugs. Current NCQA HEDIS measure technical guidelines do not provide for medical exclusions, creating barriers for plans to continually improve performance and calling into question the validity of the measure as an indicator of quality care.

- HOS Measures: We encourage CMS to recognize the significant impact COVID-19 will have on the reliability of HOS results. The survey should not be fielded during the pandemic because beneficiaries should not be asked to complete routine surveys as this time. Given the disruption to the HOS we encourage the agency to rate the HOS baseline as N/A through 2023.

  CMS is proposing to change its case-mix adjustment methodology for two measures from the Medicare HOS: the PCS measure and MCS measure. CMS also proposes to increase the minimum required denominator from 30 to 100 for the two measures. Anthem appreciates CMS' efforts to update the HOS survey methodology to more accurately reflect the patient population. Nonetheless, we still have overarching concerns with these measures, and the use of survey measures in general. Unless these modifications lead to results with similar year-over-year reliability as other Star Ratings measures, we advise removing these measures entirely until such consistency can be validated.

We also question the usefulness and validity of having the PCS and MCS measures linked back to death probability rather than actual improved health. We see this as especially concerning where pandemics such as COVID-19 could affect mortality in the Medicare population—creating further instability and inconsistency in plan results.[19]

Furthermore, while Anthem agrees with CMS' assertion that "patients are the ultimate source of information on patient outcomes," we reiterate our serious concerns with the use of survey-based measures in the Star Ratings, which require beneficiary recall and rely on perception rather than data-driven evidence and outcomes. CMS notes the limitation of survey measures in its decision to retire the Osteoporosis Testing in Older Women (Part C) HOS measure for 2023 due to "concerns about the validity of this survey measure and the ability of women to accurately recall their screening history." We continue to believe that any measures contemplated by CMS for inclusion in the Star Ratings system should be based on objective clinical criteria.

As CMS considers the addition of new longitudinal measures from the HOS, we ask the agency to increase the survey's transparency, timeliness, relevance, and data stability. In addition, we would appreciate notification regarding which Anthem beneficiaries completed the HOS so that we may conduct a root causes analysis of any issues raised. Furthermore, there is a long lag time of approximately three years between when the survey begins and when we receive any survey results. We request more real-time data on patient outcomes, so the data can be better utilized for improvement purposes.

- SUPD Measure: While CMS finalized the SUPD measure with the intermediate outcome classification in the April 2019 final rule for the 2021 Star Ratings, the agency no longer believes this is the appropriate classification. Anthem agrees. For consistency, we recommend that CMS retain the SUPD measure's weight of 1 in the 2021 Star Ratings and Improvement Measures. There is wide agreement that the SUPD measure is a process measure, and no aspect of the measure is changing specifically for 2021. Increasing the SUPD measure to a weight of 3 for 2021 and decreasing it to a weight of 1 in future years would create confusion and inconsistency in the Star Ratings program.

  Additionally, we encourage CMS to ensure the measure calculation excludes patients for whom statin use may not be medically appropriate. The medical literature shows certain demographic groups are more likely to be predisposed to statin intolerance. Providers are less likely to prescribe or continue statin use for patients who have experienced diminished effectiveness or adverse effects from the drugs. We are concerned the measure could inaccurately represent prescribing behaviors that reflect patients' medical needs. Given the breadth of clinical concerns related to this measure, we urge CMS to allow medical exclusions for this measure.

- HEDIS Transitions of Care (TOC) Measure: CMS is proposing to add the HEDIS Transitions of Care and the HEDIS Follow-up after Emergency Department Visit for Patients with Multiple Chronic Conditions measures to the 2023 Star Ratings covering the contract year 2021 Performance Period. Measuring the quality of care transitions is a complex and challenging process due to the

[19] William H. Rogers, Ph.D. et al. "Calculating Medicare Health Outcomes Survey Performance Measurement Results." February 2004. https://www.hosonline.org/globalassets/hos-online/publications/hos_calculating_pm_results.pdf.

number of providers and healthcare settings involved. Therefore, Anthem encourages CMS to ensure that the measure indicators include all providers who can appropriately support a beneficiary during a care transition and avoid limiting the measure to PCPs since patients with chronic care needs may be primarily managed by a specialist rather than a general practitioner. We also encourage the measures to accommodate virtual visits given COVID-19 and the expanded use and sophistication of telehealth in recent years.

In addition, MA plans often have programs in place (e.g., visiting nurses, or registered pharmacists who complete the medication reconciliation) to support the transitions home that do not necessarily require that a beneficiary have a PCP visit. These programs provide valuable supports and services to improve the quality of care transitions from an inpatient setting to home and should not be discounted or inadvertently discouraged as a result of this measure.

Furthermore, all component indicators that CMS lists must be satisfied to meet this contemplated measure. We are concerned that combining multiple data elements into one measure will not appropriately account for positive performance on any of the elements. For example, a plan may successfully complete the Medication Reconciliation Post-Discharge element of the measure, but may not be able to guarantee the appropriate documentation of admission and discharge dates in the PCP chart.

We are also concerned with the short timeframe to notify the PCP of an inpatient admission or discharge. Privacy and administrative limitations can prevent health plans from receiving communication that a beneficiary has transitioned from the hospital to their home. In addition, it is important for CMS to provide flexibility, particularly in the case of out-of-network and non-contracted facilities. We are concerned that the measure in its current form could be counter-productive to the ultimate goal of improving the quality of care transitions from an inpatient setting to home.

- ED Follow-up Measure: Anthem supports the concept of this measure, but we note the same concerns with this measure as the TOC measure, discussed directly above, and encourage additional flexibility for capturing follow-up visits. Methods for measuring the quality of transitions home should be validated for feasibility, appropriate methods, and best practices before implementation, particularly given the fact that COVID-19 cases are overwhelming EDs across the country. We are concerned about the accuracy of the methods being used to capture a transition into the home from the hospital and encourage the release of more data to ensure feasibility and reliability before 2021 measurement and 2023 Star Rating inclusion. Once the measure has been validated, it should be designated as a display page measure for another 2 years.

- SNP Care Management Measure: We request that CMS better align the SNP Care Management measure with compliance requirements. Specifically, the current measure does not make allowances for beneficiaries that cannot be reached, refuse to engage, or do not complete a HRA within the specified time. Subtracting these data elements that are already documented through compliance procedures would ensure appropriate data allowances are captured in the measurement calculation. These adjustments will not reduce beneficiary engagement as there is already a minimum number of telephonic outreaches that must be conducted to meet program standards. We encourage CMS to revise the measure formula to assess true compliance with all HRA requirements.

Medication Adherence Star Rating Measure Accuracy

Recommendation Summary: Patient safety and Star Ratings accuracy is compromised when a beneficiary obtains a medication without utilizing their prescription drug benefit, and their pharmacist does not file a claim. Anthem asks CMS to require a pharmacy claim submission process for cash payments, and permit MAOs to submit attestations that show the patient received their medication. This will address situations in which a beneficiary has an extended gap in their fill history, while other supplemental data shows the patient received their medication.

Patient safety issues arise when plans do not know a beneficiary has obtained a prescription medication. Therefore, in the long-term we recommend CMS develop a repository with pharmacy prescription records so that plans can better monitor prescribing and dispending patterns, and track the prescription medications beneficiaries obtain.

Recommendation Detail: The rising availability of free and low-cost generic prescription drugs from pharmacies, direct-to-consumer advertising, and drug discount programs, and the opioid epidemic have contributed to an increase in beneficiaries choosing not to present their prescription drug insurance card, and paying cash for medications. While we appreciate that CMS encourages the use of the Part D benefit, and requires beneficiaries who choose to make a cash purchase for covered Part D drugs to submit documentation to their plan, we have encountered several situations where appropriate claims documentation is not submitted. These situations negatively impact patient safety and the accuracy of Star Ratings data.

We are particularly concerned about patient safety when claims are not processed through the Part D benefit. In these situations, plans are unable to appropriately monitor safety issues such as drug interactions, opioid use, or duplicate therapies, if a beneficiary fills a cash prescription outside of their Part D benefit at a pharmacy to take advantage of a discount program. It is critical that plans are able to conduct concurrent drug utilization reviews to capture and track beneficiaries' medications to ensure patient safety.

Anthem supports efforts to increase medication adherence and patient safety, and also recognizes patients have a choice in how to pay for their medications. However, there are safety concerns when a beneficiary obtains a prescription from a pharmacy and the plan does not know what medication the beneficiary has obtained. To address this situation, we encourage CMS to require pharmacies to submit claims to Part D plans for all cash payments, and permit MAOs to submit attestations that shows the patient received their medication. In the long-term, we support the development of a registry of pharmacy records to boost oversite of prescribing and dispending to improve patient health and safety, and ensure accurate medication adherence Star Ratings scores.

MPF Price Measure Star Rating Accuracy

Recommendation Summary: We are concerned that specialty drug prices constantly fluctuate due to manufacturer pricing decisions, leading to large variances between drug costs at the POS and drug prices on the MPF. Beneficiaries' access to reliable drug pricing information and Star Ratings data depends on the accuracy of the MPF. Therefore, we request that CMS allow for corrections of specialty drug prices during the Star Ratings plan preview window to improve the accuracy of price information for beneficiaries and Star Ratings data.

Furthermore, we would like to work with CMS to increase the efficiency of the process for updating drug prices on the MPF. We also request that the agency consider an exceptions process to allow for larger price variances for high-dollar specialty drugs to hold plan Star Ratings harmless with proof a drug price has changed significantly over a two-week period.

Recommendation Detail: We request that CMS allow for corrections of specialty drug prices during the Star Ratings plan preview window to improve the accuracy of specialty drug price information for beneficiaries and Star Ratings quality data. Prices on brand name drugs change often at the manufacturer's discretion. These changes are not scheduled, and lead to price differences between the MPF and the POS. We encourage CMS to account for pharmaceutical market volatility and create allowances for updating the MPF should a drug have a rapid price swing, negatively impacting the accuracy of drug pricing information for beneficiaries and the MPF price measure data for Star Ratings.

In addition, we would like to work with CMS to increase the timeliness of the process for updating drug prices on the MPF. We are concerned that making drug price changes on the MPF can take two to four weeks, while specialty drug prices can change daily. This delay between the pricing at the POS and updates to the MPF cause higher dollar discrepancies for beneficiaries at the pharmacy counter.

As challenges ensuring the accuracy of the MPF are likely to persist, we request that the agency consider an exceptions process, similar to processes that already exist in the Part D program, to allow for larger price variances for high-dollar specialty drugs to hold plan Star Ratings harmless with proof a drug price has changed significantly over a two-week period. A 2019 AARP study found 267 widely used brand name prescription drugs increased by 5.8 percent, more than twice as fast as inflation in 2018.[20] In addition, the ratio of the increase in specialty drug prices compared to the inflation rate has increased over the past 10 years.[21] The high volume of price changes in the specialty drug market over the past decade necessitates a different process to ensure accurate MPF drug pricing data.

Measure Weights (§§ 422.166(e), 423.186(e))

Recommendation Summary: Anthem opposes increasing the weight of patient experience and complaint measures to 4, well above the weight of clinical outcomes measures. We are concerned about the unprecedented shift away from the objective clinical Star Ratings measures. Any change regarding the weight of the patient experience and complaint measures should be preceded by a critical evaluation of the CAHPS and HOS surveys given concerns about decreasing response rates, and the accuracy and reliability of survey results.

These concerns could be exacerbated this year as HOS vendors have been instructed by CMS to hold on any mailing of the surveys for 2020 given COVID-19, which could further decrease response rates impacting the accuracy and reliability of survey results. While we appreciate that the survey will be postponed until the summer, we are concerned about the long-term impact of the public health crisis on respondent's physical and mental health, and their perception of the health care system and health plans.

[20] AARP Public Policy Institute. "Brand Name Drug Prices Increase More than Twice as Fast as Inflation in 2018." November 2019. https://www.aarp.org/content/dam/aarp/ppi/2019/11/brand-name-drug-prices-increase-more-than-twice-as-fast-as-inflation.doi.10.26419-2Fppi.00073.005.pdf.

[21] Journal of Managed Care & Specialty Pharmacy. "Evaluation of Specialty Drug Price Trends Using Data from Retrospective Pharmacy Sales Transactions." September 22, 2016. https://www.jmcp.org/doi/full/10.18553/jmcp.2016.22.9.1010.

If CMS increases the weight of this measure without addressing these concerns, the Star Ratings could be inaccurate and mislead beneficiaries. We encourage CMS to continue to base the Star Ratings on a comprehensive, objective, quality review system. While we appreciate the importance of ensuring patients have a positive experience, and appropriate access to care, we encourage a slower and more thoughtful transition to increasing the weight of patient experience and complaint measures.

Recommendation Detail: CMS is proposing to increase the weight of patient experience/complaints and access measures to 4 after increasing the weights from 1.5 to 2 for the 2021 Star Ratings. We are concerned that such a change would represent a fundamental, unprecedented shift where CMS is moving the Star Ratings system away from objective clinical measures to subjective measures. As a result, beneficiary experience measures will increase from around a quarter, to half of Star Ratings measures creating a fundamental imbalance based on subjective results from a sample population of plan beneficiaries surveyed, which undermines the purpose of a comprehensive quality review system.

If CMS plans to increase the use of CAHPS and HOS, we encourage the agency to critically assess the accuracy and reliability of the surveys. Both surveys need to be modernized as response rates decline, and both beneficiaries and practitioners are suffering from survey fatigue (the surveys contain nearly 100 questions, many of which include unclear language). Additionally, operationalizing the surveys is challenging (there are only two CMS vendors that can deploy the surveys) and they have not kept pace with current survey methods and technologies. Furthermore, the transparency of the surveys could be improved as CMS does not make public the measure level response data among plans.

Lastly, the CAHPS and HOS measures should be removed from the improvement factor calculation because survey data are based on respondents' perceptions of their health status, that can change based on circumstances like COVID-19, and thus are not a true reflection of plan performance or beneficiaries' outcomes. If performed inconsistently, the improvement comparison will not be valid—further emphasizing the importance of excluding CAHPS and HOS measures from this calculation.
If CMS continues to use surveys, then we encourage CMS to survey beneficiaries throughout the year, rather than rely on a single survey that captures just one point in time. In addition, we ask CMS to inform plans of the beneficiaries they have surveyed so that we may reach out to conduct root cause analyses to address any issues they identified. We stand ready to partner with CMS to update the CAHPS and HOS surveys to improve the accuracy of the patient experience and complaint measures.

Extreme and Uncontrollable Circumstances (§§ 422.166(i), 423.186(i))

Reset Star Rating Program to Acknowledge Impacts of COVID-19

Recommendation Summary: While we appreciate CMS' proposals in the interim final rule to modify the calculation of the 2021 and 2022 Part C and D Star Ratings to address the disruption to data collection and measure scores, we are concerned the agencies proposals do not do enough to account for the full impact of the COVID-19 public health emergency on Star Ratings. We encourage the agency to make necessary changes to the 2021 and 2022 MA Star Ratings to enable plans to fully shift focus and attention to improving beneficiaries' care under these unique circumstances, and redeploy trusted resources to help members remain safely in their homes to help avoid the further spread of the virus.

We have altered our approach to ensuring our beneficiaries have access to care to comply with the CDC guidelines and the social distancing mandate to avoid large crowds. We recognize our previous focus on preventive and primary care would be counterproductive, and could lead to further spread of the virus

or take time away from emergent and urgent patient care. Therefore, we are focused on our beneficiaries' needs as they may have to self-isolate, quarantine, or shelter in place. In addition, we have shifted our efforts to ensure access to food, home care, and mail order and home delivered prescriptions, and we are encouraging beneficiaries to participate in programs to address potential depression, anxiety, or social isolation such as our Member Connect Phone Pal program.

Due to the COVID-19 pandemic, the 2021 and 2022 Star Ratings will not accurately measure the quality of MA and Part D plans across the country, and data will be incomplete at a minimum for 2021 and 2022 Star Ratings. We recommend that the agency does not calculate Stars for rating years 2021 and 2022, as is, and resets the Star Ratings program beginning with measurement period January 2021 for 2023 Star Ratings.

In the short-term, we recommend CMS provide the following immediate guidance on the Star Ratings to enable plans to focus interactions with beneficiaries and providers on the treatment and prevention of COVID-19:

- Suspend chart pulls for Healthcare Effectiveness Data and Information Set (HEDIS) measurements;
- Enable plans to shift focus from inquiries to providers as a basis for measuring Stars;
- Enable plans to cease outreach to beneficiaries for non-emergent care as a basis for measuring Stars.
- Account for the pandemic in the standard operational processes that may be impacted such as the Complaint Tracking Module (CTM); and
- Suspend enforcement of standards/metrics impacted by COVID-19, except actions that impact beneficiary access to care or the absence of which may pose potential beneficiary harm.

In the long-term, we encourage CMS to use its demonstration authority to develop an industry-wide standard that appropriately measures quality during this pandemic and provides plans with 3.5 or 3 Star Ratings with the opportunity to earn a QBP for contract years 2022 and 2023 (2021 and 2022 Star Ratings) of at least 3.5 percent. We encourage the agency to avoid using data affected by COVID-19 and other extreme and uncontrollable circumstances in the Star Ratings calculations. If CMS does not make broader changes to the Star Ratings program due to the pandemic, at a minimum, the agency should consider a broader view of the extreme and uncontrollable circumstances policy.

Recommendation Detail:

The Star Ratings will not accurately measure quality during this pandemic, and data will be incomplete at a minimum in 2021 and 2022. We appreciate CMS' efforts to maintain and improve care for beneficiaries during this public health emergency, and encourage the agency to make necessary changes to the Star Ratings to enable plans to shift focus and attention to addressing the quality of patient care during this pandemic. CMS should partner with plans to deploy trusted resources to help beneficiaries remain safely in their homes to help avoid the further spread of the virus.

Below are examples of activities that Anthem has implemented to prioritize our beneficiaries' health during this challenging time:

- Providing access to COVID-19 testing at no cost: Anthem is providing coverage of the coronavirus screening test at no out-of-pocket-cost by waiving copays, coinsurance and deductibles for the diagnostic test related to COVID-19.
- Encouraging broader use of telehealth: Our beneficiaries can see a doctor online, and receive virtual care, and flexible pharmacy benefits. For 90 days, Anthem's affiliated health plans will waive any beneficiary cost-share for telehealth visits, including visits for mental health, for our fully insured employer plans, Individual plans, Medicare plans and Medicaid plans, where permissible. In addition, we have deployed the Sydney Care COVID-19 symptom assessment tool to help determine a patient's risk for COVID-19, and whether they should visit their local health care provider for testing. To comply with the CDC guidelines and social distancing mandate to avoid large crowds, we have stopped in-person events that enabled on-site screenings/testing and beneficiary education.
- Relaxing early prescription refill limits: We are relaxing early prescription refill limits for beneficiaries who wish to receive a 30-day supply of most maintenance medications, where permissible. We are also encouraging beneficiaries who have a pharmacy plan that includes a 90-day benefit to talk to their doctor about whether changing from a 30-day supply to a 90-day supply of any prescription medicines they take on a regular basis is appropriate.
- Expanding access to 24/7 NurseLine: beneficiaries can use Anthem's 24/7 NurseLine if they suspect symptoms of COVID-19. Our nurses ask additional questions to beneficiaries with respiratory symptoms and coach members to use updated HealthWise Connect COVID-19 information and the CDC web site.
- Conducting outreach to beneficiaries: Anthem is conducting outreach call campaigns to provide beneficiaries with a touch point to answer questions, address any fears or concerns about access, and address social isolation.

The recommendations below assume the public health emergency has ended and the number of affected beneficiaries impacted has greatly decreased by January 1, 2021. For the 2021 and 2022 Star Ratings, we would recommend CMS immediately:

- Suspend chart pulls for Healthcare Effectiveness Data and Information Set (HEDIS) measurements: Impose an industry-wide cease and desist of HEDIS Medical Record Review (MRR) and follow-up to ask providers for charts and less time sensitive information. We are concerned unnecessary contact with providers can take time away from caring for patients, and many offices have closed to non-urgent patient visits. Furthermore, this change will enable plans to redeploy resources to serve our beneficiaries and collaborate with providers to support efforts to combat COVID-19.
- Enable plans to shift focus from inquiries to providers as a basis for measuring Stars: Given pandemic-related challenges we would appreciate guidance enabling plans to cease activities designed to improve Star Ratings including provider engagement activities related to preventative screenings, such as mammograms, which are considered non-emergency health services.
- Enable plans to cease outreach to beneficiaries for non-emergent care as a basis for measuring Stars: Provide guidance enabling plans to cease outreach that would be counterproductive to beneficiaries' health such as encouraging members to seek non-emergency health services

(e.g., participating in preventive screenings, making a primary care appointment), or asking beneficiaries to respond to the CAHPS or the HOS surveys at this time. To prevent the further spread of the virus, CMS should suspend any Star Ratings measures that require non-emergency care from a provider. Part C and D HEDIS measures will be particularly impacted, and CMS has already recommended postponing non-essential medical, surgical, and dental procedures during the COVID-19 response.

- Account for the pandemic in the standard operational processes that may be impacted such as CTMs: Given the impact of COVID-19 on beneficiary access as providers are deployed to focus on COVID-19 emergencies, and many providers are limiting or ceasing non-emergency visits to ease the spread of the virus, we are concerned about a potential increase in beneficiary complaints. We encourage the agency to account for the challenges of this public health emergency by holding plans harmless for CTMs outside of their control.
- Suspend enforcement of standards/metrics impacted by COVID-19: We urge the agency to waive all enforcement of standards/metrics that are impacted by the rapid proliferation of new COVID-19 guidance and administrative decisions (e.g., customer service metrics due to increased call volumes), except those that impact beneficiary access to care or the absence of which may pose potential beneficiary harm. Furthermore, we encourage the delay of all audits such as data validation, program, and financial audits to enable MAOs to focus on addressing beneficiaries' needs during the COVID-19 pandemic.
- Consider extending the telehealth flexibilities: We encourage the agency to allow telemedicine visits as valid encounters for documentation of diagnosis codes used for the calculation of risk scores. In addition, we expect that beneficiaries will have lingering concerns related to provider visits even after the pandemic, therefore, CMS should extend the telehealth flexibilities beyond the public health emergency.

During this public health emergency, the Star Ratings program should move away from the current approach of contract-level ratings, towards measuring best practices to provide quality care for beneficiaries across the MA program during the pandemic. If changes to the Star Rating program are not made, plans could conduct activities that are counterproductive to the health and welfare of beneficiaries and frontline health workers.

Due to the pandemic, reporting of quality measures will be incomplete for 2021 Star Ratings (HEDIS and CAHPS) and 2022 Star Ratings (all measures). The Star Ratings program is designed to measure health quality across the country. However, states, counties, and cities are putting in place different public health protocols to combat COVID-19, therefore, it will not be possible to fairly measure Star Ratings in 2021 or 2022.

We encourage CMS to develop an industry-wide standard that appropriately measures quality during this pandemic. We encourage the agency not to calculate Stars for rating years 2021 and 2022, as is, and reset the Star Ratings program beginning with measurement period January 2021 for 2023 Star Ratings. At a minimum, plans with a rating of 4 or more stars for the 2020 Star Ratings should continue to earn a QBP for Revenue Years 2022 and 2023. To improve program stability, all other plans with 3 and 3.5 stars in 2020 should be eligible earn up to a 3.5 percent QBP in 2022 and 2023. CMS should use its demonstration authority to make these changes.

Expand the Definition of Impacted Organizations

Recommendation Summary: We encourage the agency to avoid using data affected by COVID-19 and other extreme and uncontrollable circumstances in the Star Ratings calculations. If the agency does not make broader changes to the Star Ratings program due to the pandemic, at a minimum, the agency should consider a broader view of extreme and uncontrollable circumstances. Specifically, we request that CMS expand eligibility for the policy in the event of a state or local public health emergency, when the HHS Secretary declares a public health emergency, or in the event of a FEMA emergency or FMAG declaration for which public or individual assistance is available.
We are particularly concerned that unprecedented high-wind events, resulting in fires and evacuations across California in 2019, are not included in the list of events in the Advanced Notice that authorize the HHS Secretary to temporarily modify or waive Medicare requirements. We encourage CMS to include the fires and extreme weather conditions in California that led the Governor to declare a statewide emergency to the list of extreme and uncontrollable circumstances to achieve accurate performance measurements in the Star Ratings program.[22]

Outbreaks such as the COVID-19 pandemic may cause supply chain disruptions, prescription drug shortages, and prevent beneficiaries from obtaining necessary care, which represent extreme events over which plans have little to no control. To account for these incidents, we encourage CMS to expand and align the processes the agency plans to implement as the COVID-19 situation evolves. The agency should also consider permitting plans to make the case for such a determination by providing an impact assessment of the effect of the event on its beneficiaries and operations.

Recommendation Detail: Anthem appreciates CMS' acknowledgment of the impact of natural disasters and extreme and uncontrollable circumstances through the development of the Star Ratings policy, as well as efforts to work with plans, providers, and beneficiaries negatively impacted. We are committed to providing access to high-quality care and support services to beneficiaries living in areas impacted by disasters, and public health emergencies like COVID-19, and we are eager to work with CMS to ensure beneficiaries continue to receive necessary services and quality care despite uncontrollable circumstances. We recommend CMS expand the criteria required to trigger the Star Ratings policy, as implementation of the current policy has sparked confusion for both beneficiaries and MAOs experiencing extreme and uncontrollable circumstances.

When a federal or state emergency or disaster is declared, Anthem acts quickly to inform beneficiaries and providers of benefit changes. We work to ensure our beneficiaries receive timely access to needed healthcare services by removing barriers, making outreach calls, and expanding access to providers, medications, and replacement equipment and supplies. For example, in 2018 we leveraged our LiveHealth Online telehealth service and Employee Assistance Program to help residents in Alabama, Florida, Georgia, and North Carolina impacted by Hurricane Michael.[23] We have acted during hurricanes, fires, floods, and earthquakes to address our beneficiaries' needs – and we are currently acting quickly to care for COVID-19 patients; however, not all of these events are taken into consideration by CMS' extreme and uncontrollable circumstances policy.

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[22] Office of Governor Gavin Newsom. "Governor Newsom Declares Statewide Emergency Due to Fires, Extreme Weather Conditions." October 27, 2019. https://www.gov.ca.gov/2019/10/27/governor-newsom-declares-statewide-emergency-due-to-fires-extreme-weather-conditions/.

[23] Anthem. "Anthem Activates Plan to Help Residents Impacted by Hurricane Michael". October 11, 2018. https://ir.antheminc.com/news-releases/news-release-details/anthem-activates-plan-help-residents-impacted-hurricane-michael?field_nir_news_date_value[min]=.

Currently, the policy limits Star Ratings adjustments to "emergency areas" for "emergency periods," where Stafford Act declarations of a major disaster are applicable. In addition, the Secretary must exercise authority to temporarily modify or waive certain Medicare provisions as a result of the disaster. Finally, beneficiaries must reside in FEMA-designated individual assistance areas at the relevant time. The policy fails to acknowledge State disaster declarations, FEMA emergency declarations, or FMAG declarations that provide funds to assist in combating wildfires. The policy also fails to acknowledge state and local public health emergencies, or a public health emergency declared by the HHS Secretary absent a section 1135 waiver. Furthermore, the policy is limited to FEMA-designated individual assistance areas, but does not include instances where FEMA designates public assistance and hazard mitigation assistance areas in order to provide aid in the wake of disasters that impact local communities.

Because the current policy fails to acknowledge the impact of all disaster types on beneficiaries and MAO operational and clinical systems, the Star Ratings do not reflect the full impact of extreme and uncontrollable circumstances. This has led to inconsistencies in the quality measurement data used to calculate Star Ratings, affecting the accuracy of the quality data beneficiaries rely on to make informed plan decisions.

In particular, California has been hard hit over the past three years by large fires, other natural disasters, and now COVID-19. The fires prompted the HHS Secretary to issue a public health emergency effective February 6, 2019, as a result of the continued consequences of the wildfires on the State of California.[24] In 2019 alone, FEMA issued ten FMAG declarations for California to combat active wildfires.[25] [26]

In just one example, in October 2019, the Saddle Ridge Fire burned in Los Angeles County for 21 days, killing one person, injuring eight, destroying 19 structures and damaging 88 others, burning 9,000 acres of land, threatening 1,069 homes, and requiring the mandatory evacuation of roughly 10,000 people in and around the communities of Sylmar and Granada Hills in Los Angeles County. On October 11, Governor Newsom declared a State of Emergency in Los Angeles due to the Saddle Ridge Fire.[27] On October 11, FEMA issued an FMAG declaration for the Saddle Ridge Fire, releasing public and hazard mitigation assistance. Despite the devastating disaster, the fact that over 40,000 Anthem beneficiaries reside in Los Angeles County, and 36 percent of the members in our California HMO contract H0544 were impacted, the event did not qualify for the Star Ratings adjustment in the extreme and uncontrollable circumstances policy because the fire did not receive a major disaster declaration.

CMS has acknowledged that plans complete many preventive screenings at the end of the calendar year, so disasters towards the end of the year may have an inordinate impact on Star Ratings. These events had the potential to impact beneficiaries' ability to receive preventive screenings, and necessary care, yet no California counties are eligible for Star Ratings relief in 2021.

Furthermore, the policy as currently written is so narrowly tailored that this year only the earthquakes in Puerto Rico qualified. Despite persistent disasters, over time the number of contracts that meet the

[24] HHS, Public Health Emergency. "Renewal of Determination that a Public Health Emergency Exists." February 6, 2019. https://www.phe.gov/emergency/news/healthactions/phe/Pages/ca-wildfires-renew-30Jan2019.aspx.
[25] FEMA. "Disasters." www.fema.gov. Accessed February 19, 2020. https://www.fema.gov/disasters.
[26] FEMA. "The Disaster Declaration Process." Accessed February 19, 2020. https://www.fema.gov/disaster-declaration-process.
[27] Office of Governor Gavin Newsom. "Governor Newsom Declares State of Emergency in Los Angeles and Riverside Counties Due to Fires." October 11, 2019. https://www.gov.ca.gov/2019/10/11/governor-newsom-declares-state-of-emergency-in-los-angeles-and-riverside-counties-due-to-fires/.

eligibility criteria has steadily declined. In 2019, 77 contracts met the 25 percent threshold, and 57 met the 60 percent threshold. Therefore, of the 376 MA-PD contracts with a Star Rating in 2019, 20 percent of contracts met the 25 percent threshold, and 15 percent of contracts met the 60 percent threshold. However, in 2020, only 23 contracts met the 25 percent threshold (including one PDP), and 8 met the 60 percent threshold. Of the 401 MA-PD contracts with a Star Rating in 2020, only 5 percent of contracts met the 25 percent threshold and 2 percent of contracts met the 60 percent threshold.

The extreme and uncontrollable circumstances policy should take into account all local, state and federal public health emergency and disaster declarations to provide a consistent and accurate view of plan quality in impacted areas. CMS should consider the impact of California wildfires that are becoming an almost annual disruption to Medicare beneficiaries and Star Ratings data, and allow the FMAG declaration when public assistance is available to qualify for relief. Expanding the current policy will ensure that beneficiaries are not unfairly penalized by fewer plan benefit options when quality thresholds are impacted by extreme and uncontrollable circumstances.

Align the Definition of Impacted Organizations

Recommendation Summary: We encourage CMS to align its policies related to disasters, catastrophic events, and public health emergencies across the MA program. Harmonizing the thresholds used to require MAOs to provide benefit flexibilities, Special Enrollment Periods (SEPs), and pharmacy access will provide expanded relief for beneficiaries and ensure accurate quality measurement in the event of extreme and uncontrollable circumstances.

Recommendation Detail: Aligning Star Ratings disaster relief with the thresholds used to determine eligibility for benefit accommodations for plan beneficiaries will provide a more rational and seamless application of CMS' disaster relief provisions. In the Advanced Notice, CMS limits the Star Ratings waivers to FEMA major disaster declarations, and enumerates additional criteria that limits the application of accommodations for Star Ratings. We have identified at least four conflicting CMS policies that provide guidance to MAOs with respect to emergency access to provider networks and medications in the event of an emergency.

First, Section 150 in chapter four of the Medicare Managed Care Manual (MMCM) outlines certain MA benefit limitations that may be waived in the event of a Presidential emergency declaration, a Presidential (major) disaster declaration, or a declaration of emergency or disaster by a Governor.[28] Specifically, MAOs must allow Part A and Part B and supplemental Part C plan benefits to be furnished at specified non-contracted facilities, waive requirements for gatekeeper referrals, and reduce plan-approved out-of-network cost-sharing to in-network cost-sharing amounts.

Second, Section 30.4.4 of chapter two in the MMCM provides the HHS Secretary with authority to establish SEPs when beneficiaries are affected by a FEMA-declared weather related emergency or major disaster.[29] A beneficiary must reside in an area for which FEMA has declared an emergency or a major disaster and has designated affected counties as eligible to apply for individual or public level assistance.

[28] CMS. "Medicare Managed Care Manual - Chapter 4 - Benefits and Beneficiary Protections." April 22, 2016. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf.
[29] CMS. "Medicare Managed Care Manual - Chapter 2 - Medicare Advantage Enrollment and Disenrollment." July 31, 2018. https://www.cms.gov/Medicare/Eligibility-and Enrollment/MedicareMangCareEligEnrol/Downloads/CY_2019_MA_Enrollment_and_Disenrollment_Guidance.pdf.

In addition, the SEP is available to individuals who don't live in the affected areas, but rely on help making healthcare decisions from friends or family members who live in affected areas.

Third, in Chapter 5 of the Prescription Drug Benefit Manual (PDBM) Manual, CMS requires that if a Presidential major disaster or emergency declaration is issued or the Secretary declares a public health emergency, plan sponsors must lift "refill-too-soon" edits.[30] CMS also requires Part D sponsors to allow affected beneficiaries to obtain the maximum extended day supply, if available at the time of refill.

A fourth guidance document outlines expectations of Part C and Part D plan sponsors in the event of a Presidential emergency declaration, a Presidential (major) disaster declaration, a declaration of emergency or disaster by a Governor, or an announcement of a public health emergency by the Secretary—but absent an 1135 waiver by the Secretary. [31] The HPMS memo from 2009 combines and clarifies requirements in MA and Part D. We encourage CMS to release more comprehensive and expansive updated guidance.

We are concerned the misalignment of disaster thresholds across the MA program undermines appropriate relief to beneficiaries and plan sponsors. CMS should harmonize the thresholds, using more expansive qualifications, to ensure appropriate flexibilities in the event of extreme and uncontrollable circumstances. An emergency or disaster declaration at the local, state, or federal level should allow impacted beneficiaries to access additional benefits and prompt CMS to provide flexibility in the quality assessment of plans operating in impacted areas in order to provide appropriate and consistent relief across the program.

Aligning the type of declarations required to permit benefit limitation waivers and SEPs, as well as trigger the extreme and uncontrollable circumstances policy in Star Ratings, will greatly benefit beneficiaries recovering from the effects of emergencies, and help smooth operational challenges as plans respond to such events. We encourage CMS to further refine its extreme and uncontrollable circumstances policies across the MA program.

Avoid Penalizing Beneficiaries in the Event of a Disaster

Recommendation Summary: Anthem requests that CMS re-evaluate the application of the extreme and uncontrollable circumstances policy to contracts impacted across multiple years, and to improvement measures, to hold beneficiaries harmless. Currently, when a contract is impacted across three years, CMS will only provide relief over one year, rather than two years. Additionally, for improvement measures if the plans' Star Ratings are the same, CMS applies the more recent rating, even if the underlying measure scores are not the same.

The current policy fails to hold beneficiaries harmless by limiting the availability of quality bonus payments that plans use to lower cost-sharing and increase benefits for beneficiaries. Moving forward, CMS should account for every year the contract experiences an extreme and uncontrollable circumstance by providing relief over multiple years. In addition, if a contract gets the same Star Rating

[30] CMS. "Medicare Prescription Drug Benefit Manual – Chapter 5." September 20, 2011. https://www.cms.gov/Medicare/Prescription-Drug Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf.
[31] CMS, Center for Drug and Health Plan Choice. "Pharmacy and Provider Access during a Federal Disaster or Other Public Health Emergency Declaration," July 20, 2009.

in both years, CMS should take the higher of the two years' measure scores in order to ensure that plans and beneficiaries are truly held harmless in the event of a disaster.

Recommendation Detail: CMS' Disaster Adjustment policy is designed to take into account the effects of natural disasters, while holding beneficiaries and contracts harmless when uncontrollable conditions affect plan performance. CMS proposes if a contract experienced extreme and uncontrollable circumstances in 2022, the 2021 Star Ratings may be used, however, the 2021 Star Ratings would not be used in determining the 2023 Star Ratings if the contract was once again impacted by extreme and uncontrollable circumstances. Therefore, CMS does not take into account double impacted contracts.

In some areas of the country our contracts have experienced three straight years of natural disasters. We are concerned about CMS' proposal not to grandfather in extreme and uncontrollable circumstance relief across multiple years. We encourage CMS to grant relief beyond two years of disasters and recognize that only data that is not impacted by such circumstances should be used to calculate accurate Star Ratings measures.

Furthermore, to calculate improvement measures in light of a disaster, CMS compares the current, and previous years of a contract's Star Ratings and uses the higher Star Rating (or more recent if the two are equal) and corresponding measure scores. We are concerned the current methodology does not achieve the goal of holding beneficiaries and plans harmless the agency does not take the higher measure scores in the year in which an extreme or uncontrollable circumstance occurred.

Anthem beneficiaries in Florida experienced such an unintended consequence in the application of the disaster adjustment policy. Simply Healthcare Plans, Inc. (Simply) serves Medicare beneficiaries in South and Central Florida. Due to Hurricane Irma in September 2017, the policy was applied. However, CMS did not apply the higher of the two-year measure scores to calculate the health plan improvement measure (Measure C31). Simply's Star Ratings for three measures (measures C02: Colorectal Cancer Screening; C24: Getting Appointments and Care Quickly; C28: Care Coordination) were consistent across 2017 and 2018; but, the measure score was lower in 2018. Despite the disaster adjustment policy, CMS did not use the higher of the two measure scores because the Star Ratings were the same. The lower measure scores were used in the improvement calculation, negatively impacting the plan's overall Star Rating. Perversely, the contract would have been better off had it not made any attempts to perform well on the measure in the wake of the natural disaster, which would have negatively impacted beneficiaries.

The current policy inadvertently penalizes beneficiaries in plans like those described above. Moving forward, if a contract is impacted over multiple years, CMS should look back to the most recent unaffected year's data. In addition if a contract gets the same Star Rating in both years, CMS should take the higher of the two years' measure scores in order to ensure that plans are truly held harmless in the event of a disaster. At minimum, CMS should exclude the measure from the quality improvement calculation.

Lower Threshold of Impacted Beneficiaries

Recommendation Summary: Anthem encourages CMS to lower the 25 percent threshold of membership affected by extreme and uncontrollable circumstances to 20 percent.

Recommendation Detail: We ask CMS to reconsider the 25 percent threshold proposal that triggers the extreme and uncontrollable circumstances policy in the Star Ratings. While we appreciate CMS' attention to extreme and uncontrollable circumstances that may impact MA and Part D contract performance on Star Ratings measures and/or measure level data, we are concerned requiring contracts to have 25 percent of enrollees residing in a FEMA-designated individual assistance area at the time of the extreme and uncontrollable circumstance is setting the threshold too high. Instead, we encourage CMS to lower the threshold to 20 percent of enrollees impacted by uncontrollable circumstances, because at this lower percentage Star Ratings are materially affected.

There is precedence for a 20 percent threshold. For example, CMS asserted that for the purposes of determining quality performance scoring for performance year 2017, if 20 percent or more of an Accountable Care Organization's (ACO's) assigned beneficiaries reside in an area impacted by the disaster, the ACO's minimum quality score will be set to equal the mean Shared Savings Program ACO quality score for all ACOs for performance year 2017.[32] We encourage CMS to revisit the 25 percent threshold to harmonize extreme and uncontrollable circumstance policies across Medicare programs.

Assess Natural Disasters in Aggregate

Recommendation Summary: In California in 2019, wildfires, severe storms, and earthquakes impacted thousands of Anthem beneficiaries, and in two contracts, 25 percent and 57 percent of beneficiaries were impacted when the disasters are analyzed in aggregate. However, the current policy requires that at least 25 percent of enrollees must reside in a FEMA-designated individual assistance area at the time of the incident. We encourage CMS to clarify its methodology to look at natural disasters in aggregate, rather than per incident.

Recommendation Detail: We encourage CMS to clarify and revise its methodology to look at natural disasters in aggregate. Currently, it is unclear how the proposed policy impacts a contract with different beneficiaries affected by different disasters at different time periods. For example, a group retiree contract with members across the country may not qualify for relief because beneficiaries experience different disasters in a given year that do not individually meet the 25 percent threshold.

As shown in the data enclosed in our comments, in 2019, different beneficiaries were negatively impacted by wildfires, severe storms, and earthquakes across California. In this situation, we may not meet the required threshold for any one disaster, but we would meet the threshold when these disasters are considered in their totality. Anthem requests clarification from CMS on how to calculate the relative percentages of beneficiaries impacted by the extreme and uncontrollable circumstances policy. We encourage CMS to holistically assess the impact of natural disasters in determining application of the policy.

Permitting a Second, "Preferred," Specialty Tier in Part D (§§ 423.104, 423.560, and 423.578)

Recommendation Summary: Anthem appreciates CMS' proposal to allow for a second, preferred specialty tier. However, we are concerned the proposal in its current form will lead to higher plan costs, which in turn will increase premiums for beneficiaries. To minimize premium increases, we recommend

[32] Federal Register. "Medicare Program; Medicare Shared Savings Program: Extreme and Uncontrollable Circumstances Policies for Performance Year 2017." December 2017. https://www.govinfo.gov/content/pkg/FR-2017-12-26/pdf/2017-27920.pdf.

that CMS increase the maximum cost-sharing on the preferred specialty tier to between 25 and 33 percent coinsurance and increase the maximum cost-sharing on the non-preferred specialty tier to between 30 and 40 percent coinsurance (depending on a plan's deductible).

Recommendation Detail: CMS proposes to allow Part D sponsors to establish up to two specialty tiers and design an exceptions process that exempts Part D drugs on these tiers from tiering exceptions to non-specialty tiers. To implement this proposal, CMS would require that if a Part D sponsor has a plan with two specialty tiers, one must be a preferred tier that offers lower cost-sharing than the higher cost-sharing tier, which is subject to the proposed maximum allowable specialty-tier cost-sharing. CMS also proposes to permit Part D sponsors to determine which drugs are placed on each tier.

We appreciate CMS' effort to establish a second, preferred specialty tier. As CMS notes, this feature could improve plans' ability to negotiate with manufacturers to lower drug prices for beneficiaries. However, because cost-sharing on the non-preferred tier would not be permitted to exceed 33 percent, we are concerned that, as proposed, the additional specialty tier flexibility would put upward pressure on premiums, particularly if Part D sponsors cannot reduce net plan costs through higher rebates.

Given the potential for increased plan liability, we recommend CMS permit Part D sponsors to set the maximum permissible cost-sharing to between 25 to 33 percent coinsurance on the preferred specialty tier and between 30 and 40 percent coinsurance on the non-preferred specialty tier depending on the plan's deductible.

Related to this proposal, we also ask CMS to clarify that the second specialty tier would be in addition to the total allowed number of drug tiers, rather than in place of an existing tier.

Tier Composition

We support CMS' proposal to allow Part D sponsors to place both brand-name drugs as well as generic drugs and biosimilars on the preferred tier. If the preferred specialty tier were limited only to certain types of drugs, the ability to negotiate with manufacturers and generate meaningful reductions in drug costs for beneficiaries would be diminished.

Tiering Exceptions

We also support CMS' proposal to exempt drugs on the specialty tiers from tiering exceptions to non-specialty tiers. We ask that plans only be required to permit tiering exceptions for drugs on the non-preferred specialty tier to the preferred specialty tier if CMS increases the maximum cost-sharing amounts on the preferred specialty tier as per our recommendation above. We believe this proposal strikes the appropriate balance of affordability and access.

Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128)

Recommendation Summary: Anthem supports providing beneficiaries with tools to understand and compare costs for prescription drugs. However, we recommend CMS delay the implementation date for the beneficiary RTBT requirement until 2024 to ensure adequate time to build and test these capabilities.

Recommendation Detail: CMS is proposing to require Part D sponsors to implement a beneficiary RTBT that would allow beneficiaries to view accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information, effective January 1, 2022.

Anthem supports the development of RTBTs and believes the information provided to clinicians and beneficiaries through these tools can enhance shared decision-making and ultimately improve adherence and clinical outcomes. Given that prescribers now have access to RTBTs to provide beneficiaries with complete, accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information at the point of prescribing, we ask that the agency provide more time for development of a beneficiary-specific RTBT. The implementation of these tools to CMS' specifications will take time, resources, design, development, and testing. It's important to be thoughtful as we overlay our existing capabilities with uniform industry-wide standards.

We are concerned that premature requirements for functional capabilities and implementation will result in the deployment of tools that are not as useful to beneficiaries as they could otherwise be. Furthermore, because our planning, designing, and implementation of technology-based solutions is an 18-24-month process, should CMS move forward with the proposed effective date, we recommend January 1, 2022, be a date for voluntary adoption of RTBTs, with their required use by January 1, 2024. This extension would also make it more likely that uniform standards are sufficiently developed to allow for the effective implementation of beneficiary RTBTs.

Finally, we support the proposed flexibility to exclude the negotiated price of a drug from beneficiary RTBTs. Presenting this information to beneficiaries in addition to their out-of-pocket costs, may become too confusing and burdensome and does not provide meaningful information to most beneficiaries.

Establishing Pharmacy Performance Measure Reporting Requirements (§ 423.514)

Recommendation Summary: Anthem is focused on ensuring that we provide our beneficiaries access to high-quality pharmacy networks that incentivize lower costs and improve health outcomes. We support and are involved in efforts to develop consensus-based pharmacy performance measures through the PQA. We also support CMS' proposal to collect pharmacy performance metrics used by Part D plan sponsors to evaluate pharmacy performance once industry has had an opportunity to develop, test, and achieve consensus on the measures.

Recommendation Detail: CMS proposes to amend its reporting requirements to establish that Part D sponsors disclose to CMS the pharmacy performance measures they use to evaluate pharmacy performance as established in their network pharmacy agreements.

Pharmacies play an important role in the health of beneficiaries—especially for those with chronic conditions. For example, pharmacy efforts to ensure adherence through education, refill reminders, and out-of-pocket cost reductions using generics can all reduce disease burden and greatly improve health outcomes. We strive to provide high-quality pharmacy networks to our members, and create value-based partnerships with pharmacies that align with the goals of the Star Ratings program. Direct and Indirect Remuneration (DIR), including pharmacy price concessions, are important tools for maximizing value and keeping beneficiaries' Part D premiums low. Through our PBM arrangements, we create high-

performing pharmacy networks that are consistently monitored and include incentives that align with better beneficiary care.[33]

We support disclosing to CMS our pharmacy performance measures used to evaluate pharmacy performance. We appreciate the role CMS plays in creating alignment between the Part D sponsors, pharmacy retail networks, and medical providers to support better healthcare outcomes and cost reduction. Furthermore, we understand the need for greater consensus among Part D plan sponsors regarding measurement as consistent public reporting supports transparency and fairness among all pharmacies and PBMs.

We also support CMS' approach to have the industry first develop, test, and achieve consensus on the metrics via a measure developer. To that end, Anthem is actively engaged in PQA's transparent and consensus-driven process to streamline and enhance quality measurements for pharmacies. Through the PQA process, we are pursuing several areas for measure standardization: adherence measures for diabetes, high cholesterol, hypertension/heart disease, statin use in diabetes, and comprehensive medication review completion rate. Additional measures being explored include formulary compliance (percentage of generic usage) and a measure of a beneficiary's experience with obtaining their prescriptions at the retail pharmacy (customer service and member satisfaction).

We are encouraged that CMS proposes to continue to rely on the ongoing process being undertaken by PQA and others, prior to issuing any additional data collection guidance. This will help to ensure a robust collection of industry accepted, tested, and validated measures.

Furthermore, should CMS develop Part D Star Ratings metrics related to these measures, we recommend the agency follow its traditional approach and report the results on the display page before implementation.

In addition, while not proposed in this rule, we would like CMS to consider for future plan years, the ability for Part D plan sponsors to develop preferred specialty pharmacy networks. The innovation of preferred retail pharmacy networks has significantly reduced Part D program costs, including government costs and beneficiary premiums. By allowing Part D plans to establish preferred specialty pharmacy networks, Part D sponsors will be in a position to better manage the proliferation of specialty drug spending for beneficiaries and taxpayers. The use of specialty pharmacy networks is an important tool for keeping premiums low. The growing cost of prescription drugs in the U.S. is one of the most important and challenging health policy issues we face today, and we are committed to working with CMS to help ensure Medicare beneficiaries have access to the best possible health care in a way that maximizes value and affordability.

Medical Loss Ratio (MLR) (§§ 422.2420, 422.2440, and 423.2440)

Recommendation Summary: Anthem supports CMS' proposed change to the definition of incurred claims to allow for accurate accounting of SSBCI benefits. We encourage CMS to consider extending this

[33] In developing our preferred network, Anthem targets a broad array of pharmacies for participation including national discount chains, national drug chains, national grocery chains, regional and rural pharmacy chains, and over 5,000 independent pharmacies.

approach to allowing COVID-19 investments to be considered an incurred cost, thereby allowing such investments to be applied to the numerator of the MLR.

Recommendation Detail: We applaud CMS' proposed change as it builds on the guidance allowing plans to cover non-primarily health related Supplemental Benefits (e.g., food/produce, transportation for non-medical needs, general support for living) for chronically ill MA beneficiaries.

CMS proposes changes to the "incurred claims" definition in the MLR calculation. Specifically, to account for the expanded benefit flexibility MA plans deliver under SSBCI, which may include non-provider payments, the agency proposes to remove the specification that incurred claims are payments to providers for covered services.
The proposed changes to the definition of "incurred claims" will make it less burdensome for MAOs to include these expanded supplemental benefits in the MLR numerator and incentivize increased investments in beneficiaries and their communities through the private sector.

Given the growing body of medical evidence demonstrating 1) that food insecurity among Medicare beneficiaries significantly increases healthcare expenditures in all areas of the country, 2) the positive impact of interventions such as medically tailored meals in reducing healthcare costs in Medicare and dually eligible beneficiaries, and 3) the impact of these and similar interventions on reductions in hospital and skilled nursing admissions across multiple payer types, the proposal supports work addressing the social drivers of health to improve the lives of MA beneficiaries.[34] [35]

Furthermore, many of our SSBCI benefits are not delivered by providers. Therefore, we appreciate CMS' acknowledgement that SSBCI should be included in the numerator as expenses plans incur to deliver important new flexible supplemental benefits that help address social drivers of health.

Given the unprecedented threat of COVID-19 to our healthcare system and beneficiaries, we recommend that CMS consider extending this approach to allow COVID-19 investments in supplemental benefits to keep people in their homes to be considered an incurred cost, thereby allowing such investments to be applied to the numerator of the MLR. It's critical that all resources are brought to bear to prevent vulnerable MA beneficiaries from contracting the virus, while continuing to address food insecurity and social isolation, particularly during this public health emergency.

This proposed rule change would establish the leadership of this Administration as the first to incorporate social drivers of health into the MLR framework. The use of the SSBCI has the potential to greatly improve the health of MA beneficiaries, and we encourage CMS to enable social investments more broadly to be included in the MLR numerator. This proposed change will start to eliminate an administrative barrier to expanding the use of benefits to invest in wellness, improve health outcomes, and reduce the long-term costs of medical care.

[34] Seth A. Berkowitz et al. "Preventing Chronic Disease Section Navigation State-Level and County-Level Estimates of Health Care Costs Associated with Food Insecurity." July 11, 2019. https://www.cdc.gov/pcd/issues/2019/18_0549.htm.
[35] Seth A. Berkowitz et al. "Meal Delivery Programs Reduce the Use of Costly Health Care in Dually Eligible Medicare and Medicaid Beneficiaries." April 2018. https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2017.0999.

Dismissal and Withdrawal of Medicare Part C Organization Determination and Reconsideration and Part D Coverage Determination and Redetermination Requests (§§ 422.568, 422.570, 422.582, 422.584, 422.590, 422.592, 422.631, 422.633, 423.568, 423.570, 423.582, 423.584, and 423.600)

Recommendation Summary: We are concerned the proposed definitions do not provide the intended and necessary clarity. In particular, these definitions address situations where the requests for determination/redetermination were never valid requests. CMS should consider a new, separate classification that would not imply the request was initially valid, and also provide more clarity around the difference between dismissals and withdrawals.

Recommendation Detail: CMS is proposing to clarify the circumstances and processes for withdrawing or dismissing Part C determination and reconsideration requests and Part D coverage determination and redetermination requests. The agency is also proposing regulations to clarify processes and circumstances for withdrawing or dismissing Part C and Part D Independent Review Entity (IRE) reconsiderations.

Specifically, CMS is proposing to permit a plan to dismiss requests when 1) the individual or entity making the request is not permitted to make the request; 2) the plan determines that the individual or entity making the request failed to make a valid request; 3) the beneficiary dies while the request is pending and the beneficiary's spouse or estate has no remaining financial interest in the case and no other individual or entity with a financial interest in the case wishes to pursue the request; or 4) the individual or entity who requested the review submits a timely written request for withdrawal of their request with the plan. CMS is also proposing an avenue to appeal a plan dismissal decision through an IRE.

Anthem does not believe the proposed definitions provide clarity around these issues. We are concerned requests that were invalid to begin with cannot be dismissed or withdrawn. In such instances CMS should not continue with the plan allowances to dismiss a case that should not have been started in the first place.

CMS is proposing to permit a plan to dismiss a request for the initial plan level coverage determination when the individual or entity who requested the review submits a timely written request for withdrawal. Currently, plans use the withdrawal process, which is a different decision type than a dismissal. We recommend CMS follow the withdrawal process in this scenario, not the dismissal process. In addition, when a beneficiary dies during the request process, we recommend CMS follow the withdraw process rather than the dismissal process.

Furthermore, the agency also seeks comment on whether the proposed rules would create inconsistencies with any state-specific Medicaid procedures pertaining to dismissals or withdrawals. Medicare determination and coverage processes may be different than Medicaid, therefore, if medical care or services are not covered by Medicare, but are covered by Medicaid, withdrawing the appeal is an effective way to minimize the administrative burden of appeals in Medicare.

We encourage CMS to provide more clarity around the circumstances under which a dismissal process is followed versus a withdrawal process and the different expectations associated with these two processes.

E. Codifying Existing Part C and D Program Policy

Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services (§§ 422.100 and 422.101)

Recommendation Summary: While we appreciate CMS' consideration of the inclusion of an intermediate tier for the MOOP limit and a multi-year transition that incorporates ESRD costs to provide benefit design flexibilities, we are concerned the changes to the MOOP could be detrimental to non-ESRD beneficiaries. Inadequate payment for ESRD beneficiaries puts supplemental benefits, reduced cost-sharing, and the out-of-pocket cap protections for MA beneficiaries at risk. CMS should ensure adequate payment for ESRD beneficiaries by adjusting the benchmarks to avoid major changes for beneficiaries satisfied with their MA benefits.

Recommendation Detail: Beginning with coverage for the 2022 contract year, CMS proposes to 1) establish explicit authority for up to three MOOP limits, including the current mandatory and voluntary MOOP limits and a third, intermediate MOOP limit; 2) codify the methodology for setting MOOP limits; and 3) adjust the methodology to take into account more ESRD beneficiaries entering MA.

While the introduction of an intermediate MOOP limit to take into account a larger number of ESRD beneficiaries joining MA will make the MOOP more accurate, the policy will also increase costs for all MA beneficiaries. Instead, we encourage CMS to adjust benchmarks to account for the MOOP limit required in MA. Payment adequacy for patients with ESRD is increasingly important to enable plan sponsors to develop specialized plans that are better tailored to beneficiaries' chronic conditions.

We appreciate CMS' acknowledgement that current ESRD reimbursement is not sufficient to prevent premium increases to accommodate the higher costs of ESRD beneficiaries in MA.[36] However, we are concerned that CMS' proposal to enable MA plans to increase the MOOP will negatively impact all MA beneficiaries, while not fully addressing the payment shortfall for ESRD beneficiaries. In proposing to raise the MOOP for all MA beneficiaries, CMS is passing higher costs on to all MA consumers and setting up a situation in which beneficiaries without ESRD will subsidize those with ESRD.

Further, we are concerned the proposal could drive adverse selection. MAOs that endeavor to keep costs low for beneficiaries with a lower MOOP would disproportionately attract ESRD beneficiaries, compared to MAOs that utilize a higher MOOP. CMS is also proposing to increase the allowable increase in Total Beneficiary Cost (TBC), which would further increase costs for beneficiaries. Rather than increasing the MOOP and TBC, CMS should focus on preventing beneficiary cost increases by updating the ESRD benchmarks to directly address the payment shortfall for ESRD beneficiaries.

Plan Crosswalks for Medicare Advantage (MA) Plans and Cost Plans (§§ 417.496 and 422.530)

Recommendation Summary: We request clarity around Annual Notice of Change (ANOC) requirements when a plan crosswalks beneficiaries into two different plans.

Recommendation Detail: CMS proposes to codify crosswalk and crosswalk exception processes and conditions, including specific rules for SNPs. We request clarification as to whether two different ANOCs would be required in situations in which a plan crosswalks beneficiaries into two different plans.

[36] CMS, Medicare Drug & Health Plan Contract Administration Group, "Contract Year 2021 Part C Benefits Review and Evaluation," February 6, 2020.

Medicare Advantage (MA) and Cost Plan Network Adequacy (§§ 417.416 and 422.116)

Recommendation Summary: Anthem supports the proposed flexibilities to the MA network adequacy standards. We believe CMS' approach reflects the challenges with establishing a network in some geographies and facilitates access to telehealth innovations to close care gaps.

We recommend CMS remove outpatient dialysis from the list of facility types for which MA plans must meet time and distance standards, and allow plans to attest to providing medically necessary dialysis services in its contract application. These flexibilities will encourage competition and drive patient-centered innovation in dialysis treatment.

Particularly given the challenges associated with the COVID-19 outbreak, we appreciate that CMS has proposed flexibilities when a plan contracts with telehealth providers. We request further clarification from the agency on how MAOs can expand coverage of telehealth services beyond those approved by CMS.[37]

Recommendation Detail: Currently, CMS requires that MAOs contract with a sufficient number of specified providers/facilities to ensure that beneficiaries have adequate access to care near where they live. CMS proposes to codify most of its existing network adequacy standards, with some modifications to further account for access needs in all areas, including rural counties. These changes will also take into account the impact of telehealth providers in contracted networks.

- ESRD: We support the Administration's focus on increasing the use of home dialysis. Our ESRD SNPs have demonstrated success in providing beneficiary education around home dialysis, support services, and home care. To advance the Administration's goal of having 80 percent of new ESRD patients in 2025 either receiving dialysis at home or receiving a transplant, we encourage CMS to revise network adequacy requirements if a plan is able to show a percentage of patients utilizing home dialysis.

  CMS should also remove outpatient dialysis from the list of facility types for which MA plans need to meet time and distance standards, and allow plans to attest to providing medically necessary dialysis services in its contract application, instead of requiring each MA plan to meet time and distance standards for providers of these services. These flexibilities could help lower out-of-pocket costs for ESRD beneficiaries, and expand access to supplemental benefits and other services not found in traditional Medicare.

  We also encourage the agency to explore ways to provide dialysis in additional settings by broadening Medicare conditions of coverage for dialysis facilities. Expanding home dialysis is particularly important given the COVID-19 risks for ESRD beneficiaries. We would like to collaborate with CMS to encourage dialysis services in multiple venues by updating the Medicare conditions of coverage for dialysis facilities to include home training facilities and mobile dialysis facilities. We stand ready to partner with the Administration to achieve the 2025 goals to improve the lives of individuals with ESRD.

[37] CMS. "Information Related to Coronavirus Disease 2019 - COVID-19." March 10, 2020. https://www.cms.gov/files/document/hpms-memo-covid-information-plans.pdf.

- Telehealth: We encourage CMS to finalize its proposed 10-percentage point credit when a plan contracts with applicable telehealth providers. We believe that telehealth services can be an efficient and effective means to deliver care. Providing this credit both encourages further adoption of telehealth services for MA beneficiaries, and shows that telehealth services can be a high-quality alternative to traveling to a provider office or facility.

  We also encourage CMS to continue efforts to expand access to telehealth by providing further guidance on the ways MAOs may be approved to expand benefit packages to accommodate beneficiaries impacted by the COVID-19 outbreak, as the pandemic may provide valuable insights into flexibilities that should be made permanent.

  Furthermore, we recommend allowing telehealth encounters to be utilized for risk adjustment in 2021 and 2022 to improve risk score accuracy. Given the increasing use of telehealth to care for beneficiaries during this public health emergency, it will be important to incorporate diagnoses from telehealth encounters to maintain the stability of the MA program.

- Rural Areas: We also support CMS' proposed flexibility to implement an 85 percent time and distance standard for rural, micro, and Extreme Access Considerations counties (CEAC). Implementing this standard will increase the ability of MA plans to meet network adequacy standards, and thus increase choice and competition in rural areas. As CMS considers this change, we would also ask CMS to evaluate an 80 percent threshold, which we believe would further improve beneficiary plan choice, without creating impediments to access.

- Provider Consolidation: We echo statements CMS has received from stakeholders regarding strategies used by some providers to leverage network adequacy requirements in order to negotiate rates well above FFS. This issue may arise when all, or nearly all available providers of a certain specialty consolidate into a single practice, leading to potential negotiating challenges for MA plans working to adhere to network adequacy standards. We encourage CMS to create an exceptions process in the event a documented anticompetitive situation arises, impeding a plan's ability to achieve network adequacy.

- Certificate of Need: In addition, we support CMS' proposal that MAOs may receive a 10-percentage point credit for beneficiaries residing within published time and distance standards when provider and facility types in states are limited due to Certificate of Need laws, or other state imposed restrictions. Anticompetitive behavior increases overall health care costs for beneficiaries and taxpayers. We encourage the agency to finalize the update to network adequacy requirements as proposed.

Lastly, the data CMS uses to populate its provider availability information is not always current, shifting the burden to plans to refute inaccuracies. To this end, we urge CMS to develop a more accurate data source for provider information. We are supportive of CMS' concept to pilot the use of the National Plan and Provider Enumeration System as a "source of truth" that plans can use to validate provider directory data. In the meantime, acknowledging these errors, we ask CMS to more readily take plan data into consideration and facilitate a more streamlined exceptions process.

Past Performance (§§ 422.502 and 423.503)

Recommendation Summary: Anthem appreciates CMS' efforts to clarify and simplify the past performance methodology and the accommodation for intermediate sanctions related to D-SNPs, however, we are concerned that the proposal would be overly restrictive in its application. We encourage the agency to consider the factors in combination, as well as the size of the identified contract.

Additionally, given the negative impact of COVID-19 on Star Ratings, we recommend that CMS does not consider low Star Ratings as a determining factor to deny new contract and service area expansions. At a minimum, we encourage the agency to consider two to three years of Star Ratings performance to allow for improvement efforts to be measured and reported.

Furthermore, we recommend CMS exclude plans which have been, or will be non-renewed prior to the following contract year from the past performance review.

Lastly, given the narrow timeframe CMS proposes for review, we encourage the agency to provide plans with a remediation opportunity and an appeals process should the plan quickly address identified issues.

Recommendation Detail: CMS proposes to adopt an updated past performance methodology that uses a three pronged test as the basis for denying an MA or Part D application: 1) the imposition of Civil Money Penalties (CMPs) or intermediate sanctions, 2) failure to achieve at least a three-star Part C or Part D summary rating in the set of Star Ratings CMS issued during the 12-month review period, and 3) failure to maintain a fiscally sound operation.

Anthem appreciates the need to restrict the ability of poor performing plans to expand, particularly for plans with a history of poor performance. However, we do not believe the proposed methodology sufficiently takes into account the nature and context of performance issues over a sufficient period of time, and thus would inadvertently limit new high-quality plan offerings.

The agency previously used eleven different criteria in the past performance methodology. While the proposal does simplify the past performance evaluation, we believe CMS needs to add more nuance within the proposed criteria, potentially through the addition of a point system. For example, not all CMPs are equal in terms of severity, and a lower Star Rating on a contract that represents a small minority of an organization's business could be addressed over a two-year period, and should not halt all new contracts by that organization. We have the following specific concerns and policy recommendations related to updating the past performance methodology.

First, given the negative impact COVID-19 will have on Star Ratings, we recommend that CMS does not consider low Star Ratings as a determining factor to deny new contract and service area expansions. At a minimum, to avoid penalizing plans for Star Ratings that are not reflective of the current state of performance, we recommend CMS consider at least two years (and preferably three years to align standards across the MA program) of Star Ratings performance to allow for improvement efforts to be measured and reported.

Second, if a contract is low performing a plan may decide not to renew the contract. Therefore, we recommend CMS exclude plans from the past performance review which have been, or will be non-renewed prior to the following contract year. Such a policy would enable plans to refocus efforts on

ensuring existing Medicare contract performance remains at an acceptable level, and expanding high-quality plan choices to beneficiaries' in new service areas.

Third, for CMPs and intermediate sanctions, we ask that CMS recognize these issues may already be resolved by the time they are identified. In addition, upon further investigation the agency may conclude the sanction was unwarranted. As such, we encourage CMS to take a less restrictive approach to updating the past performance methodology and more narrowly tailor the proposal to MA plans with at least two years rather than penalizing plans, and in turn beneficiaries, for an issue that may be an anomaly over a 12-month review period.

Fourth, we also seek clarity on whether the past performance restrictions proposed would apply at the legal entity or the controlling organization level. Anthem would encourage CMS to apply restrictions at the narrower legal entity level, especially if the agency moves forward with the proposed strict evaluation criteria. CMS should consider the size of the identified contract, and plans that impact the controlling organization should have at least enough membership to generate overall Part C and D Star Ratings.

Fifth, given the narrow time frame CMS proposes to review, we also encourage the agency to provide plans with a remediation opportunity and an appeals process. The new proposed policy does not allow for an appeals path whereby a plan can address issues identified over a short period of time that are unlikely to be repeated, when the plan is otherwise capable of delivering high-quality care to beneficiaries moving forward.

Finally, CMS notes that the agency intends to exclude intermediate sanctions imposed on D-SNPs (2021 through 2025) as a basis for denying a MA or Part D application. We appreciate CMS' acknowledgement that given the new requirements of the BBA 2018, more intermediate sanctions may not be tied to overall contract performance.

Call Center Requirements (§§ 422.111 and 423.128)

Recommendation Summary: Anthem supports the codification of existing guidance and standards related to call center operations.

Recommendation Detail: We appreciate CMS' efforts to enumerate more explicit performance standards for MA and Part D customer service call centers, and ensure protections for beneficiaries. Our interpretation of the proposed requirements for call center hours is that CMS is putting into regulation the existing requirements in section 80.2 of the current Medicare Communications and Marketing Guidelines.[38] We encourage CMS to clearly reflect that existing policy in the final regulation.

[38] CMS. "Medicare Communications and Marketing Guidelines (MCMG)." September 5, 2018. https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/CY2019-Medicare-Communications-and-Marketing-Guidelines_Updated-090518.pdf.

Special Election Periods (SEPs) for Exceptional Conditions (§§ 422.62 and 423.38)

Recommendation Summary: We encourage CMS to consider and clarify SEPs for beneficiaries impacted by public health emergencies like the COVID-19 pandemic. We also request clarification regarding SEPs for D-SNPs, FIDE-SNPs, and HIDE-SNPs to account for varying state Medicaid enrollment timeframes.

Recommendation Detail: Given CMS' proposal to codify a SEP for individuals affected by a FEMA-declared weather-related emergency or major disaster, we encourage CMS to consider a SEP for public health emergencies. The COVID-19 pandemic may impact beneficiaries' ability to make informed Medicare decisions, therefore, we encourage the agency to consider the appropriateness of providing enrollment flexibilities for beneficiaries and their caregivers, and encourage alignment with the Star Ratings extreme and uncontrollable circumstances policies.

CMS also proposes to finalize several Part C and Part D SEPs that are applicable to SNPs. We request that the agency provide additional clarity regarding SEPs for D-SNPs, particularly as states move to FIDE- or HIDE-SNP models, and there may be different state Medicaid enrollment timeframes to take into account.

***

We value the partnership that we have developed with CMS and welcome the opportunity to discuss our recommendations to ensure the delivery of robust benefits and quality care via the MA and Part D programs. Should you have any questions or wish to discuss our comments further, please contact Amanda Hurley at (202) 508-7892, or amanda.hurley@anthem.com.

Sincerely,



Anthony Mader
Vice President, Public Policy

Anthem is a leading health benefits company dedicated to improving lives and communities, and making healthcare simpler. Through its affiliated companies, Anthem serves more than 79 million people, including 41 million within its family of health plans and over 2.5 million Medicare consumers. We aim to be the most innovative, valuable and inclusive partner. For more information, please visit www.antheminc.com or follow @AnthemInc on Twitter.

PUBLIC SUBMISSION

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Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2021 (CMS-4190-P)

Comment On: CMS-2020-0010-0002
Medicare and Medicaid Programs: Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly

Document: CMS-2020-0010-0529
Comment on CMS-2020-0010-0002

Submitter Information

Name: Ginny Whitman
Organization: Alliance of Community Health Plans

General Comment

Please see the Alliance of Community Health Plans' comments on the proposed rule attached.

Attachments

ACHP Comment Letter - 2021 C-D Regulation (CMS-4190-P)

ACHP
ALLIANCE OF COMMUNITY HEALTH PLANS

April 6, 2020

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted via www.regulations.gov

Re: Medicare Program; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2021 and 2022 (CMS-4190-P)

Dear Administrator Verma:

The Alliance of Community Health Plans (ACHP) is pleased to submit comments in response to the proposed rule on Medicare Advantage and Part D.

ACHP is a national leadership organization bringing together innovative health plans and provider groups that are among America's best at delivering affordable, high-quality coverage and care. The non-profit, provider-aligned health plans that are ACHP members provide coverage in all lines of business for more than 22 million Americans across 35 states and the District of Columbia. ACHP members offer five of the fourteen 5-star rated Medicare Advantage (MA) plans.

We support the overall direction of this proposed rule, appreciating that CMS has reflected a number of ACHP's previous recommendations, and offer the following comments on the proposed rule:

Executive Summary of Comments

- ***Special Supplemental Benefits for Chronically Ill:*** ACHP urges CMS to consider certain extenuating circumstances where it is not appropriate for enrollees to file a grievance or appeal. We also request CMS allow for a one-year grace period during which a MA plan is not penalized (within reason) for potential issues that arise in the offering of a new, innovative SSBCI.

- ***ACHP supports CMS' proposal to increase the weight of patient experience/complaints and access to further emphasize their importance.*** However, we strongly encourage CMS to reconsider the leap in weight from 1.5 to 4. Currently, clinical outcome measures are weighted 3. Consumer experience is a high priority for ACHP members, yet we would not

support placing greater importance on sampled measures of experience than on measures of clinical effectiveness.

- ***End-Stage Renal Disease Proposals and Provisions:*** ACHP continues to strongly recommend that the Office of the Actuary analyze the impact of using smaller geographical areas such as Metropolitan Statistical Areas or counties as the basis for ESRD dialysis benchmark rates rather than statewide rates.

- ***Telehealth/Network Adequacy:*** ACHP strongly supports the proposed 10-percentage point credit for plans using telehealth to meet network adequacy requirements for certain providers and the proposed reduced threshold for determining time and distance standards in Micro, Rural and CEAC counties. ACHP requests that CMS also provide clarification regarding the network adequacy exception and customization process.

- ***MA and Part D Prescription Drug Plan Quality Rating System***: ACHP requests that CMS perform additional analysis of the Tukey cut point methodology so plans can project and compare impact on more than just the 2018 Star Ratings. While ACHP supports increasing the weight for patient experience measures, we request CMS consider a more gradual approach and adjust the weight to 3, the same as clinical outcome measures.

- ***Maximum Out-of-Pocket (MOOP) Limits for Parts A and B Services:*** ACHP opposes the addition of a third, intermediate MOOP. We are concerned that the addition of a third MOOP would not result in strong actuarial incentives for more MA plans to offer the lowest MOOP. ACHP offers several alternatives below.

- ***Second Preferred Specialty Tier:*** ACHP supports two Part D specialty tiers to encourage the use of biosimilars.

- ***Beneficiary Real Time Benefit Tool:*** ACHP supports requiring Part D sponsors to implement a real time benefit tool capable of providing beneficiaries with timely, clinically appropriate, patient-specific formulary and benefit information in a beneficiary-specific portal or computer application.

Part C Provisions

Implementation of Certain Provisions of the BBA 2018 — Special Supplemental Benefits for Chronically Ill (SSBCI)

ACHP appreciates CMS considering our recommendation to permit greater flexibility in defining a "chronically ill enrollee." This allows for plans to identify individuals with chronic conditions who may become eligible for SSBCI. ACHP supports CMS' proposal to publish a "non-exhaustive" list of chronic conditions that would qualify an individual for SSBCI. This proposal allows ACHP members to develop MA plan benefit designs that would provide SSBCI to individuals with one or more chronic conditions that are not on the list, provided they fall within the SSBCI definition

parameters. We strongly support this flexibility as our plans are best able to identify the enrollees suffering from chronic health conditions whose health could be most improved by SSBCI.

ACHP appreciates CMS' clarification regarding appeals and grievance procedure requirements for SSBCI but urges CMS to consider extenuating circumstances. ACHP maintains that the existing regulation is insufficient to address the unique circumstances of offering SSBCI. For example, a married couple may have the same MA plan but only one qualifies for SSBCI. The wife may receive different benefits and the husband, confused by this, wants to receive the same benefits. When the husband is told he is not eligible he may file an appeal or grievance. This is not an appropriate basis for an enrollee to seek redress through existing grievances and appeals when specifically related to SSBCI.

ACHP urges the administration to allow for a one-year grace period during which an MA plan is not penalized (within reason) for potential issues that arise in the offering of a new, innovative SSBCI. ACHP member plans are consistently looking for new benefits that will help their patient populations with chronic conditions and note that it can take time for all the "kinks" to be worked out. We encourage CMS to consider adding exceptions for circumstances such as the two above.

Improvements to Care Management Requirements for Special Needs Plans (SNPs)

ACHP supports CMS' proposal to apply the chronic condition special needs plan (C-SNP) enrollee management and model of care submission requirements to dual eligible SNPs (D-SNPs) and institutional SNPs (I-SNPs). ACHP recommends that CMS clarify that "providers" follows the definition of "provider" in 42 CFR § 422.2. We also recommend CMS provide additional details about what constitutes "demonstrated expertise and training."

Dual Eligible Special Needs Plan (D-SNP) Look-Alikes

ACHP supports CMS' proposed policies that establish regulatory requirements for D-SNP look-alikes to better ensure that all MA plans serving predominantly dual-eligible individuals provide coordinated and integrated Medicare and Medicaid services. ACHP also supports the proposal to limit the availability of D-SNP look-alike plans in any state where there is a D-SNP or any other plan authorized by CMS to exclusively enroll Medicaid beneficiaries. We applaud CMS's decision to not enter into or renew a contract for a MA plan that is not a MA SNP plan based on its actual or projected enrollment of dual eligibles.

ACHP also supports CMS' proposal to codify existing sub-regulatory guidance that prohibits Medicare Advantage organizations from marketing D-SNP look-alikes as if they were D-SNPs. We share CMS' concern that these practices are misleading and designed to confuse enrollees and suggest that the plan abides by standards and provides services that it does not.

End-Stage Renal Disease Proposals and Provisions (ESRD)

While ACHP supports the new enrollment flexibilities for individuals with ESRD, we continue to be concerned about the volatility of benchmark rates after the implementation of 21st Century Cures Act.

The ESRD population is a high cost population due to the use of expensive dialysis services and because this population often has other high cost comorbidities. In addition to dialysis, these beneficiaries are more likely to be hospitalized and use more physician and costly ancillary services. These costs vary significantly between urban and rural areas of a state. As a result, the overall ESRD health care costs in a MA plan's local service area are not likely to be accurately represented under the current statewide approach. This is particularly problematic for MA plans located in urban markets.

ACHP urges the Office of the Actuary (OACT) analyze the impact of using smaller geographical areas such as Metropolitan Statistical Areas (MSAs) or counties as the basis for ESRD dialysis benchmark rates rather than statewide rates. We believe that smaller geographic areas may be a more reasonable approach with growth of this population over time and the cost differences between urban and rural areas. This will better ensure greater accuracy in the acquisition costs that will be removed from ESRD rates and will improve the ability for MA plans to improve the contracts with their respective contracted dialysis provider.

ACHP encourages CMS consider other adjustments for ESRD rates to be developed for smaller geographical areas despite the problem of low case numbers. We understand that using statewide data in constructing these rates addresses the concern of there being too few cases in smaller geographic areas to be reliable. However, ACHP offers alternatives that could account for both low case numbers and region cost variations. For example, county rates could be adjusted using credibility factors. The ESRD county benchmark could, depending upon a credibility formula for the number of ESRD beneficiaries in a county, be the actual county data blended with the statewide data, using the statewide data as a manual rate. In some instances, the county benchmark could be strictly the manual rate of the statewide data for a county with no ESRD data credibility. Or the ESRD county benchmark could be the actual county cost and utilization data if the county ESRD data is deemed to be fully credible. This approach would be similar to the methodology CMS uses for MA Part C and D bids when the plan enrollment is too small to be credible. We encourage CMS to keep an open line of communication with MA plans as it is unclear how these proposals and considerations will factor into their plan bids.

ACHP supports all dialysis cost sharing to be equivalent to in-network rates. Due to the duopoly of providers nationally (85% of patients receiving dialysis from just two providers), MA plans have largely been unable to establish payment rates similar to traditional fee-for-service Medicare. In order to facilitate beneficiary protection and reduce total Medicare spending, we request CMS update section 50.1 of the MMCM Ch. 4 to require all dialysis cost-sharing to be equivalent to in-network and also section 110.1.3 to specify that MA plans must pay for dialysis treatment in all medically necessary cases, not just when temporarily absent from the plan's service area.

ACHP supports additional analysis of the ESRD rates to better understand the volatility of these rates and to make them more accurate and more predictable. We have seen volatility of the ESRD rates in recent years, making these rates difficult to forecast. One potential analysis would be to examine the impact of using 6 years of historical data for the Average Geographic Adjustment to reduce year-to-year volatility.

ACHP encourages CMS to consider creating an ESRD Payment Risk Corridor. As noted in our comments for the Medicare Advantage Advance Notice Part I and II for 2021, ACHP requests that CMS consider through its demonstration authority or other means to implement an ESRD payment demonstration such that the payments to plans are reconciled through a risk corridor-type program. ACHP is recommending a demonstration similar to the overall structure of the payment system in the Part D program. The ESRD population is a high-risk, high cost population in which the financial results of the overall MA plan can be greatly impacted because of a few very high cost cases. Both the size of the population that might move to MA as well as the health/selection risk are highly uncertain in 2021. One secondary impact could be many MA plans moving from the voluntary out-of-pocket maximum to the mandatory maximum out-of-pocket because of the increased enrollment of this high-risk population. In addition, the appropriate elimination of the organ transplant acquisition costs from ESRD payment rates poses timing difficulties for provider contracting.

ACHP would recommend the risk corridors be implemented for at least three years, similar to how corridors were first implemented in the Affordable Care Act for the uninsured population. If the risk corridor program is deemed successful in encouraging MA plans to enroll more ESRD membership, consideration can be given to widening the risk corridors over time.

We look forward to collaborating with CMS on designing this demonstration.

Lastly, ACHP recommends CMS develop standards and guidance for MA plans offering in-home dialysis. As a relatively new flexibility, MA plans are hesitant to move forward without additional guidance from CMS regarding quality and service standards. We encourage CMS to work with ACHP member plans and their quality experts in developing in-home care models.

<u>Telehealth/Network Adequacy</u>

ACHP strongly supports CMS' proposal to give a MA plan a 10-percentage point credit in meeting network adequacy thresholds when it contracts with telehealth providers in certain specialties. The 10-percentage point credit toward the percentage of beneficiaries meeting time and distance standards would be available when telehealth benefits are offered in the following specialty areas: dermatology, psychiatry, cardiology, neurology and otolaryngology. ACHP previously recommended that telehealth services be considered when determining fulfillment of network adequacy requirements. ACHP believes that the availability of the 10-percentage point credit will make a positive and significant impact for the ACHP member plans serving rural or network-sparse regions.

ACHP supports CMS' proposal to reduce the threshold for determining if a MA plan meets time and distance standards in Micro, Rural and CEAC counties. CMS' proposal to reduce the current

threshold that requires 90% of beneficiaries have access to at least one provider and facility of each specialty within the county to 85%of beneficiaries—in Micro, Rural and CEAC counties—is a positive first step in the evolution of time and distance standards.

ACHP members in rural communities often find that there is a more limited supply of physicians, specifically specialists, compared to in urban areas. Providers are more geographically disbursed, making the same time and distance standards that are applicable in metropolitan areas, problematic for smaller community-based plans. Quantitative standards that are overly strict in such areas give the few existing providers extraordinary bargaining power to raise prices. Plan sponsors required to meet those standards are therefore unable to negotiate better rates.

Lastly, ACHP would appreciate CMS clarifying the process for requesting Network Adequacy Customization and Exceptions. While the Medicare Advantage Network Adequacy Criteria Guidance document outlines the application process and permits exceptions to time and distance standards "when the healthcare market landscape has changed or does not reflect the current CMS network adequacy criteria," ACHP seeks examples of circumstances in which an exception would be appropriate.

ACHP also requests that CMS clearly delineate when it is appropriate for a plan to request a customization versus an exception, as the Medicare Advantage Network Adequacy Criteria document does not do so.

<u>Cost Sharing Flexibility</u>

ACHP supports CMS' proposed clarifications of a plan's ability to offer reduced cost-sharing. CMS proposes to codify that a MA plan can provide reduced cost-sharing for items and services that are not basic benefits—and that if a plan should provide those reduced cost sharing amounts, they may only be offered as mandatory supplemental benefits. In addition, CMS states that it would clarify that reduced cost sharing for basic benefits specifically relates to the value of Part A and B benefits. That text, however, does not appear in the proposed regulatory language. ACHP supports the proposal and encourages CMS to finalize such clarifications.

<u>Referral/Finder's Fee</u>

ACHP encourages CMS to consider increased transparency into broker payments and contracts. While ACHP is not opposed to eliminating unnecessary or duplicative regulations, we remain concerned about the lack of transparency into referral fees for agents and brokers. Currently brokers receive a stay-in fee for beneficiaries that remain enrolled in the plan and contract the broker previously facilitated. ACHP acknowledges that this was put in place to incentivize MA member retention. However, with approximately 98% of MA enrollees continuing to enroll in the program, this policy is outdated. In addition, this fee creates an unlevel playing field between ACHP members -- community based, nonprofits -- and their national competitors.

MA and Part D Prescription Drug Plan Quality Rating System (QRS)

ACHP appreciates CMS' efforts to refine the Quality Rating System to ensure that it continues to be a relevant tool that adequately and accurately measures and fosters high quality care and coverage. ACHP encourages CMS to use our member organizations as a resource in the evolution of the Quality Rating System. ACHP member plans have successfully delivered superior value through relationship-oriented practices focused on alignment of goals, payer-provider collaboration and appropriate financial incentives. We offer our assistance and expertise to CMS in developing measure concepts that flow from these best practices.

ACHP supports new methods to identify and remove outliers, but requests that CMS delay finalizing the Tukey methodology. ACHP agrees that this appears to produce more appropriate and accurate cut points provided that CMS test this methodology against more than just the 2018 Star Rating years. In addition, ACHP requests that CMS clarify the multiplier for the Tukey's fences calculation. In some definitions, ±1.5IQR is used to identify "outliers" while ±3.0IQR defines "far out" outliers. ACHP would welcome simulated data using previous years' data to help identify how mean resampling, guardrails, and now Tukey's fences will impact the Star Ratings playing field.

ACHP supports CMS' proposal to increase the weight of patient experience/complaints and access to further emphasize their importance. However, we strongly encourage CMS to reconsider the leap in weight from 1.5 to 4. Currently, clinical outcome measures are weighted 3. Consumer experience is a high priority for ACHP members, yet we would not support placing greater importance on sampled measures of experience than on measures of clinical effectiveness.

As an alternative, ACHP encourages CMS to increase the weight of patient experience/complaints and access to a 3. This places importance on member experience without diminishing the importance of clinical outcomes. It also maintains the integrity of the Triple Aim, in which all three of the components of quality, experience and cost are equally important.

ACHP members are dedicated to the closely aligned and integrated payer-provider model, and as a result are keenly aware of the tremendous impact the current COVID-19 pandemic is already having on quality measurement operations and performance. We urge CMS to consider the impact of triage and availability of services on all performance measures when making decisions about advancements in the QPS program this year. These changes are likely to have long-lasting effects for both providers and payers.

ACHP encourages CMS to implement a consistency measure for plans maintaining overall Star ratings of 4.5 for two or more years and reevaluate the use of outdated improvement measures. Measures of improvement can blur the distinction between high-scoring plans with consistently high performance and those with more opportunity for improvement. For some high-performing plans, the ability to improve upon a particular measure narrows simply because they can top out on performance. For lower performing plans, the ability for improvement is greater even though they are starting from a lower position. ACHP is concerned that some improvement measures are no longer achieving the desired intent of rewarding plans for improvement. ACHP believes that consistency and stability in performance over time should be rewarded equally. This would promote star ratings more appropriately based on performance across the entire range of clinical, patient experience and administrative/compliance measures.

ACHP supports CMS' efforts to eliminate topped out measures and reduce the number of measures overall. ACHP agrees with the Medicare Payment Advisory Commission that there has been a proliferation of measures which yield limited information to support clinical improvement or consumer decision-making, and that dilute quality measures results. For instance, MedPAC found that of the 376 MA contracts with Star Ratings in 2019, 71 contracts had administrative measures averaging 4.5 Stars or higher, but outcomes averaging less than 3.5 Stars. We encourage CMS to continue moving forward with eliminating topped out measures and reduce the number of measures overall. Without such efforts, too many measures, and process measures in particular, increase the documentation and reporting burden for plans and providers and provide little to no benefit to consumers.

Maximum Out-of-Pocket (MOOP) Limits for Parts A and B Services

ACHP opposes CMS' proposal to add a third, intermediate MOOP configuration at the numeric midpoint between the current mandatory and voluntary MOOP limits. We are concerned that the addition of a third MOOP would not result in strong actuarial incentives for more MA plans to offer the lowest MOOP — a benefit that best serves frail and high cost/high utilization enrollees. Further, the availability of three MOOPs raises complexity for enrollees. This proposal would make it more difficult for MA plans to determine which MOOP offers the best "value," and new and existing enrollees would face more confusing choices when selecting a plan.

ACHP thanks CMS for including our recommendation to add length of stay scenarios for acute and psychiatric care. ACHP supports CMS' proposal to add a 3-day length of stay scenario for acute stays and an 8-day length of stay scenario for psychiatric care. Next to physician visits, inpatient services have the highest Medicare utilization, and therefore the largest actuarial value. A larger actuarial value offers greater incentive for a plan to choose the voluntary MOOP.

We offer several alternative approaches to encourage more MA plans to offer the voluntary MOOP, many of which could be accomplished by CMS under existing regulatory authority or through its demonstration authority.

- Raise the voluntary MOOP to an amount that represents the 87th percentile of projected Original Medicare out-of-pocket costs instead of the existing 85th percentile, while retaining the existing 95th percentile for the mandatory MOOP. We believe that by moving the voluntary MOOP and mandatory MOOP amounts closer together it will incentivize plans to move to the voluntary MOOP. MA plan cost sharing has increased significantly over the last 10 to 15 years, yet the voluntary MOOP remained at $3,400 over that same time period, which contributed to pushing more plans to the mandatory MOOP limit. As MA plans increase their cost sharing over time, the voluntary MOOP limit should increase simultaneously. For CY 2022, CMS should consider increasing voluntary MOOP to reflect the 88th percentile, for example.

- Better differentiate the MOOP cost sharing values between voluntary and mandatory MOOP. We recommend that CMS better differentiate the maximum copays between the two

MOOPs for those service categories with high utilization. The two service categories with the highest Medicare utilization are: Primary Care Physician (7a) and Physician Specialist (7d). Currently, the maximum copays for these are the same under voluntary and mandatory MOOPs. In considering which MOOP to offer as part of their overall benefit package, MA plans will take under consideration which MOOP offers service categories that will allow the plan to charge a higher copay that will result in a larger actuarial value of copayments (utilization multiplied by copays). The more service categories that CMS differentiates between the MOOPs, especially for those services with higher Medicare utilization, the more likely an MA plan will choose to offer the voluntary MOOP.

- Add new cost sharing limits for observation services and ambulance services and clearly differentiate the maximum copays for these services in the voluntary and mandatory MOOP copays.

- Vary the cost sharing limits for emergency care/post stabilization, home health services, and physician specialist services. We would recommend adding the service category—primary care physician (7a). Increasing the differential for emergency care / post stabilization is an important service category for increased copays. Increased copays on emergency room care incentivizes members to use the appropriate level of care, e.g., physician visits or urgent care, and not over utilize the higher cost ER services. Also, although we support home health service copay differentiation, it should be noted that home health services copay differentiation does not equate to much actuarial value given its low utilization. In addition, many plans do not impose home health copays primarily because it is difficult to collect copays, and many home health agencies are not set up to collect cost sharing under Medicare.

- We do not recommend any more differentiation in the nominal cost sharing limits for the first 20 days of a skilled nursing facility stay. The current differentiation between the copays is currently reasonable, and the utilization for this service is very low so there is not much of an actuarial value for a nominal copay of $10 or $20 per day on this service category, meaning it will not be much of an incentive for a plan to choose the voluntary MOOP.

- Give additional star credit rating value for a plan imposing the lower voluntary MOOP.

<u>Medicare Communications and Marketing Guidelines</u>

ACHP appreciates that CMS is codifying longstanding policies and guidance in its "*Medicare Communications and Marketing Guidelines.*" We encourage CMS to continue to provide policy interpretations of the market and communication guidelines, examples and best practices in their original format, in addition to codifying these policies. The guidelines are frequently used and read by individuals unfamiliar with regulatory and legal text. Retaining the format will reduce potential confusion and mistakes.

In response to CMS' request for comments on how to implement prohibitions related to health plan marketing during the open enrollment period, ACHP recommends that CMS provide specific examples of language that is and is not permitted.

Part D Provisions

Safe Disposal of Drugs

ACHP requests additional clarification on CMS' proposal that MA plans provide information on the safe disposal of prescription drugs when furnishing an in-home risk assessment, in both verbal and written communications. ACHP appreciates the guidance already provided on the steps needed to ensure that medications are safely disposed of and request additional clarification on whether or not the in-home risk assessment extends to outside locations where seniors reside, such as senior-living centers, nursing homes or assisted living facilities.

Eligibility for Medication Therapy Management (MTM) Programs

ACHP supports CMS' proposal to codify existing guidance permitting plans to identify their own criteria for whom to target for the MTM program. We encourage CMS to finalize the provision that would apply existing MTM program standards to at-risk beneficiaries under Section 6064 including that the enrollees must be automatically enrolled with an opt-out and that plan sponsors must offer an annual comprehensive medication review and targeted medication reviews no less than quarterly.

Permitting a Second "Preferred" Specialty Tier

ACHP supports CMS' proposal to permit a Part D plan to have up to two specialty tiers and to establish a maximum allowable cost sharing of 25 percent for plans with a full deductible and 33 percent for plans with no deductible applicable to the higher cost-sharing specialty tier. We agree that this additional flexibility could encourage a lower-cost specialty tier that includes and encourages the use of biosimilars. We expect that it could improve competition among specialty drugs and the ability of Part D sponsors to negotiate better prices with manufacturers and lower costs for beneficiaries. The addition of this second tier could generate plan savings if manufacturers start to offer rebates for specialty drugs on a preferred tier, similar to how preferred non-specialty brand drugs are administered today. Part D plans will likely save on drug ingredient costs as well.

ACHP would also support improving the incentives for plans and beneficiaries to realize greater savings when they need costly specialty treatment and we encourage CMS to study alternative catastrophic reinsurance models to incentivize the greatest savings for plans implementing a preferred specialty tier.

Beneficiary Real Time Benefit Tool (RTBT)

ACHP supports requiring Part D sponsors to implement a Real Time Benefits Tool (RTBT) capable of providing beneficiaries with timely, clinically appropriate, patient-specific

formulary and benefit information in a beneficiary-specific portal or computer application. This support is consistent with previous ACHP comments that encouraged CMS to finalize its 2019 proposal to provide more information on drug coverage and costs to clinicians at the point-of-prescribing through the use of a RTBT. At that time, we noted that prescribers as well as patients need access to three critical pieces of information: clinical appropriateness, coverage and cost. ACHP supports enhancing transparency within the pharmaceutical industry, including for patients and prescribers.

We anticipate that implementation of such a tool across Part D sponsors will not only help lower drug expenditures for the Medicare program, but also improve patient outcomes. Incorporating drug coverage and cost information, including a beneficiary's copayment or coinsurance, at the point of prescribing improves adherence. Beneficiaries may abandon their prescription when taking it to a pharmacy to be filled because they learn it is not covered or too expensive. Providing that information up front to enrollees can reduce such occurrences.

If finalized, ACHP recommends that CMS develop an optional, model tool for all health plans to use. A CMS-developed tool could reduce costs for health plans and help ensure consistent functionality across plans. While we acknowledge that some of the drug pricing information aligns for both the prescriber and beneficiary tools, we are concerned that CMS underestimates the amount of time and costs that are associated with implementing consumer-facing drug pricing tools, and recommend that the start time is delayed until Jan. 1, 2023.

ACHP supports CMS' proposal to allow Part D plans to offer rewards and incentives to encourage consumer use of the real-time benefits tools. ACHP member plans with experience in online price transparency tools report that offering rewards and incentives can build utilization and engagement. ACHP generally supports the $15 per login ($75 in the aggregate annually) cap proposed and suggests CMS implement similar discrimination bans as those required by Medicare Advantage Prescription Drug plans.

<u>Pharmacy Performance Measure Reporting Requirements</u>

ACHP supports CMS' proposal to begin to explore the use of Pharmacy Performance Measures by requiring Part D sponsors to disclose to CMS the measures they use to evaluate pharmacy performance. We agree that additional analysis in this area is important to better understand the growth in the use of financial penalties and other price concessions and the public reporting of those measures can contribute to increasing transparency.

ACHP also encourages CMS to explore the development of consensus pharmacy performance measures for a future Part D Star Ratings program that would assess Part D plan sponsors' uptake of a standard set of pharmacy performance measures or that evaluate the percent of high-performing pharmacies in the sponsors' network.

We strongly recommend, however, that CMS develop these efforts with stakeholders that can contribute based on experience and expertise. CMS should build on best practices of high-quality plans such as ACHP members. Our member plans are community-based, non-profits that have successfully delivered better value through relationship-oriented practices focused on alignment

of goals, health plan and provider collaboration and appropriate financial incentives. We offer our assistance and expertise to CMS in developing pharmacy measure concepts that flow naturally from these best practices and deliver greater value.

Conclusion

Thank you for your consideration of ACHP's comments and recommendations for the Contract Year 2021 and 2022 Medicare Advantage and Part D Proposed Rule. ACHP appreciates the Administrations' continued efforts to improve and refine the MA program. We welcome continued engagement on our member plan best practices and efforts to offer evidence based, high quality and consumer focused MA and Part D plans.

If you have questions or require additional information, please contact Michael Bagel (mbagel@achp.org), ACHP Director of Public Policy.

Sincerely,



Ceci Connolly
President and CEO
Alliance of Community Health Plans

acquisitions for kidney transplants described in section 1852(a)(1)(B)(i) of the Act. We are finalizing changes to our regulation at § 422.322 in accordance with these new statutory requirements.

c. Exclusion of Kidney Acquisition Costs From Medicare Advantage (MA) Benchmarks (§§ 422.258 and 422.306)

Consistent with how the original Medicare FFS program will cover costs of organ acquisitions for kidney transplants for individuals in an MA plan, section 17006(b) of the Cures Act also amended section 1853 of the Act to exclude these costs from the MA benchmarks used in determining payment to MA plans. Specifically, the Secretary, effective January 1, 2021, is required to exclude the estimate of standardized costs for payments for organ acquisitions for kidney transplants from MA benchmarks and capitation rates. We are finalizing changes to our regulations at §§ 422.258(d) and 422.306 in accordance with these new statutory requirements.

d. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.166, 423.182, and 423.186)

In the Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Final Rule (CMS–4182–F) (hereinafter referred to as the April 2018 final rule), we codified the methodology for the Star Ratings system for the MA and Part D programs, respectively, at §§ 422.160 through 422.166 and §§ 423.180 through 423.186. We have stated we will propose through rulemaking any changes to the methodology for calculating the ratings, the addition of new measures, and substantive measure changes.

At this time, we are finalizing the increased weight of patient experience/complaints and access measures from 2 to 4. We are also finalizing our proposal to directly remove outliers prior to calculating the cut points to further increase the predictability and stability of the Star Ratings system, but we are delaying the application of outlier deletion until the 2022 measurement year which coincides with the 2024 Star Ratings produced in October 2023. We are also finalizing removal of the Rheumatoid Arthritis Management measure. Finally, we are finalizing the update to the Part D Statin Use in Persons with Diabetes measure weighting category. Unless otherwise stated, data will be collected and performance measured using these rules and regulations for the 2021 measurement period and the 2023 Star Ratings. The remaining Star Ratings provisions of the proposed rule will be addressed later and, therefore, are not being finalized in this rule. Those provisions include codifying additional existing rules for calculating MA Quality Bonus Payments ratings, implementing updates to the Health Outcomes Survey measures, adding new Part C measures, clarifying the rules around consolidations when data are missing due to data integrity concerns, modifying the extreme and uncontrollable circumstance policy for multiple year-affected contracts and to clarify rules when data are missing due to data integrity concerns, and additional technical clarifications.

e. Medical Loss Ratio (MLR) (§§ 422.2420, 422.2440, and 423.2440)

We are finalizing our proposal to amend the MA medical loss ratio (MLR) regulation at § 422.2420 so that the incurred claims portion of the MLR numerator includes all amounts that an MA organization pays (including under capitation contracts) for covered services. Currently, incurred claims in the MLR numerator include direct claims paid to providers (including under capitation contracts with physicians) for covered services furnished to all enrollees under an MA contract. This amendment will also include in the incurred claims portion of the MLR numerator amounts paid for covered services to individuals or entities that do not meet the definition of ''provider'' as defined at § 422.2.

We are finalizing our proposal to codify in our regulations at §§ 422.2440 and 423.2440 the definitions of partial, full, and non-credibility and the credibility factors that CMS published in the May 2013 Medicare Program; Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Final Rule (78 FR 31284) (hereinafter referred to as the May 2013 Medicare MLR final rule). It is more consistent with the policy and principles articulated in Executive Order 13892 on Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication (October 9, 2019) that we codify these definitions and factors in the applicable regulations.

Additionally, we are finalizing our proposal to amend § 422.2440 to provide for the application of a deductible factor to the MLR calculation for MA medical savings account (MSA) contracts that receive a credibility adjustment. The deductible factor serves as a multiplier on the applicable credibility adjustment. This additional adjustment for MA MSAs is appropriate because the variability of claims experience is greater under health insurance policies with higher deductibles than under policies with lower deductibles, with high cost or outlier claims representing a larger portion of the overall claims experience of plans with high deductibles. This is the case because high-deductible health plan enrollees' medical expenses must exceed a higher threshold before the plan begins to incur claims costs that can be included in the MLR numerator. The deductible factor reduces the risk that an MSA contract will fail to meet the MLR requirement as a result of random variations in claims experience. We are finalizing our proposal to adopt the same deductible factors that apply under the commercial MLR regulations at 45 CFR part 158.

f. Medicare Advantage (MA) and Cost Plan Network Adequacy (§§ 417.416 and 422.116)

We are strengthening network adequacy rules for MA plans by codifying our existing network adequacy methodology and finalizing policies that address maximum time and distance standards in rural areas, telehealth, and Certificate of Need (CON) laws. The authorization of additional telehealth benefits pursuant to the BBA of 2018 incentivizes new ways for MA plans to cover beneficiary access to health care beginning in 2020. As a result, CMS has been examining its network adequacy standards overall to determine how contracted telehealth providers should be considered when evaluating the adequacy of an MA plan network. In order to expand access to MA plans where network development can be challenging, we are reducing the percentage of beneficiaries that must reside within the maximum time and distance standards in non-urban counties (Micro, Rural, and Counties with Extreme Access Considerations (CEAC) county type designations) from 90 percent to 85 percent in order for an MA plan to comply with network adequacy standards. Also, MA plans will be eligible to receive a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards when they contract with telehealth providers in the following provider specialty types: Dermatology, Psychiatry, Cardiology, Otolaryngology, Neurology, Ophthalmology, Allergy and Immunology, Nephrology, Primary Care,

the November 2018 proposed rule, we considered enhancements to the methodology that would increase the stability and predictability of the cut points and finalized in the April 2019 final rule two enhancements to the historical methodology. In the April 2019 final rule, we amended §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to add mean resampling of the current year's data to the current clustering algorithm to attenuate the effect of outliers; we also added measure-specific caps in both directions to provide guardrails so that the measure-threshold-specific cut points do not increase or decrease more than the cap from one year to the next. The IFC (CMS–1744–IFC) delays the implementation of guardrails for an additional year; thus, it will be implemented for the 2021 measurement year and the 2023 Star Ratings.

Some commenters to the November 2018 proposed rule believed mean resampling would not be sufficient to address outliers and expressed support for directly removing outliers before clustering. We did not finalize an approach for directly removing outliers in the April 2019 final rule in order to provide the public prior notice of a proposal for incorporating removal of outliers and an opportunity to comment on a specific approach and so that we could continue to evaluate the methodologies for outlier removal (84 FR 15761).

As we stated in the April 2019 final rule in response to public comments on this topic, we evaluated two options to address direct removal of outliers—trimming and Tukey outer fence outlier deletion. Under trimming, all contracts with scores below the 1st percentile or above the 99th percentile are removed prior to clustering. Although trimming is a simple way to remove extreme values, it removes scores below the 1st percentile or above the 99th percentile regardless of whether such scores are true outliers. This means in cases when true outliers are between the 1st and 99th percentile, they would not be removed by trimming, and in cases when the distribution of scores is skewed, scores that are not true outliers would be trimmed.

In the February 2020 proposed rule, we proposed to use Tukey outer fence outlier deletion as the method to identify and delete outliers before applying the already-applicable mean resampling and hierarchical clustering processes. With mean resampling, measure-specific scores for the current year's Star Ratings are randomly separated into 10 equal-sized groups. The hierarchical clustering algorithm is done 10 times, each time leaving one of the 10 groups out. The method results in 10 sets of measure-specific cut points. The mean cut point for each threshold per measure is calculated using the 10 values. Tukey outer fence outlier deletion is a standard statistical method. Tukey outer fence outliers are sometimes called Whisker outliers. Under this methodology, outliers are defined as measure scores below a certain point or above a certain point. We proposed that the lower point or the ''lower outer fence'' would be identified with this formula: (first quartile − 3.0 × (third quartile − first quartile)); and the higher point or the ''upper outer fence'' would be identified with this formula: (third quartile + 3.0 × (third quartile − first quartile)). The Tukey outer fence outlier deletion will remove all outliers based on the previous definition for the two points (that is, the lower and upper outer fences) and does not remove any cases that are not identified as outliers. Values identified as outside the Tukey outer fences would then be removed immediately prior to clustering.

We explained in the proposed rule that if Tukey outer fence outlier deletion and a 5 percent guardrail had been implemented for the 2018 Star Ratings, 2 percent of MA–PD contracts would have seen their Star Rating increase by half a star, 16 percent would have decreased by half a star, and one contract would have decreased by 1 star. For PDP contracts, 2 percent would have increased by half a star, and 18 percent would have decreased by half a star. This simulation of the impact of Tukey outlier deletion also takes into account the removal of the two Part D appeals measures (Appeals Auto-Forward and Appeals Upheld) and the Part C measure Adult BMI Assessment, because these measures will be removed starting with the 2022 Star Ratings. In general, there tends to be more outliers on the lower end of measure scores. As a result, the 1 to 2 star thresholds often increased in the simulations when outliers were removed compared to the other thresholds which were not as impacted.

We requested comments on our proposal to use Tukey outer fence outlier deletion as an additional step prior to hierarchal clustering. We explained that under our proposal in the first year of implementing this process, the prior year's thresholds would be rerun, including mean resampling and Tukey outer fence deletion so that the guardrails would be applied such that there is consistency between the years. We proposed to amend §§ 422.162 and 423.182 to add a definition of the outlier methodology (''Tukey outer fence outliers'') and to amend §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to apply the outlier deletion using that methodology prior to applying mean resampling with hierarchal clustering.

We received the following comments related to our proposal, and our responses follow:

Comment: Most commenters opposed moving forward with the Tukey outlier deletion at this time, citing a variety of different reasons. A handful of commenters raised general concerns about the Tukey outlier deletion method, mentioning criticism in academic communities about applying Tukey fences to skewed data, given what the commenters characterized as the Tukey approach's assumption of a normal distribution. Other commenters suggested additional research is needed on alternatives for removing outliers. Some commenters did not support the use of Tukey outlier deletion without more information about how the Tukey outlier fence models will be applied and more detail on CMS analyses. A couple of commenters did not support adding Tukey outlier deletion given the fluctuation it may cause in the ratings.

Response: CMS is concerned about extreme outliers influencing cut point determinations and has selected an approach to identify and remove outliers prior to clustering contract scores to determine cut points for assigning measure stars. The main objective of removing outliers is to stabilize cut points and prevent large year-to-year fluctuations in cut points caused by the scores of a few contracts. CMS selected the conservative outer-fence form of the Tukey outlier deletion method because it is transparent (easily understood and can be implemented by stakeholders with widely-available software) and robust to distributional shape (it performs as intended for this purpose across the range of score distributions seen in Star Ratings data).

CMS disagrees that the Tukey outer fence outlier approach is inappropriate for identifying the outliers to be removed from the performance score data. Even when the data are not normally distributed (for example, in a skewed distribution), the Tukey approach performs as intended. The Tukey outer fence outlier deletion approach is a standard statistical method that is non-parametric, that is, it is not dependent on distributional assumptions. We plan to adopt a more conservative definition, based on Tukey *outer* fences, that only removes scores that are extreme outliers. This approach removes fewer outliers at both extremes of the score distribution than the inner

fence approach. We plan to identify and remove extreme outliers immediately prior to applying the clustering algorithm to set cut points. The Tukey outer fences would be calculated from the set of measure scores after removing contracts that are to be excluded from clustering (such as because the measure is voluntary for that contract).

The first step in applying the Tukey outlier deletion method is calculating the first quartile (Q1) and third quartile (Q3) of the score distribution: 25 percent of scores fall below Q1, another 25 percent of scores fall above Q3, and the remaining 50 percent of scores fall between Q1 and Q3. Next, we calculate the interquartile range (IQR), the difference between the third and first quartiles (IQR = Q3 − Q1), which refers to the range of the middle 50 percent of all scores. The Tukey outer fence method identifies extreme outlier as those that are below (Q1 $-3 \times$ IQR) or above (Q3 + $3 \times$ IQR).

We examined the use of trimming as an alternative outlier removal approach and found very similar results as those described in the proposed rule from using the Tukey approach. We performed simulations that trimmed any scores that were above the 99th percentile or below the 1st percentile, trimming values at the tail ends of the distribution prior to clustering. The method had effects on Star Ratings similar to those of the Tukey method. An important strength of the Tukey outer fence outlier deletion method over the trimming method is that trimming removes a fixed proportion of plan scores for each measure, regardless of whether those scores are distant from the center of the score distribution. In contrast, the Tukey outer fence method removes only true outliers that are the most distant from the center of scores.

Comment: Some commenters suggested alternatives to outlier deletion to help improve the stability of cut points. A commenter suggested that CMS might consider cut points using plans in similar geographic areas with similar characteristics. Another suggested CMS explore other classification methods such as Isolation Forest, DBSCAN, or k-means clustering. A couple of commenters recommended a guardrail cap less than 5 percent.

Response: CMS agrees that stability is a goal for the cut points, but we disagree with the recommendations of the commenters to achieve that stability. Setting regional or geographic benchmarks (cut points) would lead to a 5-star contract in one area differing in terms of performance from a 5-star contract in another area. The Medicare program does not set regional standards, but rather applies a single national standard to evaluate plan performance. As required under section 1851(d), CMS disseminates information to Medicare beneficiaries (and prospective Medicare beneficiaries) on the different coverage options to promote an active, informed selection among such options. This includes plan quality and performance indicators to compare plan options. In order to compare in a consistent way, CMS uses a single national standard since different regional cut points could hide deficiencies in different areas. Additionally, many measures are based on compliance with Medicare rules and requirements (for example, call center measures and appeals measures) and reflect compliance with Medicare program requirements, not comparative compliance. Using regional cut points would warp the results and complicate our use of Star Ratings under §§ 422.504(a)(17), 422.510(a)(4)(ix), 423.505(a)(26), and 423.509(a)(4)(x).

Regarding the choice of clustering method, hierarchical clustering is one of the most commonly used methods for clustering observations into groups. There are pros and cons of all methods for clustering, including those identified by the commenters. We have considered other methods and believe hierarchical clustering is the best option for the Part C and D Star Ratings program because it is well understood, easily implemented, and performs well for a variety of different data distributions. The other very commonly used clustering algorithm is k-means, however one key weakness of that approach is that the final set of clusters depends on the initial random assignment of points to clusters and it is highly sensitive to the initial placement of cluster centers. Specifically, when the algorithm is repeated on the same dataset it may result in different cluster assignments. Additionally, the k-means method is sensitive to outliers (for example, Gan and Ng (2017),[20] Govender and Sivakumar (2020) [21]), and therefore it would not resolve the issue that outliers can influence estimated thresholds. The commenter also noted other clustering algorithms that are less commonly used. For example, weaknesses of DBSCAN include sensitivity to parameters and inability to handle clusters of points of varying densities, which makes DBSCAN less attractive for clustering measure scores. Isolation Forest is an outlier or anomaly detection technique on the basis of decision trees that is not directly related to clustering measure scores into 5 groups.

Comment: A couple of commenters opposed Tukey outlier deletion since they were concerned it would make it harder for plans with more complex populations to perform well, including SNP plans. A commenter noted the current national emergency emphasizes the need for the cut point methodology to separate out plans with high proportions of dually-eligible, disabled, and low-income individuals.

Response: The issues of whether it is harder for plans with complex populations to perform well in Star Ratings and the method by which we stabilize thresholds for cut points are unrelated. The strategy of removing outliers for stability of cut points does not affect how performance is compared across plans with and without complex populations.

In simulations of Star Ratings calculated using the Tukey outer fence outlier approach, we found that the effect of outlier removal on SNP versus non-SNP contracts was not very different. When outlier measure scores were removed as a part of our simulation using the data for the 2018 Star Ratings, overall summary ratings shifted from 4 to 3.5 stars for approximately 4 percent of contracts without a SNP, and for about 5 percent of contracts with a SNP for the contracts with overall ratings. The removal of outliers will not necessarily have consistent year-to-year impacts, and is dependent on where contracts fall in the measure score distributions, with contracts near the bottom of a score range being the most likely affected.

CMS adopted the categorical adjustment index (CAI) to address the concern that plans with more complex populations have lower ratings based on the population served under the contract. The CAI advances more equitable plan comparisons because it generates Star Ratings that contracts would have received if they had all served the same patient population. That is, the CAI adjusts for within-contract disparities based on measures that are not otherwise adjusted for patient characteristics. CAI coefficients are estimated each year so if there is a differential impact of COVID–19 on the measures of performance for contracts with a higher percentage of dual eligible and disabled beneficiaries versus contracts with a lower percentage of enrollees with those social risk factors, the CAI values would reflect these

[20] Gan, G., & Ng, M.K. (2017). K-means Clustering with Outlier Removal. *Pattern Recognit. Lett., 90,* 8–14.

[21] Govender, P. & Sivakumar, V. (2020). Application of k-means and hierarchical clustering techniques for analysis of air pollution: A review (1980–2019). Atmospheric Pollution Research. 11(1), 40–56.

differences. The CAI will continue to adjust for the percentage of LIS/DE and disabled beneficiaries within the contract in accordance with §§ 422.166(f)(2) and 423.186(f)(2), and therefore will adjust for these differences for contracts with and without a SNP.

Comment: A commenter suggested that CMS retire measures from the program when there are one percentage point differences in the same direction between cut points year over year.

Response: CMS does not consider the size of changes in performance from year-to-year to be a criterion for retirement of a measure, particularly when there is still room for improvement on the measure. CMS retires or removes measures from Star Ratings when there is a change in clinical guidelines that mean that the measure specification is no longer believed to align with or promote positive health outcomes and when measures show low statistical reliability. These standards are in §§ 422.164(e)(1) and 423.184(e)(1), and we explained how we interpret and apply the standards in the April 2018 final rule. When measure scores are ''topped out'' (that is, show high performance across all contracts), this decreases the variability across contracts and makes the measure unreliable. On average, measures improve year-to-year in the 1 to 3 percentage point range, with the exception of new measures where the performance generally has more substantial room for improvement or in situations where a structural change occurs (for example, implementation of EHR tools) that significantly alter performance on the measure.

Comment: A couple of commenters suggested convening a Technical Expert Panel (TEP) to provide input into the Tukey outlier deletion.

Response: A TEP comprised of representatives across various stakeholder groups convened on May 31, 2018 to provide feedback to the RAND Corporation, the current CMS contractor for the Part C and D Star Ratings program to obtain input on a number of issues, including increasing the stability of cut points (*https://www.rand.org/pubs/conf_proceedings/CF391.html*). This TEP focused on different ways to increase stability of cut points, including outlier deletion, but did not focus on the different methods for deleting outliers. We do not believe another TEP is necessary to specifically address this topic given the RAND TEP already expressed strong support for directly addressing outliers and this methodology for removing outliers is a widely accepted methodology for removing outliers.

Comment: A handful of commenters wanted to see the impact on their individual plans to be able to fully understand the effect of Tukey outlier deletion.

Response: CMS plans to display simulations of Tukey outlier deletion with mean resampling and guardrails for contracts to view in HPMS for the 2021, 2022, and 2023 Star Ratings prior to implementing the Tukey outlier change effective with the 2024 Star Ratings. These simulations will use the actual data that will be populating the 2021, 2022 and 2023 Star Ratings and will include all of the changes finalized related to cut point calculations. As noted in the NPRM, for the first year (2024 Star Ratings), we will rerun the prior year's thresholds, using mean resampling and Tukey outer fence deletion so that the guardrails would be applied such that there is consistency between the years. This, therefore, will be done for the simulations using the 2021 Star Ratings. This will provide information for multiple years for plans to see how the cumulative impact of the changes will impact the cut points going forward. Please note that currently mean resampling will be implemented with the 2022 Star Ratings, guardrails will be added with the 2023 Star Ratings, and Tukey outlier deletion will be implemented with the 2024 Star Ratings. Our planned simulations will illustrate the cumulative effect of all of these policies.

Comment: A commenter said CMS could further address outliers by removing contracts that are not eligible for Quality Bonus Payments such as 1876 cost plans and Medicare-Medicaid Plans.

Response: CMS does not include Medicare-Medicaid Plans in the calculation of cut points for the Part C and D Star Ratings since they currently do not receive Star Ratings on Medicare Plan Finder; however, although not eligible for bonuses, 1876 cost plans are part of the Part C and D Star Ratings program (see § 417.472(k)) and have historically received Star Ratings on Medicare Plan Finder so these contracts are included in the cut point calculations. Otherwise, the ratings for public reporting would not be comparable for beneficiaries to use in evaluating their coverage choices.

Comment: A commenter asked for clarification about whether measures in the program for three or fewer years would be included in the Tukey outlier deletion.

Response: We are finalizing the proposed amendment to apply Tukey outlier deletion to all non-CAHPS measures, beginning with the 2024 Star Ratings. This application will be for all such measures regardless of the number of years the specific measure has been used in the Star Ratings program.

Comment: A number of commenters suggested publishing cut points in advance of the measurement year by relying on the data from earlier time periods, reinstituting pre-determined 4-star thresholds, or designing cut points that establish clear national standards of care. Some of the commenters noted that announcing cut points prior to the measurement period would help plans and providers engage in value-based contracts that incentivize higher quality.

Response: CMS understands the interest in setting pre-determined cut points prior to the measurement year, but as stated previously in the April 2019 final rule (84 FR 15752–15754) there are numerous challenges in setting pre-determined cut points, including older data not being reflective of current performance, average performance not always increasing in a linear manner, external factors resulting in significant changes in performance from year to year, larger gains in performance generally seen for newer measures, and the rate of change differing for low performing contracts compared to higher performing ones. Additionally, the measures included in the Star Ratings program do not have national standards of care that plans or providers should meet; thus, it would be challenging to come to consensus on national standards to rate plans in the Star Ratings program. If using older data to predict or establish cut points, we risk causing unintended consequences such as disincentivizing quality improvement or setting cut points that are not aligned to significant changes in industry performance. For example, no one could have predicted the significant impacts the COVID–19 pandemic would have on industry performance for various Star Ratings measures. The current methodology of hierarchal clustering using the current year's data will adjust cut points for the unforeseen impact on plan performance across the program. Since the clustering methodology compares relative performance, it protects plans from unanticipated impacts on industry performance. If there were pre-determined thresholds based on historical data or an independent standard, plans could end up all with uniformly low ratings when unanticipated situations such as the COVID–19 pandemic occur.

Comment: A number of commenters recommended including outliers in the

cut point calculations since they represent the true performance of contracts on the measures. Commenters stated that without including these outliers, CMS would not fully be representing industry performance. Other commenters noted that with the current data integrity polices in place for the Star Ratings program, these outliers are legitimate measure-level contract scores.

Response: CMS agrees that an outlier may be a legitimate score for a particular contract, but we also know that extreme outliers for a measure in a given year can impact statistical analyses such as clustering. In the April 2019 final rule (84 FR 15755–15758) we received stakeholder feedback that in addition to guardrails and mean resampling we should directly address the impact of outliers. Although mean resampling does not directly address outliers, it helps mitigate the effect of outliers because when establishing the thresholds each data point (including outliers) is omitted from 10 percent of the cut points that are estimated (cut points are repeatedly estimated on ten subsets each containing 90 percent of the measure scores) and then averaged across the ten 90 percent samples following resampling. However, based on feedback from the industry to further increase the stability of the cut points and to prevent large fluctuations in cut points from one year to the next caused by the scores of a few contracts, we proposed in the February 2020 proposed rule to more directly remove extreme outliers and are finalizing that policy.

Comment: A handful of commenters supported the addition of Tukey outlier deletion to the cut point methodology, while some suggested delaying implementation or viewing Tukey outlier deletion as an interim solution to improving the stability of the cut points. A commenter suggested phasing in outlier deletion over a multi-year period by putting the cut points with Tukey outlier deletion on display for two years.

Response: We appreciate the support for the addition of Tukey outlier deletion to the cut point methodology and have decided to delay the implementation for an additional year recognizing that there may be fluctuations in measure-level scores as a result of the COVID–19 pandemic. We will also display simulations for the 2021, 2022, and 2023 Star Ratings in HPMS for contracts to see the impact of removing outliers on their stars.

Summary of Regulatory Changes

After consideration of the comments and for the reasons indicated in the proposed rule and our responses to the related comments, we are finalizing as proposed the definition ''Tukey outer fence outliers'' and the specific formulae used. We are finalizing revisions to §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to apply the Tukey outlier deletion methodology prior to applying mean resampling with hierarchal clustering as proposed with one modification. To allow for potential fluctuations in measure-level scores as a result of the COVID–19 pandemic during the 2021 measurement year, we are delaying the addition of Tukey outer fence outlier deletion to the clustering methodology for non-CAHPS measures until the 2022 measurement year and the corresponding 2024 Star Ratings. Moving the effective date will provide an opportunity for MA and Part D contracts to view simulated results using Tukey outlier deletion for the 2021, 2022, and 2023 Star Ratings in HPMS. We note that the regulation text in this final rule incorporates the changes made by the IFC to §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) during the period between the proposed rule and this final rule. The effect of Tukey outlier deletion would create a savings of $935 million for 2025, increasing to $1,449.2 million by 2030.

3. Removing Measures (§§ 422.164, 423.184)

The regulations at §§ 422.164 and 423.184 specify the criteria and procedure for adding, updating, and removing measures for the Star Ratings program. Due to the regular updates and revisions made to measures, CMS does not codify a list in regulation text of the measures (and specifications) adopted through rulemaking for the MA and Part D Star Ratings Program (83 FR 16537). CMS lists the measures used for the Star Ratings each year in the Technical Notes or similar guidance document with publication of the Star Ratings. In the February 2020 proposed rule, CMS proposed the removal of the Rheumatoid Arthritis Management measure from the Star Ratings program for performance periods beginning on or after January 1, 2021.

CMS proposed to remove the Rheumatoid Arthritis Management measure from the Part C Star Ratings for the 2021 measurement year and the 2023 Star Ratings. The measure steward, NCQA, is retiring this measure from the HEDIS measurement set for the 2021 measurement year due to multiple concerns. For example, there are concerns that the performance on the measure may not reflect the rate at which members get anti-rheumatic drug therapy because sometimes these medications are covered by Patient Assistance Programs, which do not generate claims. In terms of the measure construction, the measure assesses only if members received a disease-modifying anti-rheumatic drug once during the measurement year, rather than assessing if members remain adherent to the medication. Additionally, it is unclear, based on the evidence, whether patients in remission should remain on these medications. Since NCQA plans to retire this measure from the HEDIS measurement set, CMS proposed to remove it starting with the 2023 Star Ratings.

Below we summarize the comments we received and provide our responses and final decisions.

Comment: Most commenters supported the retirement of the Rheumatoid Arthritis Management measure and offered a number of reasons for their support. Approximately half of the commenters who supported removal believed current measure specifications erroneously include certain patients in the measure denominator: Those receiving medication through clinical trials, patient assistance programs, or other ways of paying; patients in remission or managing their illness with other drugs; and patients who have side effects or cannot tolerate disease-modifying anti-rheumatics drugs (DMARDS). A couple of commenters noted that the rate of medication adherence would be a better measure of patient outcomes than the current focus on DMARD dispensing. Individual commenters raised a number of additional issues with the measure: The role of the rheumatologist is not captured by the current measure; the measure has low reliability; there is no clinical consensus on whether patients in remission should remain on DMARD medications or should stop taking them at some point; removal of the measure will streamline ratings systems since NCQA has retired the measure from HEDIS; and continued use of the measure would promote unnecessary use of DMARDS.

Response: CMS will pass along to the measure developer suggestions made by commenters for additional research and new directions. NCQA has retired this measure and therefore there will be no data for CMS to use in the Star Ratings program for the 2023 Star Ratings and beyond, so CMS will remove the measure from the Parts C and D Star Ratings.

Comment: A couple of commenters disagreed with CMS's proposal and offered similar explanations and recommended actions for CMS to take

TABLE 2 TO PARAGRAPH (E)(3)(i)(C)—Continued

Minimum ratio	Large metro	Metro	Micro	Rural	CEAC
Psychiatry	0.14	0.14	0.12	0.12	0.12
Pulmonology	0.13	0.13	0.11	0.11	0.11
Rheumatology	0.07	0.07	0.06	0.06	0.06
Urology	0.12	0.12	0.10	0.10	0.10
Vascular Surgery	0.02	0.02	0.02	0.02	0.02
Cardiothoracic Surgery	0.01	0.01	0.01	0.01	0.01
Acute Inpatient Hospitals	12.2	12.2	12.2	12.2	12.2

(ii)(A) *Number of beneficiaries required to cover.* (*1*) The number of beneficiaries required to cover is calculated by multiplying the 95th percentile base population ratio by the total number of Medicare beneficiaries residing in a county.

(*2*) CMS uses its MA State/County Penetration data to calculate the total number of beneficiaries residing in a county.

(B) *95th percentile base population ratio.* (*1*) The 95th percentile base population ratio is:

(*i*) Calculated annually for each county type and varies over time as MA market penetration and plan enrollment change across markets; and

(*ii*) Represents the proportion of Medicare beneficiaries enrolled in the 95th percentile MA plan (that is, 95 percent of plans have enrollment lower than this level).

(*2*) CMS calculates the 95th percentile base population ratio as follows:

(*i*) Uses its most recent List of PFFS Network Counties to exclude any private-fee-for-service (PFFS) plans in non-networked counties from the calculation at the county-type level.

(*ii*) Uses its most recent MA State/County Penetration data to determine the number of eligible Medicare beneficiaries in each county.

(*iii*) Uses its Monthly MA Enrollment By State/County/Contract data to determine enrollment at the contract ID and county level, including only enrollment in regional preferred provider organization (RPPO), local preferred provider organization (LPPO), HMO, HMO/provider sponsored organization (POS), healthcare prepayment plans under section 1833 of the Act, and network PFFS plan types.

(*iv*) Calculates penetration at the contract ID and county level by dividing the number of enrollees for a given contract ID and county by the number of eligible beneficiaries in that county.

(*v*) Groups counties by county designation to determine the 95th percentile of penetration among MA plans for each county type.

(f) *Exception requests.* (1) An MA plan may request an exception to network adequacy criteria in paragraphs (b) through (e) of this section when both of the following occur:

(i) Certain providers or facilities are not available for the MA plan to meet the network adequacy criteria as shown in the Provider Supply file for the year for a given county and specialty type.

(ii) The MA plan has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria, but are currently available and accessible to most enrollees, consistent with the local pattern of care.

(2) In evaluating exception requests, CMS considers whether—

(i) The current access to providers and facilities is different from the HSD reference and Provider Supply files for the year;

(ii) There are other factors present, in accordance with § 422.112(a)(10)(v), that demonstrate that network access is consistent with or better than the original Medicare pattern of care; and

(iii) Approval of the exception is in the best interests of beneficiaries.

■ 13. Section 422.162 is amended in paragraph (a) by adding a definition for ''Tukey outer fence outliers'' in alphabetical order to read as follows:

§ 422.162 Medicare Advantage Quality Rating System.

(a) * * *

Tukey outer fence outliers are measure scores that are below a certain point (first quartile − 3.0 × (third quartile − first quartile)) or above a certain point (third quartile + 3.0 × (third quartile − first quartile)).

* * * * *

■ 14. Section 422.166 is amended—

■ a. By revising paragraph (a)(2)(i); and

■ b. In paragraphs (e)(1)(iii) and (iv) by removing the phrase ''weight of 2'' and adding in its place ''weight of 4''.

The revision reads as follows:

§ 422.166 Calculation of Star Ratings.

(a) * * *

(2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data. Effective for the Star Ratings issued in October 2022 and subsequent years, CMS will add a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from 1 year to the next. Effective for the Star Ratings issued in October 2023 and subsequent years, prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for 3 years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years in the program.

* * * * *

§ 422.258 [Amended]

■ 15. Section 422.258 is amended in paragraphs (d)(3), (d)(5) introductory text, (d)(5)(i) introductory text, (d)(5)(ii), and (d)(6)(i) by removing the reference ''§ 422.306(c)'' and adding in its place the reference '' § 422.306(c) and (d)''.

165. Section 422.306 is amended—

■ a. In the introductory text by:

■ i. Removing ''§§ 422.308(b) and 422.308(g)'' and adding in its place ''§ 422.308(b) and (g)''; and

■ ii. Removing the phrase ''year under paragraph (c) of this section'' and adding in its place the phrase ''year under paragraph (c) of this section and costs for kidney acquisitions in the area for the year under paragraph (d) of this section''; and

■ b. By adding paragraph (d).

The addition reads as follows:

§ 422.306 Annual MA capitation rates.

* * * * *

(d) *Exclusion of costs for kidney acquisitions from MA capitation rates.* Beginning with 2021, after the annual capitation rate for each MA local area is determined under paragraph (a) or (b) of

provided to substantively updated measures for the first year they are returned to the Star Ratings (86 FR 5919). In subsequent years, the measure (both new measures and substantively updated measures) would be assigned the weight associated with its category, which is what happens with new measures as well. In addition, we are proposing to revise the heading for paragraph (e)(2) to reflect how the provision addresses the weight of both new and substantively updated measures.

We welcome comments on this proposal.

F. Guardrails (§§ 422.166(a)(2)(i) and 423.186(a)(2)(i))

In the April 2019 final rule, we amended §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) by adding guardrails, which are measure-specific caps to Star Ratings cut points in both directions so that the measure-threshold-specific cut points do not increase or decrease more than the value of the cap from one year to the next. The intent of this change in methodology was to increase the predictability and stability of cut points. As described in the April 2019 final rule at 84 FR 15754, a trade-off of increasing the predictability of cut points is the inability to keep pace with any unanticipated changes in industry performance. Based on recent experience with calculating Star Ratings during the COVID–19 PHE and analyses of the data for the 2022 Star Ratings, we are proposing to modify the current hierarchical clustering methodology that is used to set cut points for non-CAHPS measure stars at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) by eliminating the guardrails that restrict the maximum allowable movement of non-CAHPS measure cut points.

When we initially proposed guardrails so that the cut points for non-CAHPS measures do not increase or decrease more than the cap from one year to the next, we recognized that with guardrails there may be an inability for thresholds to fully keep pace with changes in performance across the industry. A cap on upward movement can inflate the measure-level Star Ratings if true improvements in performance cannot be fully incorporated in the current year's ratings. If overall industry performance shifts upward on a measure, the Star Ratings cut points affected by a cap for that measure may not fully take into account this upward shift in industry performance. While we recognized the possibility at the time we finalized the guardrails policy, we now have evidence from the 2022 and 2023 Star Ratings that shows that unintended consequence of the policy. For example, for the 2023 Star Ratings for Part C Osteoporosis Management in Women who had a Fracture, the four star threshold without the cap was greater than or equal to 60 percent, but this threshold was reduced to greater than or equal to 55 percent when guardrails were applied. In effect, the cap makes it easier for contracts to receive four stars than it would have been if there was no cap. In this example, because of the cap, a contract with performance of 57 percent would receive a four star rating when, without the cap, the contract would receive a three star rating. This is diluting the value of receiving four stars for contracts that would have received four stars without the cap since some contracts received four stars for performance that ordinarily would not qualify for four stars. Conversely, a cap on downward movement can decrease the measure-level Star Ratings when industry performance overall shifts downward, since the ratings cannot be adjusted fully for downward shifts in performance. For example, for the 2023 Star Ratings for Colorectal Cancer Screening, the one star cut point was higher (43 percent) than it would have been without a cap (38 percent), and therefore more contracts received a one star rating on that measure than they would have if there were no cap. During the COVID–19 PHE, we saw that industry performance declined on some measures included in the 2022 Star Ratings and for other measures industry performance increased. In order to allow non-CAHPS cut points to move with these changes in industry performance, we adopted a delay in the implementation of guardrails in the interim final rule titled ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' which appeared in the **Federal Register** on April 6, 2020 with a March 31, 2020 effective date [194] at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i).

The intent of guardrails was to improve predictability and stability of cut points from one year to the next. At the time the addition of guardrails to the Star Ratings methodology was finalized, we also finalized the addition of mean resampling to the hierarchical clustering methodology to reduce the sensitivity of the clustering algorithm to outliers and reduce the random variation that contributes to fluctuations in cut points. Mean resampling was implemented beginning with the 2022 Star Ratings. Since the addition of guardrails was finalized, we also finalized in the June 2020 final rule at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) adding Tukey outlier deletion to the hierarchical clustering methodology to improve the predictability and stability of cut points. (85 FR 33833–36). Tukey outlier deletion will be implemented beginning with the 2024 Star Ratings and will remove extreme outliers before the clustering algorithm is applied; this will improve the predictability and stability of cut points, which in turn minimizes the need for the guardrails to achieve such goals and weakens the rationale of the guardrails policy at the time the policy was finalized.

After the April 2019 final rule was published, we have learned during the COVID–19 pandemic that it is important for cut points to adjust for unforeseen circumstances that may cause overall industry performance to either increase or decrease. During the 2020 measurement year, we saw both significant increases and significant decreases in scores across some of the Star Ratings measures.[195] As an example, there was a significant shift downward in performance for the Breast Cancer Screening measure during the 2020 measurement year. For Breast Cancer Screening, the 5-star cut point for the 2021 Star Ratings was greater or equal to 83 percent, while for the 2022 Star Ratings it was greater or equal to 76 percent. This drop in the 5-star cut point reflects the change in industry performance. If bi-directional guardrails had been applied for the 2022 Star Ratings, this cut point would have been 78 percent rather than 76 percent, resulting in more contracts earning 4 stars rather than the 5 stars that they would have earned when compared to the performance of their peers in the absence of guardrails. Similarly, there was a significant shift downward in performance for the Diabetes Care—Eye Exam measure during the 2020 measurement year. For Diabetes Care—Eye Exam the 1-star cut point for the 2021 Star Ratings was less than 63 percent, while for the 2022 Star Ratings it was less than 52 percent. This significant drop in the 1-star cut point reflects the downward shift in industry performance. If bi-directional guardrails had been applied for the 2022 Star Ratings, this cut point would have been 58 percent, resulting in some contracts earning 1 star for this measure rather

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than 2 stars when compared to the performance of their peers in the absence of guardrails. There was also a significant shift upward in performance for the MTM Program Completion Rate for CMR for PDPs during the 2020 measurement year. The MTM 5-star cut point for the 2021 Star Ratings was greater than or equal to 61 percent, while for the 2022 Star Ratings it was greater than or equal to 74 percent. This increase in the 5-star cut point reflects the change in industry performance. If bi-directional cut points had been applied for the 2022 Star Ratings, this cut point would have been 66 percent rather than 74 percent resulting in more contracts receiving 5 stars. These examples from the 2020 measurement year have led us to believe that bi-directional guardrails can inappropriately limit the ability of cut points to shift when there are unanticipated shifts in industry performance, causing misclassification in the measure-level Star Ratings assignments.

In addition, the combination of mean resampling and Tukey outlier deletion, with Tukey outlier deletion being finalized after the bi-directional guardrails policy, will provide sufficient predictability and stability of cut points from one year to the next when there are not significant changes in overall industry performance, but at the same time allow cut points to adjust when there are significant changes in performance as there was during the COVID–19 pandemic. We believe it is important for cut points to be allowed to shift by more than 5 percentage points when there are unanticipated, large changes in industry performance in the future. We are proposing at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to modify the language so that guardrails for non-CAHPS measures will only be effective through the 2025 Star Ratings released in October 2024, and not apply for the 2026 Star Ratings or beyond.

We welcome feedback on these changes.

G. Health Equity Index Reward (§§ 422.166(f)(3) and 423.186(f)(3))

As discussed in section III.A of this proposed rule, advancing health equity is the first pillar of the 2022 CMS Strategic Plan and a goal of the CMS national quality strategy. In reports on accounting for Social Risk Factors (SRFs) in value-based purchasing programs, the National Academies of Sciences, Engineering, and Medicine (NASEM) define Social Risk Factors (SRFs) as factors related to health outcomes that are evident before care is provided, are not consequences of the quality of care, and are not easily modified by healthcare providers.[196] CMS agrees with the NASEM definition of SRFs because it captures the elements we consider important in defining SRFs. There are often disparities in health care and outcomes between groups with and without social risk factors (SRFs). For example, the within-contract LIS/DE and non-LIS/DE differences in performance for Part C and D Star Ratings measures can be found at: *2022 Categorical Adjustment Index Measure Supplement Dec 10 2020 (cms.gov).*

The current approach to addressing SRFs in the Part C and Part D Star Ratings program has focused on adjusting for the average within-contract disparities in performance through the Categorical Adjustment Index (CAI), as described at §§ 422.166(f)(2) and 423.186(f)(2), in order to not inappropriately penalize or reward health and drug plans for factors that are difficult for plans to control. For certain current Star Ratings measures, it may be more difficult for most plans to achieve the same level of care for groups that are socioeconomically disadvantaged, disabled, or more complex due to a variety of issues, including transportation issues, lower health literacy, communication challenges, and residential instability. The CAI is a factor that can be positive or negative and is added to a contract's overall and summary Star Ratings that adjusts for the average within-contract performance disparity based on a contract's composition of Low Income Subsidy/Dual Eligible (LIS/DE) and disability status enrollees.

The CAI was implemented in the Part C and Part D Star Ratings program to address SRFs while measure stewards evaluated adjustment on a measure-specific basis. The CAI is a data-driven approach to account for within-contract disparities in performance associated with SRFs in Star Ratings measures that are not already adjusted according to the measure specifications developed by measure stewards. The CAI does not incentivize contracts to focus on reducing disparities. Although all contracts have incentives in the Star Ratings program to improve performance, there are currently no methodological adjustments that specifically create incentives to address disparities of care among a contract's enrollees.

In addition to adjusting for within-contract disparities through the CAI, we also want to encourage MA organizations, cost plans, and Part D plan sponsors to better identify and then address disparities in care provided to enrollees with a particular SRF, with the ultimate goal of reaching equity by eliminating health disparities or differences in contract performance by SRFs, consistent with CMS efforts to advance health equity.

CMS has developed a health equity index (HEI) that we are proposing for use in the Part C and Part D Star Ratings that would reward contracts for obtaining high measure-level scores for the subset of enrollees with specified SRFs. Our intent in implementing an HEI is to improve health equity by incentivizing MA, cost plan, and PDP contracts to perform well among enrollees with specified SRFs. The CAI is designed to improve the accuracy of performance measurement, while not masking true differences in performance between contracts; in contrast, our proposed HEI reward is specifically designed to create an incentive to reduce disparities in care. The HEI, therefore, does not replace the CAI but rather assists plan sponsors in better identifying and then addressing disparities in care provided to members with a particular SRF, with the ultimate goal of reaching equity in the level and quality of care provided to enrollees with SRFs. There would be no changes to the current CAI with the implementation of the proposed HEI reward.

We are proposing to replace the current reward factor described at §§ 422.166(f)(1) and 423.186(f)(1) with the new HEI reward at proposed §§ 422.166(f)(3) and 423.186(f)(3) starting with the 2027 Star Ratings; the HEI for the 2027 Star Ratings would be calculated using data collected or used for the 2026 and 2027 Star Ratings. The current reward factor was included in the Part C and Part D Star Ratings program beginning with the 2009 Star Ratings with the purpose of creating additional incentives for high and stable relative performance across measures by discouraging contracts from having a lot of variation in performance across measures (that is, a mix of low performance and high performance across measures). At the beginning of the Star Ratings program, the distribution of ratings across contracts looked very different, with overall performance much lower than it is today. Over time, we have established additional methodological enhancements to incentivize performance improvement across

[196] Social Risk Factors: Definitions and Data √ Accounting for Social Risk Factors in Medicare Payment √The National Academies Press | *https://nap.nationalacademies.org/read/23635/chapter/4.*

such as telephone numbers and language preference information provided directly by the MA and PDP contract. There are detailed specifications for data collection [201] for vendors to follow; CMS conducts oversight of the data collection efforts of the approved survey vendors.

Measures derived from Prescription Drug Event (PDE) data, Medicare Beneficiary Database Suite of Systems, enrollment data from Medicare Advantage Prescription Drug (MARx) system, and other Federal data sources (for example, FEMA disaster designations) also cannot be appealed for data accuracy because we are pulling data from the system of record or authoritative data source. Part D sponsors submit PDE to CMS via the Drug Data Processing Systems (DDPS), which processes and validates the data. Sponsors must meet the PDE submission deadline to be included in the annual Part D payment reconciliation, and sponsors must certify the claims data (42 CFR 423.505(k)(3)). As another example, enrollment data used in the Star Ratings are also used for the monthly payment of contracts and any discrepancies would have been resolved through retroactive adjustments as needed. Similarly, Medicare Plan Finder (MPF) pricing files cannot be appealed. Plans use the Health Plan Management System (HPMS) Part D Pricing File Submission (PDPFS) module to submit their drug pricing and pharmacy data for posting on the MPF. After the data are submitted, CMS performs a multi-step validation. Validation results are provided to sponsors to correct their data or to attest to the accuracy of the data prior to display on MPF. Part D sponsors are required to perform their own quality assurance checks before submission to ensure that the files are complete and accurate.[202]

Further, in conducting the reconsideration under § 422.260(c), the reconsideration official reviews the QBP determination, the evidence and findings upon which it was based, and any other written evidence submitted by the organization or by CMS before the reconsideration determination is made. Currently, § 422.260(c)(1)(i) provides that the request for reconsideration must specify the given measure(s) in question and the basis for the MA organization's reconsideration request; the alleged error could impact a measure-level score or Star Rating, or the overall Star Rating. The request must include the specific findings or issues with which the MA organization disagrees and the reason for the disagreement, as well as any additional evidence that the MA organization would like the reconsideration official to consider, as the basis for reconsideration. Currently, § 422.260(c)(2)(v) provides that the MA organization must provide clear and convincing evidence that CMS's calculations of the measure(s) and value(s) in question were incorrect; in other words, the burden is on the MA organization to prove an error was made in the calculation of their QBP rating. We are proposing to revise this standard to require the MA organization to prove by a preponderance of evidence that CMS's calculations of the measure(s) and value(s) in question were incorrect and to add additional language at § 422.260(c)(2)(v) clarifying that the burden of proof is on the MA organization to prove an error was made in the calculation of the QBP status. We believe that the appropriate standard of proof is the preponderance of the evidence.

If the hearing officer's decision is in favor of the MA organization, the MA organization's QBP status is recalculated using the corrected data and applying the rules at §§ 422.160 through 422.166. Under our current implementation of § 422.260, recalculation could cause the requesting MA organization's QBP rating to go higher or lower. In some instances, the recalculation may not result in the Star Rating rising above the cut-off for the higher QBP rating. We are proposing additional language at § 422.260(c)(1)(i) to clarify that ratings can go up, stay the same, or go down based on an appeal of the QBP determination.

Under § 422.260(d), CMS may revise an MA organization's QBP status at any time after the initial release of the QBP determinations through April 1 of each year on the basis of any credible information, including information provided during the administrative review process, requested by a different MA organization, that demonstrates that the initial QBP determination was incorrect. CMS issues annual guidance to MA organizations about the QBP appeal process available under § 422.260 each November titled, for example, ''Quality Bonus Payment Determinations and Administrative Review Process for Quality Bonus Payments and Rebate Retention Allowances.'' We interpret and implement § 422.260 through this guidance and our administration of the annual administrative review process.

When the reconsideration official or hearing officer's decision for a particular appeal or other credible information suggests that there was a systematic error impacting all or a subset of contracts, the QBP status of all contracts is re-calculated using the corrected data and applying the rules at §§ 422.160 through 422.166. If the re-calculated QBP rating for a contract other than the appealing contract results in a lower rating, the original preliminary QBP rating will be used. Thus, a contract's QBP rating will not be decreased by CMS as a result of a systematic re-calculation for the current Star Ratings and associated QBP year to correct a systematic calculation error; however, the issue identified will be addressed in the next year's Star Ratings. However, if the QBP rating is higher for a contract after the systematic re-calculation, the new rating will be used. For example, if CMS has to do a systematic re-calculation for the 2023 Star Ratings following the release of the preliminary 2024 QBP ratings, a contract's 2023 Star Ratings used for the 2024 QBP ratings will not be decreased but the change that caused a systematic recalculation will be addressed when the 2024 Star Ratings are calculated. If the re-calculation of the 2023 Star Ratings results in a higher rating for a contract, the higher rating will be used. We propose to add language at § 422.260(d) to clarify that a reopening of a QBP determination to address a systemic calculation issue that impacts more than the MA organization that submitted an appeal would only be updated if it results in a higher QBP rating for other MA organizations that did not appeal. This is how we have historically noted how we would handle this type of systemic calculation error as described in our annual HPMS memo released in November each year.

We welcome comments on this proposal.

K. Calculation of Star Ratings (§§ 422.166(a)(2)(i) and 423.186(a)(2)(i))

In the June 2020 final rule, we finalized use of Tukey outlier deletion effective for the Star Ratings issued in October 2023 and subsequent years. (85 FR 33833–36) In the rulemakings since that time, we have not proposed to eliminate the Tukey outlier deletion aspect of the Star Ratings methodology.

[201] MA and PDP CAHPS Survey administration protocols are contained in the *MA & PDP CAHPS Survey Quality Assurance Protocols & Technical Specifications* and are available at *https://ma-pdpcahps.org/en/quality-assurance/*. The *HOS Quality Assurance Guidelines and Technical Specifications* manual details the requirements, protocols, and procedures for the HOS administration and are available at *https://www.hosonline.org/en/program-overview/survey-administration/*.

[202] See May 28, 2021 HPMS memorandum, Contract Year (CY) 2022 Part D Pricing Data Submission Guidance. *https://www.cms.gov/files/document/cy2022drugpricingsubmissionguidelines05282021final.pdf*

As we stated in May 2022 final rule (87 FR 27766), we will implement Tukey outlier deletion beginning with the 2024 Star Ratings to help improve stability of cut points and prevent cut points from being influenced by outliers. We further stated that with Tukey outlier deletion, extreme outliers will be removed from measure scores prior to clustering to prevent outliers from impacting cut points for all contracts. However, it appears that the sentence in §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) (''Effective for the Star Ratings issued in October 2023 and subsequent years, prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed.'') was inadvertently removed from the codified regulation text. We are proposing a technical amendment to fix this codification error from the May 2022 final rule. In addition, although the provision regarding application of the Tukey outlier deletion policy was originally at the end of paragraph (a)(2)(i) in each regulation, we are also proposing a non-substantive technical change to move the sentence about removal of Tukey outer fence outliers earlier in §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) since Tukey outlier deletion is applied prior to the other steps. We believe that this makes the regulation text clearer.

We welcome comment on this proposal.

VI. Updates to Programs of All-Inclusive Care for the Elderly (PACE) Policy

A. Contract Year Definition (§ 460.6)

Sections 1894(a)(9) and 1934(a)(9) of the Act define the trial period for PACE organizations as the first 3 contract years operating a PACE program under a PACE program agreement. Sections 1894(e)(4) and 1934(e)(4) of the Act require CMS, in cooperation with the State administering agency, to conduct a comprehensive annual review of the PACE organization's operation of the PACE program during the trial period to assure compliance with all significant requirements. The rule titled ''Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE)'', which appeared in the November 24, 1999 issue of the **Federal Register** (64 FR 66234) (hereinafter referred to as the 1999 PACE interim final rule) defined a contract year at § 460.6 as the term of the PACE program agreement, which is a calendar year, except that a PACE organization's initial contract year may be from 12 to 23 months, as determined by CMS. This enables CMS to adjust the length of the initial contract year so that it always ends on December 31 and subsequent contract years align with a standard annual calendar year consisting of 12 months (64 FR 66236). For example, for a PACE organization that signs a program agreement in March 2022, CMS would extend the organization's initial contract year through December 31, 2023, so that all future contract years would align with calendar years.

As previously stated, CMS is required to conduct comprehensive reviews during a PACE organization's trial period to assess all significant regulatory requirements, and these reviews must be conducted on an annual basis for the first 3 contract years. Currently the first trial period contract year may include up to 23 months, but the subsequent two trial period contract years are limited to 12 months, each beginning on January 1 and ending on December 31. CMS has developed audit protocols to comprehensively assess PACE organizations which require the availability of multiple months of program data and typically take 6 to 9 months to complete, including pre-audit data collection, audit fieldwork, and the corrective action period which allows time for PACE organizations to correct deficiencies identified during audits. CMS must conduct the first trial period audit within the first contract year in order to comply with the statutory and regulatory requirements. However, our ability to schedule and conduct the first trial period audit is limited by when a PACE organization enters into a program agreement, the current contract year definition in § 460.6, and when the PACE organization begins enrolling participants during their first contract year. Depending on when the program agreement is signed, the first trial period audit may be required within 12 months from the contract start date which we believe is not a sufficient length of time for new PACE organizations to establish their operations before undergoing an audit.

In order to have enough data to conduct a comprehensive audit, CMS has found it necessary to allow a PACE organization to operate with enrollees for at least 6 months before conducting its first trial period audit, which may not occur until the latter half or end of their first contract year. However, unless the first trial period audit is scheduled early in the calendar year, we encounter significant operational challenges conducting subsequent audits for the second and third years of the trial period in accordance with statutory and regulatory requirements, while still giving PACE organizations sufficient time between audits to ensure they are able to fully correct the deficiencies identified during an audit before CMS collects data for the next audit. Specifically, delaying the first trial period audit until later in the calendar year to ensure adequate PACE organization operational experience, reduces the time between audits, which creates overlap between timeframes to correct deficiencies and the data collection period for subsequent trial period audits. For example, under the current contract year definition, a PACE organization that enters into a program agreement on January 1, 2023 must receive its first comprehensive trial period audit by December 31, 2023, its second trial period audit in 2024, and its third trial period audit in 2025. If CMS first audits the PACE organization in early 2023, we would not have enough data to conduct a comprehensive review. However, waiting to schedule the first audit until later in 2023 reduces the timeframe within which CMS can schedule the second and third trial year audits required in 2024 and 2025. Given that a PACE organization may need 9 months to complete the first trial period audit initiated in 2023, and multiple months of data are required for each audit, it is operationally challenging for CMS to schedule and complete the next 2 annual audits within the trial period while still affording PACE organizations a sufficient amount of time between audits to correct identified deficiencies.

CMS therefore proposes to amend the definition of contract year at § 460.6 to state that a PACE organization's initial contract year may be 19 to 30 months, as determined by CMS, but in any event will end on December 31. Under the proposed contract year definition, although the duration of the initial contract year of the trial period would change, the initial contract year would continue to begin when the program agreement is signed and end on December 31 to ensure subsequent contract years follow the standard annual calendar year cycle. For PACE organizations with an initial contract year start date of January 1 through June 1, CMS would extend the initial contract year through the following year. For example, for a program agreement signed on January 1, 2024 or up until June 1, 2024, the initial contract year would end December 31, 2025. The second and third contract years would begin on January 1, 2026 and January 1, 2027, respectively. Additionally, for PACE organizations with an initial contract year start date of July 1 through December 1, CMS would

provided to substantively updated measures for the first year they are returned to the Star Ratings (86 FR 5919). In subsequent years, the measure (both new measures and substantively updated measures) would be assigned the weight associated with its category, which is what happens with new measures as well. In addition, we are proposing to revise the heading for paragraph (e)(2) to reflect how the provision addresses the weight of both new and substantively updated measures.

We welcome comments on this proposal.

F. Guardrails (§§ 422.166(a)(2)(i) and 423.186(a)(2)(i))

In the April 2019 final rule, we amended §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) by adding guardrails, which are measure-specific caps to Star Ratings cut points in both directions so that the measure-threshold-specific cut points do not increase or decrease more than the value of the cap from one year to the next. The intent of this change in methodology was to increase the predictability and stability of cut points. As described in the April 2019 final rule at 84 FR 15754, a trade-off of increasing the predictability of cut points is the inability to keep pace with any unanticipated changes in industry performance. Based on recent experience with calculating Star Ratings during the COVID–19 PHE and analyses of the data for the 2022 Star Ratings, we are proposing to modify the current hierarchical clustering methodology that is used to set cut points for non-CAHPS measure stars at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) by eliminating the guardrails that restrict the maximum allowable movement of non-CAHPS measure cut points.

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[195] 2022 Star Ratings Fact Sheet. *https://www.cms.gov/files/document/2022-star-ratings-fact-sheet1082021.pdf.*

than 2 stars when compared to the performance of their peers in the absence of guardrails. There was also a significant shift upward in performance for the MTM Program Completion Rate for CMR for PDPs during the 2020 measurement year. The MTM 5-star cut point for the 2021 Star Ratings was greater than or equal to 61 percent, while for the 2022 Star Ratings it was greater than or equal to 74 percent. This increase in the 5-star cut point reflects the change in industry performance. If bi-directional cut points had been applied for the 2022 Star Ratings, this cut point would have been 66 percent rather than 74 percent resulting in more contracts receiving 5 stars. These examples from the 2020 measurement year have led us to believe that bi-directional guardrails can inappropriately limit the ability of cut points to shift when there are unanticipated shifts in industry performance, causing misclassification in the measure-level Star Ratings assignments.

In addition, the combination of mean resampling and Tukey outlier deletion, with Tukey outlier deletion being finalized after the bi-directional guardrails policy, will provide sufficient predictability and stability of cut points from one year to the next when there are not significant changes in overall industry performance, but at the same time allow cut points to adjust when there are significant changes in performance as there was during the COVID–19 pandemic. We believe it is important for cut points to be allowed to shift by more than 5 percentage points when there are unanticipated, large changes in industry performance in the future. We are proposing at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to modify the language so that guardrails for non-CAHPS measures will only be effective through the 2025 Star Ratings released in October 2024, and not apply for the 2026 Star Ratings or beyond.

We welcome feedback on these changes.

G. Health Equity Index Reward (§§ 422.166(f)(3) and 423.186(f)(3))

As discussed in section III.A of this proposed rule, advancing health equity is the first pillar of the 2022 CMS Strategic Plan and a goal of the CMS national quality strategy. In reports on accounting for Social Risk Factors (SRFs) in value-based purchasing programs, the National Academies of Sciences, Engineering, and Medicine (NASEM) define Social Risk Factors (SRFs) as factors related to health outcomes that are evident before care is provided, are not consequences of the quality of care, and are not easily modified by healthcare providers.[196] CMS agrees with the NASEM definition of SRFs because it captures the elements we consider important in defining SRFs. There are often disparities in health care and outcomes between groups with and without social risk factors (SRFs). For example, the within-contract LIS/DE and non-LIS/DE differences in performance for Part C and D Star Ratings measures can be found at: *2022 Categorical Adjustment Index Measure Supplement Dec 10 2020 (cms.gov).*

The current approach to addressing SRFs in the Part C and Part D Star Ratings program has focused on adjusting for the average within-contract disparities in performance through the Categorical Adjustment Index (CAI), as described at §§ 422.166(f)(2) and 423.186(f)(2), in order to not inappropriately penalize or reward health and drug plans for factors that are difficult for plans to control. For certain current Star Ratings measures, it may be more difficult for most plans to achieve the same level of care for groups that are socioeconomically disadvantaged, disabled, or more complex due to a variety of issues, including transportation issues, lower health literacy, communication challenges, and residential instability. The CAI is a factor that can be positive or negative and is added to a contract's overall and summary Star Ratings that adjusts for the average within-contract performance disparity based on a contract's composition of Low Income Subsidy/Dual Eligible (LIS/DE) and disability status enrollees.

The CAI was implemented in the Part C and Part D Star Ratings program to address SRFs while measure stewards evaluated adjustment on a measure-specific basis. The CAI is a data-driven approach to account for within-contract disparities in performance associated with SRFs in Star Ratings measures that are not already adjusted according to the measure specifications developed by measure stewards. The CAI does not incentivize contracts to focus on reducing disparities. Although all contracts have incentives in the Star Ratings program to improve performance, there are currently no methodological adjustments that specifically create incentives to address disparities of care among a contract's enrollees.

In addition to adjusting for within-contract disparities through the CAI, we also want to encourage MA organizations, cost plans, and Part D plan sponsors to better identify and then address disparities in care provided to enrollees with a particular SRF, with the ultimate goal of reaching equity by eliminating health disparities or differences in contract performance by SRFs, consistent with CMS efforts to advance health equity.

CMS has developed a health equity index (HEI) that we are proposing for use in the Part C and Part D Star Ratings that would reward contracts for obtaining high measure-level scores for the subset of enrollees with specified SRFs. Our intent in implementing an HEI is to improve health equity by incentivizing MA, cost plan, and PDP contracts to perform well among enrollees with specified SRFs. The CAI is designed to improve the accuracy of performance measurement, while not masking true differences in performance between contracts; in contrast, our proposed HEI reward is specifically designed to create an incentive to reduce disparities in care. The HEI, therefore, does not replace the CAI but rather assists plan sponsors in better identifying and then addressing disparities in care provided to members with a particular SRF, with the ultimate goal of reaching equity in the level and quality of care provided to enrollees with SRFs. There would be no changes to the current CAI with the implementation of the proposed HEI reward.

We are proposing to replace the current reward factor described at §§ 422.166(f)(1) and 423.186(f)(1) with the new HEI reward at proposed §§ 422.166(f)(3) and 423.186(f)(3) starting with the 2027 Star Ratings; the HEI for the 2027 Star Ratings would be calculated using data collected or used for the 2026 and 2027 Star Ratings. The current reward factor was included in the Part C and Part D Star Ratings program beginning with the 2009 Star Ratings with the purpose of creating additional incentives for high and stable relative performance across measures by discouraging contracts from having a lot of variation in performance across measures (that is, a mix of low performance and high performance across measures). At the beginning of the Star Ratings program, the distribution of ratings across contracts looked very different, with overall performance much lower than it is today. Over time, we have established additional methodological enhancements to incentivize performance improvement across

[196] Social Risk Factors: Definitions and Data √ Accounting for Social Risk Factors in Medicare Payment √The National Academies Press | *https://nap.nationalacademies.org/read/23635/chapter/4.*

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Docket: CMS-2022-0191
Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024

Comment On: CMS-2022-0191-0001
Medicare Program: Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, etc.

Document: CMS-2022-0191-0674
Comment on CMS-2022-0191-0001

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General Comment

Please see attached AHIP comment.

Attachments

AHIP_Comments_CY2024 MA Proposed Rule 2.13.23

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February 13, 2023

Administrator Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services (CMS)
Attention: CMS-4201-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications ("Proposed Rule")

Dear Administrator Brooks-LaSure:

Americans agree: The Medicare Advantage (MA) and Part D programs are enormously successful models of public/private partnerships that offer choice, competition, and innovation in their coverage and care. These programs deliver high-quality, affordable coverage and care to tens of millions of America's seniors and people with disabilities. AHIP[1] welcomes the opportunity to comment on the Proposed Rule, which would have significant impacts on these programs.

More than 30 million Americans have chosen MA – almost half of those eligible for Medicare. MA plans deliver better services, better access to care, and better value than the original Medicare program. Enrollees in MA are more racially and ethnically diverse and are more satisfied with their coverage than those in original Medicare. MA also enjoys strong bipartisan support.[2] And more than 50 million enrollees are receiving robust access to prescription drugs through Part D plans.[3] Despite exorbitant launch prices for new drugs and out-of-control drug price increases on existing medicines, Part D plans have kept premiums steady by negotiating lower costs with drug manufacturers and pharmacies, using available, tested and effective cost management and negotiating tools.

[1] AHIP is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to market-based solutions and public-private partnerships that make health care better and coverage more affordable and accessible for everyone. Visit www.ahip.org to learn how working together, we are Guiding Greater Health.
[2] See, e.g., the recent letter to CMS from a bipartisan group of more than 60 Senators.
[3] More than 27 million receive their Part D coverage through MA plans.

To build on these successes, AHIP supports a number of proposals that would strengthen consumer protections while retaining flexibility, choice, competition, and value. **At the same time, we are concerned that certain proposals would reduce funding or increase costs without benefiting seniors and people with disabilities.** Further, the sweeping changes under consideration here, when combined with recent statutory changes and other payment and regulatory changes either finalized or proposed elsewhere, will increase financial and operational uncertainties and create new barriers to the continued availability of high-value, affordable coverage. Accordingly, **we urge CMS to consider how the combined impacts of these numerous changes could inhibit innovation, increase confusion and complexity, and ultimately harm seniors and people with disabilities**. We also urge CMS to consider regulatory approaches that will ensure stability and value for the tens of millions of people these programs serve. The following is a summary of key areas of support and concern, with more information in our attached detailed comments.

Key Proposals We Support Include:

- **New Marketing Requirements That Would Protect Medicare-Eligible Americans Without Unduly Burdening Access to Help in Choosing Medicare Options.** AHIP appreciates CMS' efforts to enhance federal requirements designed to protect Medicare-eligible Americans from misleading advertising, and to reduce confusion and abrasion. AHIP supports many of CMS' proposals to add new marketing standards and oversight requirements to the robust rules already in place. However, as discussed in our attached detailed comments, CMS should reconsider how certain proposals such as mandated waiting periods for meetings with trusted agents and brokers could unduly inconvenience seniors and people with disabilities who face social barriers, mobility challenges, or rely on trusted family members or caregivers who have limited availability to participate in multiple sessions with the Medicare-eligible person. In addition, we believe certain proposals require longer implementation timelines than CMS has proposed given the need for additional CMS guidance, revised materials and/or updated training.

- **New Prior Authorization Standards That Clarify MA Flexibilities Without Unduly Limiting the Ability to Promote High Value Care.** We appreciate that CMS recognizes utilization management tools like prior authorization (PA) are an important means to coordinate care, reduce inappropriate utilization, and promote cost-efficient care. Numerous studies have found Americans frequently receive inappropriate care in a variety of settings for many different medical procedures, tests, and treatments.[4] PA can ensure care is delivered in the most appropriate setting, at the most appropriate frequency, and by the most appropriate provider. At the same time, health insurance providers have been working hard to

[4] The Institute of Medicine has confirmed that geographic variations in spending are substantial, pervasive, and persistent over time and there is little to no correlation between spending and health care quality. In a national survey of over 2,000 physicians, most (64.7%) reported at least 15-30% of medical care is unnecessary.

make PA more efficient, more effective, and less burdensome.[5] We support CMS proposals that build on these efforts by clarifying the scope of permissible PA, increasing transparency, and (in a separate proposed rule) expanding electronic PA. However, in our detailed comments we urge CMS to retain long-permitted flexibilities in the MA program so plans can encourage the delivery of high-quality care in safe, cost-effective alternative settings that are covered in the original Medicare program. We also are concerned about the feasibility of implementing new restrictions and process mandates for 2024 given MA bid cycle and operational needs.

- **Provisions That Would Promote Health Equity.** AHIP continues to strongly support CMS' efforts to advance health equity. We support provisions in the Proposed Rule such as enhancing digital health literacy and using quality improvement program activities to reduce disparities in health and health care. We also support CMS' efforts to develop a health equity index reward in the Star Ratings Program but have concerns with methodological and design issues in the index proposed by CMS. Additionally, we recommend that CMS improve enrollee data collection and align data collection standards across programs.

Key Areas of Concern Include:

- **Star Ratings Program Changes That Would Not Increase Quality but Would Reduce Benefits or Increase Premiums.** We have serious concerns with proposed changes to the Star Ratings program, including proposals to eliminate the reward factor and limit application of the hold harmless policy for the improvement measures, which would make it more difficult for MA plans to obtain funds to offer more choices, expand supplemental benefits, and keep premiums low. We are also concerned that implementation of Inflation Reduction Act (IRA) changes in Part D could further negatively affect certain Star Ratings measures and plan performance due to factors outside of plan control. While we appreciate CMS proposing to decrease the weight of survey measures relative to the weight of clinical outcome measures as AHIP has previously recommended,[6] the overall impact of the Star Ratings proposals would be higher premiums and/or reduced benefits for enrollees, impacts that would disproportionately affect seniors and people with disabilities in underserved communities without increasing quality.

[5] In July 2022, AHIP posted a comprehensive report on how health insurance providers have delivered on their commitments to improve PA for patients and providers. This report follows up on the 2018 Consensus Statement among providers, health insurers, and other stakeholders recommending opportunities to improve the PA process.
[6] At the same time, we encourage CMS to review separate comments that AHIP members may submit on this topic so the agency more fully appreciates the investments MA plans have made to improve patient experience and their perspectives on the potential implications of the proposed change. We also urge CMS to continue working with the Agency for Health Research and Quality (AHRQ) and National Committee for Quality Assurance (NCQA) to research longer-term solutions to improve the CAHPS survey and response rates.

- **New Network Requirements That Would Fail to Account for Provider Shortages and Related Factors.** Every day, health insurance providers work with people, providers, and communities to ensure access to mental health care and support through methods such as coordinating and integrating mental health with medical and physical health care, expanding access to telehealth appointments, and reducing the stigma associated with mental health conditions. We also recognize that with more Americans of all ages seeking mental health care, capacity is being stretched to its limits. AHIP and our member organizations have developed specific policy recommendations to improve access, care, and equity for patients.[7] Certain CMS proposals build on these efforts - such as promoting continuity of care for behavioral health services through MA care coordination programs. However, we have significant concerns that proposals to apply new time and distance standards to three behavioral health specialty types and to impose appointment wait time mandates for behavioral health and primary care fail to appropriately account for provider shortages and other factors outside plan control. A more flexible approach is needed to accommodate these reasonable factors and avoid placing unreasonable expectations or burdens on providers.

- **Proposed Changes to Part D Medication Therapy Management (MTM) Program Requirements That Would Be Costly and Disruptive**. Given major changes to Part D taking affect under the IRA, CMS should not be mandating a rapid increase in staffing and administrative structure to implement proposed expanded eligibility criteria for MTM programs. Before any such changes are made, additional analysis is needed to assess the effectiveness of the MTM program and alternative methods already being used by plans and contracted providers. However, if the proposal is finalized, we urge that changes be phased in over time.

Overall Concerns with Magnitude of Proposed Changes Affecting MA. In addition to our comments on the specific provisions in the Proposed Rule, it is important to consider them on a combined basis and in the context of a broader set of policy changes affecting the MA program.

- **Taken together, CMS in one plan year is making (or proposing to make) sweeping changes affecting critical components of the MA program without a comprehensive assessment of the combined impacts of those measures.** The sheer magnitude of changes in the Proposed Rule is extensive, with major proposals affecting key MA elements including utilization management, marketing, and Star Ratings. At the same time, there are other major changes outside the Proposed Rule affecting the MA program: the recently issued final Risk Adjustment Data Validation rule; the significant proposed changes in the interoperability rule that will affect the MA program; and proposed major changes relating to the risk adjustment model and other payment components in the 2024 Advance Notice.

[7] https://www.ahip.org/resources/a-vision-for-improved-mental-health-care-access-for-every-american.

- **We are concerned that CMS has not considered how provisions applying similar approaches to different policy objectives could adversely affect enrollees.** For example, the Proposed Rule would expand situations in which MA plans must proactively conduct outreach to members after a primary care or mental health provider leaves a network. This change should not be considered in a vacuum; adding more outreach to the robust proactive communications that MA plans already conduct (e.g., care coordination activities, claims/appeals processes, etc.) creates the risk that seniors and people with disabilities come to view the combined impacts of these contacts as overly aggressive and intrusive rather than helpful.

- **The changes are taking place while plans are working to implement the biggest changes to the Part D program since its inception due to the recently enacted IRA.** Changes in Part D can have significant impacts on MA organizations, including increasing the cost of providing Part D coverage as supplemental benefits, and focusing organizational time and resources on comprehensive implementation efforts.

- **These provisions are on top of the numerous changes that have been made to the MA and Part D programs in prior years**, some of which are now being undone under the Proposed Rule. It means MA plans are required to devote significant resources each year to implementation, training, provider contracting, communications, and other actions – resources that could otherwise be used to provide additional benefits to enrollees.

The cumulative impact of those factors is significant. They create tremendous uncertainty that inhibits planning and investments in long-term innovations. These changes impose higher administrative costs due to factors outside of plan control. Compliance is more challenging when systems and training requirements must be constantly updated, particularly when paired with extremely short implementation deadlines that fail to reflect MA and Part D bidding cycles and operational and contracting needs. The accumulated changes also create more confusion and complexity for enrollees, family members, agent/brokers, and providers. **Ultimately, all these factors combine to increase program costs, limit choice, reduce supplemental benefits, and/or increase premiums.**

As the MA program continues to grow, we urge CMS to account for how so much uncertainty and change can undermine the ability of MA plans to continue offering innovative, affordable options to seniors and people with disabilities. We recommend that CMS seriously consider options to bring more stability to the program by limiting the number and scope of changes, extending implementation timelines, and other approaches. We look forward to discussing those strategies with CMS.

The Value of Medicare Advantage

MA delivers better services, better access to care, and better value through innovative, patient-centered programs that improve quality and reduce costs for seniors and the most vulnerable Americans with disabilities.

Care for diverse and vulnerable populations. Medicare Advantage plans care for a growing share of Medicare beneficiaries dually eligible for Medicare and Medicaid benefits. In 2019, 44% of dual-eligible beneficiaries were enrolled in MA, up from 25% in 2013[8], and research shows dual-eligibles enrolled in MA have greater health needs than those in original Medicare.[9] MA also serves a more racially and ethnically diverse population. In 2020, 30% of MA enrollees were minorities, compared with 20% of those in original Medicare.[10] Minority populations are especially prevalent among those who choose MA plans that combine both medical and prescription drug coverage with monthly premium beyond the standard Part B premium.[11]

In 2020, over half of all racial and ethnic minorities were enrolled in MA, up dramatically from 2006, when only about a third of minorities chose MA.[12] Recent research shows MA plans have made substantial progress in reducing health disparities for racial and ethnic minorities and rural populations across key health measures such as getting an annual flu vaccine, diabetic eye and kidney exams, and access to preventive and ambulatory services.[13]

Greater care coordination and more comprehensive benefits. MA plans work with their members to prevent, detect, and manage chronic conditions through programs that better integrate and coordinate care compared to original Medicare. MA plans also provide more comprehensive benefits than original Medicare. Some of these essential benefits include integrated dental, hearing, and vision coverage along with innovative telehealth options. In recent years, MA plans began offering new types of benefits that address various social barriers to better health, such as wellness programs and nutrition, transportation, and in-home caregiver services, and the availability of these benefits has grown tremendously. In 2022, 1,034 plans offer a new type of health-related benefit designed to help support enrollees such as in-home support services, home-based palliative care, adult day services, or caregiver support, and

[8] Murphy-Barron, C, Pyenson, B, Ferro, C, et. al. “Comparing the Demographics of Enrollees in Medicare Advantage and Fee-For-Service Medicare.” Milliman. October 2020.
[9] NORC at the University of Chicago. “Analysis of COVID-19 Impact on Medicare Advantage and Fee-for-Service Beneficiaries.” May 2021.
[10] AHIP. “Medicare Advantage Demographics Report.” January 2023.
[11] NORC analysis of June 2021 CMS Medicare enrollment and demographic data, conducted for AHIP. December 2021.
[12] Trish, E, Valdez, S, et. al. "Substantial Growth In Medicare Advantage And Implications For Reform.” Health Affairs. 42. No 2 (2023): 246-251.
[13] RAND Health Care. “Trends in Racial, Ethnic, Sex, and Rural-Urban Inequities in Health Care in Medicare Advantage: 2009-2018.” December 2021.

increase of 111% since the benefits were first made available in 2020.[14] The availability of special supplemental benefits for chronically ill Americans – benefits like nutrition support, transportation for non-medical needs, or structural home modifications to support independent living – have grown even faster, increasing by almost 400% to more than 1200 plans in 2022.[15]

More financial security. All MA plans deliver affordable coverage to members by capping annual out-of-pocket costs while individuals with original Medicare coverage alone are exposed to extraordinarily high cost-sharing. MA premiums continue to decline, falling 8% from 2022 to an average of $18 a month in 2023.[16] Further, the Medicare Payment Advisory Commission (MedPAC) reports that in 2023, 99% of those eligible for Medicare have an option to enroll in a MA plan that offers drug coverage for no additional cost.[17]

Better health outcomes. MA has been shown to provide better quality of care on various clinical quality measures[18], reduce hospital admissions and readmissions as well as patient days spent in rehabilitation facilities and nursing homes[19,20,21], and lower hospital use in the last days of life.[22] Peer-reviewed research has found that MA plans outperform original Medicare across a range of metrics, including better access to preventive care and better clinical outcomes.[23] For example, MA enrollees are more likely to receive important preventive services like annual wellness exams and cognitive screenings than their counterparts in original Medicare.[24]

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[14] ATI Advisory. "New, Non-Medical Supplemental Benefits in Medicare Advantage in 2022." January 2022. Accessed at https://atiadvisory.com/wp-content/uploads/2022/01/Plan-Year-2022-Medicare-Advantage-New-Non-Medical-Supplemental-Benefits.pdf.
[15] Id.
[16] CMS. CMS Releases 2022 Premiums and Cost-Sharing Information for Medicare Advantage and Prescription Drug Plans. September 2021. Accessed at https://www.cms.gov/newsroom/press-releases/cms-releases-2023-premiums-and-cost-sharing-information-medicare-advantage-and-prescription-drug.
[17] Medicare Payment Advisory Commission. "The Medicare Advantage Program: Status report and mandated report on dual-eligible special needs plans." January 2023 Public Meeting.
[18] Agarwal, R., Connolly, J., Gupta, S., et al. Comparing Medicare Advantage And Traditional Medicare: A Systematic Review. *Health Affairs* 40(6): 937-944. June 2021.
[19] Kumar, A., Rahman, M., Trivedi, Amal, N. et al. Comparing post-acute rehabilitation use, length of stay, and outcomes experienced by Medicare fee-for-service and Medicare Advantage beneficiaries with hip fracture in the United States: A secondary analysis of administrative data. *PLoSMed* 15(6): e1002592.
[20] Jung D., DuGoff E., Smith M., Palta M., Gilmore-Bykovskyi A., Mullahy J. Likelihood of hospital readmission in Medicare Advantage and Fee-For-Service within same hospital. *Health Serv Res*. 2020;55:587–595.
[21] Schwartz, A., Slaoui, K., Foreman, R., et al. Health Care Utilization and Spending in Medicare Advantage vs. Traditional Medicare: A difference-in-difference analysis. Jama Health Forum. 2021.
[22] Sungchul, P., Teno, J., White, L., Coe, N. Effects of Medicare advantage on patterns of end-of-life care among Medicare decedents. Health Serv Res. February 13, 2022.
[23] DuGoff, E., Rabak, R., Diduch, T., et al. Quality, Health, and Spending in Medicare Advantage and Traditional Medicare. *The American Journal of Managed Care* 27(9). September 2021.
[24] Jacobson, M., Thunell, J., and Zissimopoulos, J. Cognitive Assessment at Medicare's Annual Wellness Visit in Fee-For-Service and Medicare Advantage Plans. *Health Affairs* 39 (11): 1935–1942. November 2020.

Research also suggests that MA does a better job in addressing complex care needs than original Medicare. In one cross-sectional study of 1.8 million Medicare beneficiaries, those enrolled in MA had lower rates of hospital stays, ED visits, and 30-day readmissions. Overall, the study found that among Medicare beneficiaries with complex care needs, those enrolled in MA had lower rates of acute care utilization, suggesting that managed care activities in MA may influence the nature and quality of care provided to these beneficiaries.[25]

Studies have also found better outcomes for patients with specific chronic diseases when they are covered by MA. When compared to patients with original Medicare, MA members with end stage renal disease have lower mortality and reduced utilization.[26] Further, MA members with diabetes and cardiac disease experienced fewer emergency room visits and hospitalizations and better quality scores compared with those covered under original Medicare.[27] Lastly, MA members who experience a hip fracture have shorter lengths of stay and fewer hospital readmissions.[28]

Cost efficiency for seniors and taxpayers. For many years, average MA plan bids for delivering the basic Medicare benefit have been well below original Medicare costs — 83% of original Medicare, based on the latest MedPAC estimates.[29] Research provides examples of how MA plans achieve these savings: for example, through more efficient prescribing of Part B drugs and MA enrollees receiving care from more efficient providers.[30] Further, according to MedPAC, average payments to MA plans in 2023 are projected to be on par with original Medicare costs while MA offers supplemental benefits and enhanced financial security for seniors.[31] In fact, in areas where MA enrollment is higher relative to original Medicare, additional MA enrollment leads to slower original Medicare costs and spending growth as

[25] Antol, D., Schwartz, R., Caplan, A., Casebeer, A., Erwin, J., Shrank, W., Powers, B. Comparison of Health Care Utilization by Medicare Advantage and Traditional Medicare Beneficiaries with Complex Care Needs. JAMA Health Forum. 2022.
[26] Powers, B., Yan, J., Jingsan, et al. The Beneficial Effects of Medicare Advantage Special Needs Plans for Patients with End-Stage Renal Disease. *Health Affairs* 39(9): 1486–1494. September 2020.
[27] Landon, B., Zaslavsky, A., Saunders, R., et al. A comparison of relative resource use and quality in Medicare Advantage health plans versus traditional Medicare. *American Journal of Managed Care* 21(8): 559-566. August 2015.
[28] Kumar, A., Rahman, M., Trivedi, Amal N. et al. Comparing post-acute rehabilitation use, length of stay, and outcomes experienced by Medicare fee-for-service and Medicare Advantage beneficiaries with hip fracture in the United States: A secondary analysis of administrative data. *PLoSMed* 15(6): e1002592. June 2018.
[29] Medicare Payment Advisory Commission. January 2023 Public Meeting Presentation. January 2023.
[30] Anderson, K., Polsky, D., Dy, S., et. al. Prescribing of low-versus high-cost Part B drugs in Medicare Advantage and traditional Medicare. *Health Serv Res.* 2021.
[31] Medicare Payment Advisory Commission. January 2023 Public Meeting Presentation. January 2023.

providers employ MA practice patterns and care guidelines for their remaining original Medicare patients.[32,33,34,35]

Leading the way in value-based care. MA plans are leading the way in leveraging value-based payment arrangements, working with providers to bring better quality and more affordable care to patients. In 2021, more than half (58%) of health care payments from MA plans were tied to alternative payment models in 2020, compared to 47% in original Medicare and 40% overall.[36]And research shows that these alternative payment arrangements mean MA patients get higher value care. One recent study found that those enrolled in MA received 9.2% fewer low-value services than those in original Medicare. The MA enrollees in health maintenance organizations and those in primary care organizations reimbursed within advanced value-based payment models had the lowest rates of low-value care.[37] Another study showed MA plan value-based payment arrangements with providers resulted in lower costs, improved patterns of utilization, and higher survival rates.[38]

High satisfaction. A recent survey finds continued high satisfaction with the MA program with 94% of senior voters with MA reporting satisfaction with their health care coverage. A strong majority of senior voters with MA are satisfied with access (95%) and affordability (90%) of medical care through their MA coverage. Among rural voters with MA, nearly all (96%) are satisfied with access of medical care through their MA coverage. Nine in ten voters with MA are satisfied with their prescription drug coverage (90%, including 60% very satisfied) and preventive services they receive (92%, including 64% very satisfied). Nine in ten (93%) voters with MA would recommend their coverage to their families or friends based on their personal experience.[39]

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[32] Johnson, G., Figuero, J., Zhou, X., et al. Recent growth in Medicare Advantage enrollment associated with decreased fee-for-service spending in certain US counties. *Health Affairs* 35(9): 1707-1715. September 2016.
[33] Callison, K. Medicare managed care spillovers and treatment intensity. *Health Economics* 25(7):873-887. July 2016.
[34] Baicker, K., Robbins, J. Medicare payments and system-level health-care use: The spillover effects of Medicare managed care. *American Journal of Health Economics* 1(4):399-431. October 2015.
[35] Baicker, K., Chernew, M., Robbins, J. The spillover effects of Medicare managed care: Medicare Advantage and hospital utilization. *Journal of Health Economics* 32(6):1289-1300. December 2013.
[36] Health Care Payment Learning & Action Network. APM Measurement: Progress of Alternative Payment Models. November 2022. Available at: https://hcp-lan.org/apm-measurement-effort/2022-apm/.
[37] Boudreau, E., Schwartz R., Schwartz, A., Navathe A., Caplan, A., et.al. Comparison of Low-Value Services Among Medicare Advantage and Traditional Medicare Beneficiaries. *JAMA Health Forum.* 2022;3(9):e222935. doi:10.1001/jamahealthforum.2022.2935.
[38] Mandal, A. Tagomori, G., Felix, Randell V. et al. Value-based contracting innovated Medicare Advantage healthcare delivery and improved survival. *American Journal of Managed Care* 23(2): e41-e49. February 2017.
[39] Morning Consult National Poll. December 6-9, 2022. Available online at: https://medicarechoices.org/americans-like-ma-2023/.

Seniors and the most vulnerable Americans with disabilities deserve to know they can count on the essential benefits and affordable, high-quality coverage they need to stay healthy. That's why more than 30 million Americans – some 46% of all those eligible for Medicare – choose MA – with a recent study in *JAMA Health Forum* finding that more Americans are switching to MA plans from original Medicare.[40]

Conclusion

Again, we appreciate the opportunity to comment on the Proposed Rule and your continued commitment to partner with MA and Part D plans. Attached are detailed comments on the foregoing proposals and other provisions in the Proposed Rule. Our recommended changes are designed to maintain and grow strong and stable MA and Part D programs so the millions of seniors and people with disabilities who rely on them continue to receive the high-quality, coordinated care they deserve. We look forward to continuing to work together on policies that ensure affordable and innovative choices in MA and Part D to improve the health and well-being of Americans.

Sincerely,



Matthew Eyles
President & Chief Executive Officer

[40] Unuigbe, A., Cintina, I., Koenig, L. Beneficiary Switching Between Traditional Medicare and Medicare Advantage Between 2016 and 2020. *JAMA Health Forum.*3(12):e224896. December 29, 2022.

AHIP Detailed Comments
Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs

General comment on effective date for new requirements

The MA and Part D Proposed Rule for CY 2024 codifies a number of existing provisions of MA and Part D guidance and adds a significant number of new requirements. It appears that the new provisions are generally effective for 2024 with some exceptions (e.g., certain Star Ratings proposals).

Discussion and Recommendations:

Given the volume and complexity of the changes proposed to take effect for CY 2024, CMS should provide MA plans with more time to implement the new requirements included in the Proposed Rule. By the time this rule is finalized, plans may have only several weeks to fully assess all of the changes to existing program requirements, adequately reflect these changes in their 2024 bids, modify contracts, and make systems and other operational changes needed to meet the 2024 effective date. **We therefore urge CMS to delay the effective date to 2025 or later for new regulatory requirements that are finalized under this rule and are not required by statute or existing rules to take effect by 2024, including but not limited to:**

- **Proposed changes to MA plan use of utilization management (UM) policies and tools.** Given the volume and complexity of the expansive set of proposed changes, as discussed in more detail below, we urge CMS to delay until 2026 the effective date of new regulatory requirements focused on UM that are finalized under this rule. A 2026 effective date would also align with CMS' proposed 2026 effective date for its Advancing Interoperability and Improving PA proposed rule[41] that also impacts MA plans.

- **Changes to Part D Medication Therapy Management (MTM) program requirements.** For reasons we detail in our comments below, AHIP recommends CMS not proceed with implementing the proposed MTM Program eligibility requirements. However, if CMS decides to proceed with expanding enrollment in the program in a final rule, we urge it to be done via a gradual/phased-in approach that allows plan sponsors sufficient time to adapt and scale up to better accommodate these new requirements. AHIP believes that—at a minimum—this approach is less disruptive (and costly) to enrollees, the Medicare program, and plans than simply adopting these changes as proposed and increasing enrollments by 64% in less than a year. These additional burdens would also be imposed at the same time as

[41] 87 FR 76238, December 13, 2022.

program changes imposed by the Inflation Reduction Act (IRA) provisions and other significant CMS policy changes are being implemented into Medicare.

- **Changes to the MA network standards and provider directories**. We recommend CMS delay the requirement for the addition of the proposed new directory data elements until solutions like CMS' National Directory of Healthcare Providers & Services (NDH) are further explored and implemented to address the inherent challenges of provider directories. We also recommend CMS provide plans more time, up to CY 2025, to meet the new network adequacy requirements for behavioral health (BH) services. Workforce shortages and other factors outside plan control should also be addressed through a modified network adequacy exceptions process.

- **Changes to the marketing requirements that rely on issuance of sub-regulatory guidance in advance of 2023 annual enrollment period (AEP).** Given the breadth and scope of the proposed changes to the marketing rules, we are concerned that by the time the final rule and sub-regulatory guidance are released, plans and their partners may not have sufficient lead time to implement all of the finalized marketing related changes impacting the AEP for CY 2024. We recommend CMS consider a 2025 effective date to ensure successful implementation.

II. Implementation of Certain Provisions of the Bipartisan Budget Act of 2018, the Consolidated Appropriations Act, 2021, and the Inflation Reduction Act of 2022

A. Applying D-SNP Look-Alike Requirements to Plan Benefit Package Segments (§§ 422.503(e), 422.504, 422.510 and 422.514)

CMS proposes to extend its regulatory prohibition on dual-eligible special needs plan (D-SNP) "look-alikes" to the segment level in cases where an MA plan benefit package (PBP) includes multiple segments with different benefit designs. In a conforming change, CMS proposes to provide itself with authority to sever the D-SNP "look-alike" segment from the related MA plan, which would allow the remaining segments of that MA plan to continue (along with any other MA plans offered under the same contract).

CMS proposes to identify existing MA plans as D-SNP "look-alikes" if they either project dual enrollment of at least 80% in their bids or have actual enrollment that exceeds the same regulatory threshold. Currently, the standard for existing plans is based only on actual enrollment. CMS specifies that the change would take effect for 2024.

Finally, CMS proposes to add regulatory language that would expressly permit termination of an MA contract when the contract meets the criteria for a D-SNP "look-alike" plan.

Discussion and Recommendations:

While AHIP has raised concerns in the past with the "look-alike" policy, the proposal to apply it to plan segments that meet the test for D-SNP "look-alike" plans would be a logical extension of such policy, and we appreciate the conforming change to allow remaining segments of the plan and other plans under the same contract to continue.

We also reiterate our prior concerns about the policy's failure to distinguish between full-benefit and partial-benefit dual eligibles for purposes of identifying D-SNP "look-alike" plans. While we understand the concern of CMS and states that "look-alike" plans may result in the diversion of full-benefit dual eligibles from integrated D-SNPs, partial-benefit dual eligibles are not eligible for Medicaid benefits (except for coverage of Medicare cost sharing) and cannot benefit from integrated D-SNPs to the same extent as full-benefit dual eligibles. Moreover, partial dual eligibles can benefit from the tailored care management approaches used by many MA plans and the supplemental benefits that MA plans can offer, especially special supplemental benefits for the chronically ill (SSBCI). **Therefore, we continue to urge CMS to reconsider the practice of including of partial dual eligibles in calculating the 80% threshold for "look-alike" plans.**

Regarding the proposed authority for CMS to terminate a MA contract that includes a plan that meets the criteria for a "look-alike" plan, we urge CMS to provide details regarding the circumstances under which it would use that authority instead of taking more incremental measures to achieve compliance with the "look-alike" policy.

Another issue noted by some of our members is that confusion can arise when crosswalk transactions are processed between segmented and non-segmented plans due to the variety of permissible scenarios. We understand that in some cases, crosswalk transition plans for 2023 were approved by CMS but MA plans later experienced incorrect denials during the plan crosswalk process despite the prior approval. **With respect to crosswalking, we recommend the agency provide full details of requirements and status of approvals in the CMS Health Plan Management System (HPMS).**

B. Part D Special Enrollment Period Change Based on CAA Medicare Enrollment Changes (§ 423.38)

CMS proposes to align the timeframe for use of the Part D special enrollment period (SEP) based on new Medicare Part B general enrollment period (GEP) enrollment effective date parameters stemming from the Medicare enrollment statutory changes made by the Consolidated Appropriations Act, 2021(CAA).

Discussion and Recommendations:

We support CMS' proposal to align the timeframe for use of the Part D SEP based on new Medicare Part B GEP enrollment effective date parameters.

C. Alignment of Part C and Part D Special Enrollment Periods with Medicare Exceptional Condition Enrollment (§§ 422.62 and 423.38)

CMS proposes to add corresponding exceptional condition SEPs for MA and Part D enrollment to align with the Medicare enrollment statutory changes made by the CAA. Therefore, individuals who use an exceptional condition SEP to enroll in premium Part A and/or Part B would be provided an opportunity to enroll in a MA or Part D plan, provided that the individual meets applicable eligibility requirements for the plan.

Discussion and Recommendations:

We support CMS' proposal to align the Part C and Part D SEPs with the Medicare exceptional condition enrollment.

III. Enhancements to the Medicare Advantage and Medicare Prescription Drug Benefit Programs

A. Health Equity in Medicare Advantage (MA) (§§ 422.111, 422.112, and 422.152)

CMS proposes the following changes for CY 2024 to support the advancement of health equity in MA:

- Equitable access – Current regulations require that MA coordinated care plans ensure that covered services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds. CMS proposes to specify additional populations to whom this requirement would apply.

- Improvements to provider directories – CMS proposes to add two new required data elements to MA provider directories: providers' cultural and linguistic capabilities (including American Sign Language (ASL)) and notations for providers waived to treat patients with medications for opioid use disorder (MOUD).

- Digital health education – CMS would require MA plans to develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy to assist with accessing any medically necessary covered telehealth benefits. Plans would also be required to make information about their programs available to CMS upon request.

- Change to quality improvement program requirements – CMS would require MA plans to incorporate one or more activities into their overall Quality Improvement Programs that help to reduce disparities in health and health care among their enrollees.

Discussion and Recommendations:

AHIP and our members strongly support the promotion of culturally competent care and equitable access to services for Medicare enrollees. We believe that everyone deserves affordable, high-quality health coverage and care. AHIP members have taken action to reduce disparities by addressing social drivers of health. Evidence shows that these solutions are working. For example, studies have found reduced health disparities for racial and ethnic minorities and rural populations served by MA plans across several key health measures, such as annual flu vaccines, diabetic eye and kidney exams, and access to preventive services.[42] MA plans are also increasingly using expanded regulatory flexibility to offer more benefits, including non-medical services and supports, to enrollees in need to help address social drivers of health and advance health equity. Research demonstrates that services and interventions that address the health-related social needs of MA beneficiaries can result in improved quality of life, improved health outcomes, and reductions in unnecessary health care utilization.[43]

In general, we support CMS' proposals to advance health equity. We ask CMS to ensure that the program requirements take into account data collection and other challenges that must be overcome for plans to identify individuals and populations facing health disparities and subsequently initiate activities and strategies to reduce such disparities. For example, some of the categories of underserved populations discussed under the agency's equitable access proposal are not clearly defined (e.g., religious minorities, areas with high levels of deprivation, people otherwise adversely affected by persistent poverty or inequality) or may present challenges to MA organizations with respect to beneficiary sensitivities around health plan collection of self-reported data (e.g., gender identity and sexual orientation). We therefore request that CMS consider the following comments and recommendations related to the health equity proposals:

- Equitable Access – To ensure that services are provided in a culturally competent manner and enrollees have equitable access to services under the Medicare fee-for services (FFS) and MA programs, we recommend that CMS take the following additional steps:

    + Improve data standards. Robust, accurate, actionable, and standardized demographic data is fundamental to advancing health equity. Current data content standards (whether from Office of Management and Budget, CMS, 2020 Census, or the 2011 Department of Health

[42] RAND Health Care. "Trends in Racial, Ethnic, Sex, and Rural-Urban Inequities in Health Care in Medicare Advantage: 2009-2018." December 2021.
[43] Innovative-Approaches-to-Addressing-SDOH-for-MA-Beneficiaries-FINAL.pdf (bettermedicarealliance.org); SDOH-MA-IssueBrief-2021.pdf (ahip.org).

and Human Services' recommendations proposed in the Affordable Care Act), unfortunately continue to lead to varied, inaccurate, incomplete, or missing data, with significant percentages of respondents selecting "Other" because current data response options often do not align with how people identify themselves. To improve upon existing demographic data standards, AHIP convened diverse groups of health insurance providers and other stakeholders (e.g., patients representing different communities, providers, community-based organizations, and others) for over 18 months from 2020 to 2022 in a Health Equity Workgroup and employed an evidence-based and stakeholder-driven process to develop improved data standards[44] using culturally appropriate framing that align with how people identify themselves. We are encouraged by the updated draft standards published by the Office of Management and Budget (OMB) on January 27, 2023, and we will be submitting comments.[45] **We welcome the opportunity to continue to discuss our recommended demographic data standards[46] in more detail with CMS.**

+ Improve data collection. Data collection through enrollment forms continues to be a critical part of efforts to address health equity and social drivers of health. **We recommend CMS propose further changes to the Medicare FFS and MA enrollment forms to enable collection of more sociodemographic information directly from enrollees.** AHIP and our members also welcome the opportunity to work with CMS to educate Medicare enrollees about the value of self-reported sociodemographic data and the guardrails for protecting the privacy and security of their data.

+ Support broader data collection through a phased approach. Sociodemographic data collected and reported by health plans, hospitals, clinicians, and other providers is critical in informing care and in identifying and reducing health disparities. **We recommend CMS support incremental steps to facilitate broader data collection and reporting by stakeholders on a wider set of sociodemographic data.** Plans, hospitals, clinicians, and other organizations will need to design, align, implement, test, evaluate, and revise data collection and application workflows. Accordingly, CMS should focus initially on a small number of social needs and/or demographic data elements with interoperable codes, and then add additional data elements in subsequent years in a phased approach.

+ Support alignment of data standards. A major challenge to equity efforts is that health plans, hospitals, and clinicians are following various federal and state data collection requirements on demographics and social needs. Varying data collection standards hinder

[44] AHIP letter, "Improving Demographic Data Standards to Advance Health Equity," October 2022. Available online at: https://www.ahip.org/documents/AHIP-Letter-on-Demographic-Data-Standards-with-Appendix.pdf.
[45] 88 FR 5375, January 27, 2023.
[46] AHIP letter, "Improving Demographic Data Standards to Advance Health Equity," October 2022. Available online at: https://www.ahip.org/documents/AHIP-Letter-on-Demographic-Data-Standards-with-Appendix.pdf.

efforts to aggregate, analyze, and enable apples-to-apples comparisons across markets and across health care entities and the ability to measure improvement. Having interoperable patient demographic data would allow the health care ecosystem to collect this data when most appropriate and convenient for patients and share the information with other partners with patients' consent to inform their care and population health management efforts, as well as to more effectively address disparities in access to care and outcomes. To promote interoperability across different standards and codes, AHIP mapped our demographic data standards to standardized codes (e.g., LOINC, SNOMED, ICD-10) and developed a data documentation framework that provides guidance on how frequently each question should be asked and how various responses should be coded.[47] **We recommend CMS support alignment of demographic data standards at the ecosystem level through federal policy changes to advance health equity.**

+ Incentivize use of standardized codes. Use of standardized codes by providers continues to lag. Many providers are still not aware of the availability and value of codes (such as Z codes, LOINC codes, or SNOMED codes) to document patients' health-related social needs. Many electronic health record (EHR) systems do not have easy ways to add Z codes to a patient's problem or diagnostic list. Providers also have concerns with adding Z codes to a patient's problem or diagnostic list because the provider may then feel responsible for addressing the patient's health-related social needs that occur outside of the clinician's office. **We recommend CMS educate providers about the value of standardized coding. Additionally, CMS should consider developing incentive programs to increase provider use of standardized codes. CMS should also work with ONC to incentivize EHR system developers to implement modifications that facilitate the use of all available interoperable codes, including Z codes, LOINC codes, and SNOMED codes.**

We also have the following comments and recommendations related to the other health equity proposals:

- Improvements to provider directories. MA plans work continuously to improve provider directories. Maintaining accurate directories is a shared responsibility between clinicians, facilities, and health insurance providers. Despite the best efforts of health insurance providers, including direct outreach to providers, electronic solutions, advanced analytics and artificial intelligence methods, and ongoing validation and audits, directories remain less than 100 percent accurate. Experience shows there are two formidable barriers to ensuring fully accurate provider directory information: (i) many providers do not consistently provide updates to their contact information, or they may provide inaccurate information; and (ii)

[47] AHIP letter, "Improving Demographic Data Standards to Advance Health Equity," October 2022. Available online at: https://www.ahip.org/documents/AHIP-Letter-on-Demographic-Data-Standards-with-Appendix.pdf.

there is no single "source of truth" for provider information that can be leveraged to verify information contained in directories.

We believe a public-private partnership between the federal government, providers, payers, and solutions vendors is needed to streamline collection of directory information and improve directory accuracy. AHIP supports CMS' proposal to explore a National Directory of Healthcare Providers & Services (NDH) as indicated in our comments in response to CMS' request for information on development of an NDH.[48] AHIP has recommended that CMS first work with stakeholders to develop the core set of provider directory data elements (such as languages spoken) supported by the NDH, as well as potential extension elements that may be required. A cohesive, national approach to building a technology-enabled infrastructure would help ensure accuracy of directories, reduce burdens on providers and plans, and improve efficiency. CMS should also conduct a provider directory education campaign to encourage providers to respond to questions from health plans related to provider directories and related provider information.

AHIP and our members appreciate the importance of non-English speaking patients or those with limited English proficiency being able to receive care in their preferred language. However, we have heard from AHIP members who operate Medicaid managed care organizations (which are already subject to a regulatory requirement regarding cultural and linguistic capabilities in provider directories), that despite good faith efforts to collect this type of data, many providers do not share information on the languages they speak or their cultural capabilities. Thus, when a provider returns a question about cultural and linguistic capabilities with a 'blank' data field, it is unclear whether this means that for example the provider only speaks English, or whether the information was simply not included. **If this provision is finalized, we ask CMS to use its authority to encourage healthcare provider organizations to maintain this data for their own individual clinicians, so that accurate and complete information may be provided to MA organizations and other payors.**

We also note that the prescribing of medications for opioid use disorder (MOUD) is an area that is evolving, particularly with the recent enactment of Section 1262 of the Consolidated Appropriations Act of 2023 (CAA), which removed the federal requirement for practitioners to submit a Notice of Intent (i.e., have a waiver commonly referred to as an "X-Waiver") to prescribe medications, like buprenorphine, for the treatment of opioid use disorder. **Given the recent enactment of this legislative provision that likely will significantly expand the number of eligible prescribers, we recommend CMS not adopt its directory proposal related to prescribers of MOUD. CMS should first consider and analyze the impact of**

[48] AHIP Press Release, "Working with CMS to Improve Provider Directories Accuracy," October 2022. Available online at: https://www.ahip.org/news/press-releases/ahip-looks-forward-to-working-with-cms-to-improve-provider-directories-accuracy.

the recent legislative change on its proposal and then modify its proposal with a new notice and comment opportunity.

For the reasons discussed above, AHIP recommends CMS delay the requirement for the proposed new directory data elements until solutions like an NDH are further explored and implemented to address the challenges of provider directories. If CMS moves forward and adopts these two new data elements for MA provider directories, we urge CMS not to penalize plans undertaking good faith efforts to collect information and improve their provider directories until the NDH or an equivalent solution is available to providers and plans.

- Digital health education. While telehealth helps increase safe access to care, especially during a pandemic, it can create or exacerbate disparities in access by leaving some populations behind. Research conducted prior to the pandemic revealed that older Americans, people residing in rural communities, vulnerable populations, racial and ethnic minorities, and people with lower socioeconomic means are disadvantaged by this "digital divide" and may be unable to take full advantage of telehealth opportunities.[49] Many individuals face challenges to using telehealth, including a lack of access to the internet; an inability to afford the technologies needed to access telehealth, such as phones, computers, connectivity devices, and data plans; and a limited understanding of how to access virtual care.[50]

  AHIP member plans embrace digital solutions that help increase access to care and want to ensure that the enrollees they serve can access safe and convenient care, regardless of where they live or their economic situation. To that end, many health insurance providers continue to work with their provider partners to bridge the digital divide. Low digital health literacy is a significant obstacle in achieving telehealth equity, and many older adults with low digital health literacy experience gaps in access to the health care they need.

  We support CMS' proposal for MA plans to develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy. Additionally, we appreciate and support CMS' proposal to provide MA plans with broad flexibility to design their own digital health literacy screening programs or procedures. Consistent with CMS' proposal to provide plans with broad discretion, we recommend that plans should be able to use a program that is narrow in scope during the initial years to meet this requirement. This would allow plans more time to assess and test various screening and educational tools and programs for feasibility and effectiveness. This flexible approach would also allow for innovation. There are currently different definitions, standards, and vocabulary related to digital health literacy, and the field continues to evolve.

[49] AHIP Issue Brief, "Bridging the Digital Divide for Consumers." Available online at: https://www.ahip.org/documents/202011-AHIP_IB-DigitalDivide.pdf.
[50] Id.

We also encourage CMS to develop a working group comprised of AHIP members and other stakeholders that could come together to consider and discuss research-driven standards, studies, and examples of effective programs to improve digital health literacy.

- Change to quality improvement program requirements. Quality improvement programs are an important vehicle for MA plans to develop and execute activities designed to reduce disparities in health and health care, and advance equity in the health and health care of MA enrollee populations, especially those that are underserved. MA plans are already addressing disparities and gaps in care for underserved populations through a variety of quality initiatives. **We appreciate and support CMS' proposal to provide MA plans with broad discretion in the types of activities they can develop and implement to meet this proposed new quality improvement program requirement.**

B. Behavioral Health in Medicare Advantage (MA) (§§ 422.112, 422.113, and 422.116)

CMS proposes several changes to MA program requirements intended to improve access to behavioral health (BH) services in MA including the following:

- Addition of three new BH specialty types to network adequacy standards. CMS proposes to add clinical psychology, clinical social work, and prescribers of MOUD to network adequacy time and distance evaluations.

- Application of telehealth credits to the three new BH specialty types. CMS proposes to apply the 10-percentage point telehealth credit policy to help MA plans satisfy network adequacy requirements for the three new BH specialty types listed above.

- Addition of BH services to care coordination programs. CMS proposes to add BH services to the list of services for which MA plans must have a care coordination program in place to ensure continuity of care.

- Codification of appointment wait time standards for primary care and BH services. CMS proposes to codify in regulation appointment wait times recommended in sub-regulatory guidance for primary care services and to also extend these suggested wait times to BH services: (i) urgently needed services or emergency—immediately; (ii) services that are not emergency or urgently needed but require medical attention—within 1 week; and (iii) routine and preventive care—within 30 days.

Discussion and Recommendations:

AHIP members are committed to ensuring that MA enrollees have access to the covered BH services they need. Americans are continuing to experience a dramatic increase in BH needs, including in the areas of mental health and substance use disorders (SUD). The increase in demand is outpacing the supply of BH professionals. The Government Accountability Office's (GAO) October 2022 report[51] on the BH professional workforce in the U.S. included the following findings: (i) approximately half of U.S. counties did not have an active psychiatrist or addiction medicine specialist; (ii) more than 150 million people live in federally designated mental health professional shortage areas; and (iii) in the near future, the U.S. will face shortages of mental health providers ranging from 14,280 to 31,109.

In the face of these challenges, MA plans have taken important steps to optimize the existing workforce and improve access to BH services including the following:

- Understanding consumers' experiences accessing BH services. In June 2022, AHIP conducted a nationwide survey[52] of enrollees in MA plans and other kinds of health coverage to understand their experiences accessing care, whether their treatments were covered by insurance, and if insured patients were satisfied with the results. The survey results make it clear: an overwhelming majority of individuals report being satisfied with the mental health care they sought and received through their health insurance providers. Key findings from AHIP's survey included: (i) nearly all respondents who sought mental health care for themselves or someone within their household over the past two years received treatment; (ii) nearly 3 in 4 insured Americans (73%) found it easy to get the care they needed; (iii) more than two-thirds of respondents were able to find an appointment with a provider in less than a month; and (iv) 9 in 10 reported being satisfied with the mental health support they received, including half who said they were very satisfied.

- Access to behavioral telehealth services. MA plans also continue to advance a variety of solutions to further improve access to BH services, including expanding access to telehealth and digital tools for BH services. Telehealth and digital tools can help Medicare enrollees better engage in their health by offering convenience and flexibility. That is why **AHIP strongly supports CMS' proposal to apply telehealth credits to the three new BH specialty types as discussed below.**

- BH integration. Another area of focus for health insurance providers has been integrating mental health support into primary care settings. For example, health insurance providers have promoted collaborative care and enhanced care coordination models by providing primary care clinicians with tools and training to identify and care for their patients' mental

[51] Behavioral Health: Available Workforce Information and Federal Actions to Help Recruit and Retain Providers. Government Accountability Office. October 21, 2022.
[52] AHIP Mental Health Access Survey. June 2022. Available online at: https://www.ahip.org/resources/ahip-mental-health-access-survey-june-2022.

health needs. This allows primary care clinicians to be better equipped to integrate physical and mental health care, treat mild/moderate conditions, and consult with or refer patients to specialists when appropriate. **We continue to encourage CMS to consider the inclusion of the Collaborative Care Model (CoCM) and other enhanced care coordination approaches to support BH integration in future Center for Medicare and Medicaid Innovation (CMMI) demonstration models.**

- AHIP Board of Directors Statement of Commitment. On August 23, 2022, AHIP's Board of Directors released a new Statement of Commitment[53] and a detailed advocacy vision[54] to further improve access to mental health care and SUD treatment for every American. These commitments build on health insurance providers' extensive history of improving access to effective, high-quality care and treatment choices, while offering new solutions for public sector and private market partners to work together to overcome barriers that persist.

In addition to noting the concerted efforts by AHIP and our members to improve access to and quality of BH services, we have the following specific comments and recommendations in response to several BH related provisions included in the proposed rule.

- Addition of three new BH specialty types to network adequacy standards. Regarding clinical social work, we ask CMS to clarify that all disciplines that fit within this category (e.g., licensed independent social workers) would be countable toward meeting adequacy standards. We are concerned, however, about the ability of the current exceptions process under the MA program to address legitimate network challenges that MA plans may face with the proposed addition of the three new BH specialty types (clinical psychology, clinical social work, and prescribers of MOUD) to the MA network adequacy standards. For example, MA plans could face challenges meeting the time and distance standards due to a variety of factors, including but not limited to provider shortages, contracting practices, geographic issues, and other unique community characteristics or health care needs. Plans should also be able to use other provider specialty types (e.g., mental health counselors, licensed therapists, nurse practitioners, etc.) to satisfy the BH related network adequacy requirements. Accordingly, **if CMS were to finalize this proposal, the factors discussed above should be incorporated into the exceptions process for network adequacy, in addition to the justifications allowed under current rules. We also urge CMS to provide more time for plans to meet the standards by delaying the effective date until CY 2025.**

[53]AHIP Board of Directors Statement of Commitment. August 2022. Available online at: https://www.ahip.org/resources/ahip-board-of-directors-statement-of-commitment-improving-access-to-and-quality-of-mental-health-and-addiction-support.
[54] AHIP Statement, "A Vision for Improved Mental Health Care Access for Every American." Available online at: https://www.ahip.org/resources/a-vision-for-improved-mental-health-care-access-for-every-american.

In addition, as noted above, the prescribing of MOUD is an area that is evolving, particularly with the recent enactment of Section 1262 of the CAA, which removed the federal requirement for practitioners to submit a Notice of Intent (i.e., obtain a waiver commonly referred to as an "X-Waiver") to prescribe medications, like buprenorphine, for the treatment of opioid use disorder. Given the recent enactment of this legislative provision **that significantly expands eligible prescribers, we recommend CMS not adopt its proposal related to prescribers of MOUD. CMS should first consider and analyze the impact of the recent legislative change on its proposal and then modify its proposal with a new notice and comment opportunity.**

- Application of telehealth credits to the three new BH specialty types. Expanding access to BH care through telehealth, virtual visits, and other innovative uses of technologies can connect people to the BH support they need. If CMS finalizes this proposal, **AHIP strongly supports CMS' related proposal to apply the 10-percentage point telehealth credits to the three new BH specialty types (clinical psychology, clinical social work, and prescribers of MOUD).**

- Addition of BH services to care coordination programs. AHIP and our members support the goal of including BH services as part of MA plans' care coordination programs. However, **we recommend CMS provide additional time for plans to secure and implement the necessary contracts to add BH services to existing care coordination programs. We urge CMS to delay implementation of this proposal to CY 2025.**

- Codification of appointment wait time standards for primary care and extension to BH services. As discussed earlier, provider availability for BH can vary considerably based on a number of factors outside of plan control. Those and other factors can also affect appointment wait times for BH and primary care providers (PCPs). That is why we appreciate CMS' current guidelines in Chapter 4 of the Medicare Managed Care Manual (MMCM) that provide examples of reasonable appointment wait times for PCPs and also recognize that plans should have the flexibility to consider other factors, including "the enrollee's need and common waiting times for comparable services in the community."[55] We are concerned that the proposal to mandate requirements for primary care without the flexibilities identified in the MMCM, and extending such requirements to BH, would place additional burden on providers and may discourage them from participation in MA plan networks in the future. The expiration of the COVID-19 public health emergency (PHE) declaration could also impact providers and plans in meeting these standards, especially for BH services. For example, if federal rules such as the Ryan Haight Act are reinstated, in-person appointments would be required (in lieu of telehealth) for addiction services or to prescribe controlled substances for BH conditions. **We urge CMS not to adopt strict rules**

[55] Chapter 4 of the Medicare Managed Care Manual, Section 110.1.1, Provider Network Standards.

for appointment wait times and continue to provide plans with flexibility in meeting these network standards consistent with current sub-regulatory guidelines.

D. Enrollee Notification Requirements for Medicare Advantage (MA) Provider Contract Terminations (§§ 422.111 and 422.2267)

CMS currently requires MA plans to make a good faith effort to provide notification to MA enrollees at least 30 calendar days before the effective date of termination of a provider network participation contract. The rule currently applies to enrollees who are patients seen on a regular basis by the provider whose contract is terminating. (CMS proposes to codify sub-regulatory guidance that defines "regular basis" as "enrollees who are assigned to, currently receiving care from, or have received care within the past three months from a provider or facility being terminated".) However, for PCPs, the notice requirement applies to all enrollees who are patients of that PCP. CMS is proposing to modify these rules and to specify the requirements for the content of the notification to enrollees about a provider contract termination. Specifically, CMS proposals would:

- Preserve the phrase "good faith effort" for enrollee notification timeframes for for-cause provider contract terminations but remove "good faith effort" for no-cause provider contract terminations. CMS reasons that MA organizations should be able to meet a CMS established enrollee notification requirement in these no-cause cases on a timely basis.

- For patients of terminating PCPs: (i) extend the notice requirement to all enrollees who have ever been patients of these terminating PCPs (not just current patients); (ii) increase the notice requirement from 30 to 45 calendar days; and (iii) require both written and telephonic notice for contract terminations (the standard is written only for other provider types). MA organizations would be required to continue attempting to reach the enrollee by telephone to provide notice of the termination of the provider from the network when a call goes unanswered.

- Apply those same special rules for terminating PCPs to terminating BH providers.

CMS is also soliciting comment on two issues: 1) how many telephonic attempts are required to notify enrollees of a provider termination, and 2) whether an enrollee who is impacted by a provider contract termination should be eligible for an SEP.

Discussion and Recommendations:

While AHIP supports efforts to ensure enrollees have accurate, up-to-date information about their MA plan, including providers leaving the plan's network, we have several concerns with the proposals described here:

- The assumption that notification can always be provided at least a certain period of time before a no-cause termination ignores the reality that in many cases, providers fail to provide adequate notice when choosing to leave the network. The plan can have limited ability to enforce a timely notice requirement in a network contract, as the key enforcement tool – removal from the plan network – is the very action the provider has taken. **We urge CMS to retain the "good faith" standard when the provider is the party terminating the contract.**

- Requiring notification to any enrollee who has ever seen a terminating BH provider or PCP is unreasonable. An enrollee who receives notification of a provider termination after having seen the terminating provider only once, several years ago, is likely to view the notification as wasteful rather than helpful. While CMS cites continuity of care and the need to preserve ongoing provider relationships as justification for the expanded notification requirements for BH and PCPs, an individual who is no longer a current patient by definition does not have an ongoing relationship and is unlikely to be under an existing care plan with the provider. Therefore, **CMS should retain the existing notification requirements with respect to which patients should be contacted. At a minimum, CMS should limit the notification requirements to enrollees who have seen the terminating BH provider or PCP in the past year.**

- The proposal to require notification by phone every time a primary care or BH provider leaves the plan's network may be unhelpful and unwelcome by many enrollees. As CMS notes elsewhere in the proposed rule, many enrollees already report receiving too many phone calls. There is a significant risk that many will view a phone call notifying them of a provider termination for which they have already received written notice (and for a provider they may have not interacted with for years) as unnecessary and bothersome. Moreover, members may be more likely to misinterpret multiple phone calls as 'spam' calls that have nefarious intent. We also note that the requirement would add administrative burdens relating to messaging, tracking, and receiving increased call center inquiries following unanswered calls and voicemails. This will increase plan costs, which ultimately could have negative impacts on bids and benefits. The proposal also ignores the reality that providers leaving a plan's network are likely to contact affected patients who have approaching appointments.

  We urge CMS to withdraw this proposal and retain existing regulatory requirements that require enrollee notification by mail. Written notices provide enrollees with the time needed to digest the information and decide on the best action based on the information provided and offer an opportunity for the individual to share clear, accurate information with caregivers or trusted advisors for assistance in decision-making. In the event CMS finalizes the requirement for plans to notify enrollees by phone whenever a BH or PCP the individual has ever seen leaves the plan's network, we also ask

that CMS clarify how this requirement interacts with the recent announcement from the Federal Communications Commission of enforcement of rules that limit certain calls made to a residence.[56]

E. Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools (§§ 422.101, 422.112, 422.137, and 422.138)

CMS proposes a number of significant changes related to UM and prior authorization (PA) requirements under MA including:

- Permitted uses of PA. CMS proposes to specify that MA plans are permitted to use PA for one or more of the following purposes: (i) to confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations for the specific item or service; (ii) for basic benefits, to ensure an item or service is medically necessary based on standards specified in § 422.101(c)(1) (which includes the permissible coverage criteria in the regulations; the assessment of whether an item or service is reasonable and necessary under the Medicare statute; the enrollee's medical history, physician recommendations and clinical notes; and involvement of the MA organization's medical director as appropriate); or (iii) for supplemental benefits, to ensure that the furnishing of a service or benefit is clinically appropriate.

- Adherence to Medicare FFS guidelines. CMS would specify that MA plans must comply with general coverage and benefit conditions included in original Medicare laws, including coverage criteria for inpatient admissions, requirements for coverage of Skilled Nursing Facility (SNF) Care and Home Health Services, and Inpatient Rehabilitation Facilities (IRF) coverage criteria. CMS indicates this would require MA plans to follow specific coverage criteria established in applicable Medicare statute, regulations, national coverage determinations (NCDs), and local coverage determinations (LCDs), when making medical necessity determinations.

- Ability to use internal plan coverage criteria for other benefits. Under the proposal, when coverage criteria are not fully established in applicable Medicare statute, regulation, NCDs or LCDs, MA plans would be permitted to create and use internal coverage criteria to make medical necessity determinations provided certain conditions are met:

[56] https://www.federalregister.gov/documents/2023/01/20/2023-00634/limits-on-exempted-calls-under-the-telephone-consumer-protection-act-of-199.

+ The coverage criteria would have to be based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available. (The proposal would define "widely-used treatment guidelines" and acceptable clinical literature.)

+ MA plans would need to provide a public summary of evidence that was considered during the development of the plan's internal coverage criteria for medical necessity determinations, a list of sources of such evidence, and an explanation of the rationale supporting the adoption of the coverage criteria.

- Establishment of UM committee. CMS would require MA plans to establish a "Utilization Management Committee to review all utilization management, including prior authorization policies, annually and ensure they are consistent with current, traditional Medicare's national and local coverage decisions and guidelines."[57]

- Length of approvals and transition requirements. CMS proposes to require, with respect to basic benefits, that MA plans provide for an enrollee undergoing an active course of treatment: (i) approval of a PA request for the entire duration of the approved course of treatment, and (ii) for an enrollee who enrolls in an MA plan (including enrollees new to a plan and new to Medicare), a minimum 90-day transition period when the active course of treatment had previously started, even if furnished by an out-of-network provider. The proposal says that the MA plan "must not disrupt or require reauthorization" for such active course of treatment during the 90-day transition period.

CMS explains several important implications of the proposed changes – for step therapy and for existing coverage flexibilities in areas such as discharges from acute care hospitals.

First, when MA plans are required to adhere to specific Medicare guidelines, step therapy would be permitted only to the extent the step therapy is permitted under the original Medicare guidelines. (At the same time, CMS indicates that MA plans could still use PA to deny coverage for a particular item or service if it is not reasonable and necessary based on the medical necessity determination requirements in the Medicare guidelines.) Conversely, when MA plans are allowed to create internal coverage criteria under CMS' proposal, step therapy would be permissible - if current evidence in widely used treatment guidelines or clinical literature require another item or service to be provided first. CMS also notes this proposal does not affect Part B drugs for which existing rules authorize use of step therapy in certain cases.

Second, CMS specifies in the preamble that MA plans would be restricted in the ability to limit "when and how" they cover basic Medicare FFS benefits.[58] CMS explains that "when care can

[57] 87 FR 79452 at pages 79454-79455.
[58] 87 FR 79452 at page 79502.

be delivered in more than one way or in more than one type of setting, and a contracted provider has ordered or requested Medicare covered items or services for an MA enrollee, the MA organization may only deny coverage of the services or setting on the basis of the ordered services failing to meet the [Medicare coverage rules]."[59] This restriction applies even to cases where an MA plan denies a particular item or service and redirects the enrollee to a different clinically appropriate item or service. CMS acknowledges this would be narrower than current policy, established in a June 2000 final rule, which provided that "…when a health care service can be Medicare-covered and delivered in more than one way, or by more than one type of practitioner, that an MA plan could choose how the covered services will be provided."[60] Thus, for example, if an enrollee in an MA plan is "discharged from an acute care hospital and the attending physician orders post-acute care at a SNF because the patient requires skilled nursing care on a daily basis in an institutional setting, the MA organization cannot deny coverage for the SNF care and redirect the patient to home health care services unless the patient does not meet the coverage criteria required for [Medicare FFS coverage of] SNF care."[61]

CMS also requests comments on early termination of services in post-acute care settings by MA plans and other possible changes to better manage incentives between MA plans and post-acute care providers to deliver the best possible care for Medicare beneficiaries. Additionally, CMS encourages MA plans to adopt gold carding programs that would allow providers to be exempt from PA and provide more streamlined medical necessity review processes for providers who have demonstrated compliance with a plan's gold carding requirements.

Discussion and Recommendations:

AHIP has the following comments and recommendations in response to CMS' expansive set of UM proposals:

Background on value of PA. AHIP appreciates CMS' acknowledgement in the proposed rule that UM policies are an important means to coordinate care, reduce inappropriate utilization, and promote cost-efficient care under MA. Our members support the use of evidence-based clinical policies, including those specified under Medicare FFS rules and guidelines, to ensure the right care is provided to MA enrollees at the right place, and at the right time.

PA is one of many tools health insurance providers use to promote safe, timely, evidence-based, affordable, and efficient care. MA plans and other health insurance providers have adopted a range of evidence-based UM tools, including PA, to help ensure patients receive optimal care based on well-established evidence of efficacy and safety, while providing benefit to the individual patient. Under the supervision of medical professionals, PA can reduce inappropriate

[59] 87 FR 79452 at page 79507.
[60] Id.
[61] 87 FR 79452 at page 79502.

care by catching unsafe or low-value care, or care not consistent with the latest clinical evidence. Low-value or otherwise inappropriate care can contribute to potential harm to patients and unnecessary costs.

The evidence showing the value of PA is clear. For nearly two decades, numerous studies have documented that Americans frequently receive inappropriate care in a variety of settings for many different medical procedures, tests, and treatments.[62] The Institute of Medicine has confirmed that geographic variations in spending are substantial, pervasive, and persistent over time and there is little to no correlation between spending and health care quality.[63] Needless medical tests are unsupported by evidence, causing harm and wasting billions. In a national survey of over 2,000 physicians, most (64.7%) reported at least 15-30% of medical care is unnecessary.[64] A January 2023 study also demonstrates how savings associated with PA far exceed the administrative costs.[65]

The MA program rules support the use of PA as a critical tool to ensure Medicare enrollees receive safe, effective, and appropriate care. Moreover, CMS has repeatedly recognized PA as an important tool to protect patients and has taken a number of actions to thoughtfully expand its use under original Medicare. Additionally, in response to recommendations from the GAO[66] and the Medicare Payment Advisory Commission (MedPAC),[67] original Medicare has implemented evidence-based guidelines and PA for outlier professionals to address the overuse and misuse of imaging services, which can expose patients to unnecessary and potentially harmful radiation, unnecessary surgery and office visits, undue stress, and add wasteful costs to the health care system.

In July 2022, AHIP posted a comprehensive report[68] on how health insurance providers have delivered on their commitments to improve PA for patients and providers. This report follows up

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[62] AHIP Medical Management Resources. Available online at: https://www.ahip.org/issues/medical-management.
[63] Committee on Geographic Variation in Health Care Spending and Promotion of High-Value Care; Board on Health Care Services; Institute of Medicine; Newhouse JP, Garber AM, Graham RP, et al., editors. Variation in Health Care Spending: Target Decision Making, Not Geography. Washington (DC): National Academies Press (US); 2013 Oct 1. Summary. Available from: https://www.ncbi.nlm.nih.gov/books/NBK201637/.
[64] Lyu H, Xu T, Brotman D, Mayer-Blackwell B, Cooper M, Daniel M, et al. (2017). "Overtreatment in the United States." PLoS ONE 12(9): e0181970. https://doi.org/10.1371/journal.pone.0181970.
[65] Brot-Goldberg, Z., Burn, S., Layton, T., Vabson, B. "Rationing Medicine Through Bureaucracy: Authorization Restrictions in Medicare." January 2023.
[66] GAO Report. "Medicare: CMS Should Take Actions to Continue Prior Authorization Efforts to Reduce Spending." Available online at: https://www.gao.gov/products/gao-18-341#:~:text=GAO%2D18%2D341%20Published%3A,or%20items%20like%20powered%20wheelchairs.
[67] MedPAC Chapter 10: Medicare Coverage Policy and Use of Low-Value Care (June 2018 report). Available online at: https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports-jun18_ch10_medpacreport_sec-pdf/.
[68] AHIP report available online at: https://www.ahip.org/documents/AHIP-1P-Consensus-Statement-Actions-072722-FINAL.pdf

on the 2018 Consensus Statement[69] among providers, health insurers, and other stakeholders recommending opportunities to improve the PA process. Since then, health insurance providers have taken and continue to take concrete actions to help achieve the shared goal of making PA more efficient, more effective, and less burdensome.

Below we identify specific proposals we support, as well as concerns and recommendations on other proposals. We recommend that CMS work with plans and providers to ensure these processes work as effectively as possible. Health insurance providers are continually improving PA programs to reduce physician and enrollee burdens and improve outcomes for patients. We also urge CMS to adopt policies that encourage widespread provider adoption of electronic prior authorization (ePA) technology and look forward to submitting recommendations to increase adoption of ePA by providers in our comments in response to CMS' Advancing Interoperability and Improving PA proposed rule.[70]

Proposals we support:

- Clarification of standards. Despite the importance of PA and the steps health insurance providers have taken to make PA more efficient, more effective, and less burdensome, we acknowledge that providers and others continue to raise concerns about the burdens and impacts of PA along with questions about the scope of permissible PA. For that reason, **we support CMS providing additional clarity about the scope of permissible PA.** However, as noted below, we are concerned that certain aspects of the proposal would eliminate long-permitted flexibilities which have allowed MA plans to encourage high-quality, cost-effective care alternatives. We also have other concerns about the proposal, including the proposed effective date for implementing new restrictions and process mandates relating to PA that are discussed in more detail below.

- Public summary of evidence requirement. **We support CMS' requirement for plans to make publicly available the evidence that they considered during the development of their internal medical necessity coverage criteria. CMS should also provide plans with flexibility for meeting the requirement for making this information publicly available.** This proposal would increase transparency into MA plans' medical necessity decision making and ensure consumers and others are better informed about the evidence-based coverage criteria that MA plans use to make medical necessity determinations.

- Establishment of UM committee. In the preamble, CMS indicates that its proposed requirement for MA plans to establish a UM committee would enable the UM committee to

[69] 2018 Prior Authorization Consensus Statement. Available online at: 2018 Prior Authorization Consensus Statement.
[70] 87 FR 76238, December 13, 2022.

operate similarly to a plan's Pharmacy and Therapeutics (P&T) committee. CMS would require plans to meet committee membership requirements outlined in the rule but would also provide plans with flexibility to define the structure and appropriate additional responsibilities of the UM committee. **We support CMS' proposal to provide flexibility for plans to meet this requirement but also recognize that plans may need more time to identify qualified committee members. CMS notes that MA plans could establish a UM committee that largely mirrors their P&T committee. We recommend that CMS also clarify in the final rule that to support efficiencies, MA plans could also use their UM committee to meet the existing P&T committee requirements. Additionally, we recommend CMS permit MA plans, or the parent organization of one or more MA plans, to use one UM committee to serve multiple MA plans when the MA plans are offered under the same legal entity.**

Proposals that raise concerns:

- Adherence to Medicare coverage guidelines – in general. AHIP members have expressed concerns about circumstances under which coverage criteria specified under original Medicare are not fully established or are ambiguous. Required adherence to questionable clinical criteria under original Medicare could lead to worse patient health outcomes, higher costs for the Medicare program, and fewer affordable, high-quality plan choices for beneficiaries. While the proposed rule permits the use of internal plan criteria when original Medicare coverage criteria are not fully established, **we further recommend CMS ensure the agency has a process in place to consider questions and provide clarity on which Medicare guidelines fail to meet the regulatory requirement and therefore permit use of internal plan coverage criteria.**

  We have also heard concerns about guidelines that may be in place but do not reflect current medical or scientific evidence or literature. In such cases, there could be increased risks of patients receiving low value care and experiencing adverse health impacts. **We urge CMS to ensure that NCDs are timely reviewed to reflect the most recent medical or scientific evidence or literature. We further encourage CMS to ensure that Medicare Administrative Contractors (MACs) are timely reviewing LCDs to ensure that they are also based on the most recent medical or scientific evidence or literature.**

  Finally, we have serious concerns that the proposal would require MA plans to follow "coverage criteria for inpatient admissions at 42 CFR 412.3." That regulatory provision includes CMS' "two-midnights" policy for determining when an individual qualifies for an inpatient admission under original Medicare. CMS guidance acknowledges that the two-midnights rule is a "Medicare claims processing procedure" and CMS has said it would not interfere with how MA plans and contracted hospitals establish their criteria for determining

inpatient admissions as compared to observation stays.[71] The proposal would reverse this approach, thereby interfering with MA/hospital contracting and likely raising costs for delivering MA benefits. Moreover, applying the two-midnights rule to MA enrollees would not expand coverage for items or services, but could (depending on plan design) actually impose higher cost sharing liabilities on enrollees. We also note that unlike original Medicare, MA plans have the authority and commonly cover a skilled nursing facility stay without a preceding three-day inpatient admission, further limiting any benefit the proposal could have in terms of coverage for post-acute care. **We urge CMS to modify any final provision to carve out the two-midnights policy from Medicare coverage requirements to which MA organizations must adhere.**

- Limits on use of step therapy. There are medical conditions that may have several medical coverage or medication options. Although their clinical effectiveness may be the same, the patient safety considerations and coverage costs may be very different. Step therapy enables an enrollee to obtain the item, service, or medication they need, but at a lower cost. In 2019, CMS acknowledged the value of step therapy when the agency affirmatively permitted MA plans to apply step therapy to manage Part B drugs.[72] In August 2018, CMS stated that "using step therapy plans could ensure that a senior who is newly diagnosed with a condition begin treatment with a cost-effective biosimilar before progressing to a more costly drug therapy should the initial treatment be ineffective. By implementing step therapy along with care coordination and drug adherence programs in MA, it will lower costs and improve the quality of care for Medicare beneficiaries."[73] **We urge CMS to consider more flexibility to allow step therapy by MA plans that reflects current medical or scientific evidence or literature, even if not expressly permitted under specific original Medicare guidelines. We strongly support CMS' continued flexibility with respect to step therapy for Part B drugs and believe similar benefits to patients and taxpayers could be realized for other items and services.**

- Post-acute care and similar limits on use of PA. We have very serious concerns with CMS' proposal to eliminate more than 20 years of flexibility under the MA program to limit "when and how" original Medicare covered benefits are covered. This proposal would undermine efforts to move towards value-based care and would increase overall costs under the program and thereby adversely affect enrollees and taxpayers without improving patient health outcomes. CMS' Medicare FFS demonstrations have shown that care can be delivered in more than one way or in more than one type of setting. For example, CMS' Comprehensive Care for Joint Replacement Model and Bundled Payments for Care Improvements Model have shown that greater use of home health care instead of institutional post-acute care can

[71] 78 FR 50495 at page 50934.
[72] CMS Fact Sheet. Available online at: https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-prior-authorization-and-step-therapy-part-b-drugs.
[73] Id.

reduced costs without harming patient outcomes. These results have also been discussed in peer-reviewed publications, and these strategies have been implemented by many organizations, including accountable care organizations. A recent Kaiser Family Foundation assessment of post-acute care utilization research found that MA enrollees use less institutional post-acute care in comparison to original Medicare enrollees, with similar or slightly better outcomes.[74,75] MA plans play a vital role in ensuring that their enrollees have access to high-quality, cost-effective care. Limiting plan flexibilities to manage post-acute care would undermine efforts to move towards value-based care and increase costs without improving patient health outcomes. **We therefore urge CMS to not adopt policies that would place limits on plan flexibility to manage post-acute care.**

- 90-day transition period coverage requirement. In the preamble, CMS explains that its 90-day transition period coverage proposal "mirrors Part D transition requirements and using the same period will ensure consistency across the MA and Part D programs. In addition, use of one consistent transition period will likely make it easier for new enrollees to understand their transition coverage."[76] CMS also proposes to define an active course of treatment as "a course of treatment in which a patient is actively seeing the provider and following the course of treatment."[77]

  We are very concerned about the implementation challenges, including the broad coverage scope, associated with the 90-day transition period coverage requirement. The proposed requirement to cover transitional care without the ability to apply PA could increase the risk of fraud, waste and abuse and could have other unintended consequences for the program. We also believe that the 2024 proposed effective date is premature. In its Advancing Interoperability and Improving PA proposed rule[78] CMS' proposal to require a Payer-to-Payer application programming interface (API) to facilitate exchange of information between payers regarding a PA coverage decision for an active course of treatment does not take effect until 2026. We believe this exchange capability should be operational prior to the implementation date for this new coverage requirement. **We strongly recommend CMS delay and not finalize the 90-day transition period coverage requirement proposal until unintended consequences are addressed and until the Payer-to-Payer API is fully functioning. If CMS decides to finalize this proposal, we urge the agency to apply a 2026 effective date.**

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[74] Ochieng, N. and Biniek, J. "Beneficiary Experience, Affordability, Utilization, and Quality in Medicare Advantage and Traditional Medicare: A Review of the Literature." September 2022. Available online at: https://www.kff.org/report-section/beneficiary-experience-affordability-utilization-and-quality-in-medicare-advantage-and-traditional-medicare-a-review-of-the-literature-report/.
[75] Barnett ML, Wilcock A, McWilliams JM, et al. "Two-year Evaluation of Mandatory Bundled Payments for Joint Replacement." *N Engl J Med*. 2019;380(3):252-262.
[76] 87 FR 79452 at page 79505.
[77] 87 FR 79452 at page 79714.
[78] 87 FR 76238, December 13, 2022.

- Full course of treatment requirement. The proposed definition and preamble discussion related to "course of treatment" is broad in scope. It is unclear whether this proposed coverage requirement applies to a continuity of care period or would require approval in perpetuity. We are concerned that it may be misinterpreted to mean that there is no clear time limitation and potentially no limitation on a provider continuing to furnish services that are outside the scope of the original coverage approval. This uncertainty could allow for inappropriate coverage. This lack of clarity could also increase risk for fraud, waste and abuse and costs for beneficiaries and the health care system as a whole. **We recommend CMS clarify in the final rule its definition and coverage expectations related to a "course of treatment." CMS should also provide examples of what is and is not permissible to ensure that treatments that are not medically necessary under Medicare FFS guidelines are not required to be covered under this policy. It is also unclear whether a plan would be required to approve the exact course of treatment included in the original coverage request. This clarity is needed to ensure consistent application of CMS' policy. We believe CMS policy should also ensure that plans have the ability to approve periodic courses of treatment consistent with their internal plan coverage criteria. Additionally, we recommend that in the final rule, CMS make it clear that its transition coverage requirement is limited to 90 days. CMS should allow a plan to work with their MA enrollee after the 90-day transition period to find an in-network provider to continue their care.**

- Encourage use of gold carding programs. Health insurance providers remain committed to improving the PA process. As part of health insurance providers' long-standing commitment to the 2018 Consensus Statement and continued process improvements, AHIP recently surveyed health insurance providers on the use and impact of gold carding programs with a focus on how these programs impact patient care. AHIP's research[79] found that the use of gold carding has increased since 2020—and gold carding programs are most effective when they are used selectively and are continually re-evaluated to ensure patients are receiving the high-quality care they deserve. Additional findings included: (i) health insurance providers are using gold carding programs more frequently to improve efficiency and speed; (ii) gold carding programs work better for some services than others; (iii) gold carding programs include providers with sufficient PA volume and low denial rates; (iv) frequent reviews of provider performance are vital; (v) gold carding programs have mixed reviews; and (vi) concerns about care quality for patients and challenges with implementation are top reasons for discontinuing gold carding programs. **AHIP agrees that gold carding can be helpful in targeting PA requirements where they are needed most and reducing the**

[79] AHIP Survey on Gold Carding Programs. July 2022. Available online at: https://www.ahip.org/resources/new-survey-effective-gold-carding-programs-are-based-on-evidence-and-value-for-patients.

administrative burden on high-performing health care providers. AHIP considers gold carding programs to be a contract issue between a plan and a network provider. As such, and given the varied experience and customized nature of effective gold carding programs, AHIP does not support the mandating of these programs under MA.

- Effective Date. Given the volume and complexity of the changes CMS proposes to make under the UM requirements section of the regulation, MA plans should be provided at least two additional years to implement any finalized requirements. As previously indicated, by the time this rule is finalized, plans may only have several weeks to fully assess all the changes to existing program requirements, adequately reflect these changes in their 2024 bids, modify contracts, and make systems and other operational changes needed to meet the 2024 effective date. Moreover, if the proposal for establishment of a UM committee is finalized, each plan committee would be required to review and possibly have to modify all UM policies to ensure that they are consistent with MA program rules. This work would be considerable and time-consuming. **We therefore urge CMS to delay the effective date to 2026 for new regulatory requirements focused on UM, including the establishment of a UM committee, that are finalized under this rule. A 2026 effective date would not only provide plans with sufficient time to meet new requirements, but also aligns with CMS' proposed 2026 effective date for its Advancing Interoperability and Improving PA proposed rule[80] that impacts MA plans.**

F. Request for Comment on the Rewards and Incentives Program Regulations for Part C Enrollees (§ 422.134 and Subpart V)

CMS asks for stakeholder feedback on whether the agency should issue additional guidance on the definition of "cash equivalent" within the context of MA rewards and incentives programs and the use of gift cards that may be redeemed only at specific retailers.

Discussion and Recommendations:

AHIP supports the use of rewards and incentives programs as a means of encouraging healthy behaviors and promoting the efficient use of health care resources among MA enrollees. We appreciate CMS' ongoing commitment to providing guidance to MA organizations on the design and use of such programs to drive better health outcomes.

We believe additional guidance on the definition of "cash equivalent" within the context of rewards and incentives program would be helpful, and ask CMS to clarify rules on the offering of gift cards that can be redeemed at specific retailers or a specific category of items or services as reward items. As CMS notes in the rule's preamble, there are currently

[80] 87 FR 76238, December 13, 2022.

several different interpretations on the permissible use of such gift cards. Additional guidance from CMS will ensure that MA organizations are able to provide appropriate incentives and rewards as part of efforts to improve enrollee health and wellness.

H. Review of Medical Necessity Decisions by a Physician or Other Health Care Professional with Expertise in the Field of Medicine Appropriate to the Requested Service and Technical Correction to Effectuation Requirements for Standard Payment Reconsiderations (§§ 422.566, 422.590, and 422.629)

Current regulations state that if an MA organization expects to issue a partially or fully adverse medical necessity decision based on the initial review of the request, the organization determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision. CMS proposes to require that for adverse medical necessity decisions, coverage determinations would have to be reviewed by a licensed physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the service at issue. Under the proposal, the health care professional would not need to be the same specialty or sub-specialty as the treating physician or health care professional; CMS indicates that plans would have discretion to determine on a case-by-case basis what constitutes appropriate expertise based on the services being requested and relevant aspects of the enrollee's health condition.

Discussion and Recommendations:

AHIP agrees that health care professionals making coverage decisions should have the expertise in the field of medicine or health care that is appropriate for the service at issue. **We also strongly support CMS' decision not to require the case reviewer involved to be of the exact same specialty or sub-specialty as the treating physician. Such a restrictive approach would not only be cost-prohibitive but would be highly problematic.** In the proposed rule, CMS provides an example of a qualified reviewer. CMS explains that "if a plan intends to deny a request for a home nebulizer, the organization determination request should be reviewed by a health professional with respiratory expertise, such as a respiratory therapist."[81] We also believe that the language in the final rule should provide sufficient flexibility to support plan use of a physician specialized in for example internal medicine for this particular case. Internal medicine physicians are also familiar with the reasons why a home nebulizer may be medically necessary, such as for severe asthma or Chronic Obstructive Pulmonary Disease (COPD) and can order them.

[81] 87 FR 79452 at page 79510.

We therefore strongly support CMS' intent to allow flexibility for a plan to determine on a case-by-case basis what constitutes appropriate expertise based on the services being requested and relevant aspects of the enrollee's health condition, and to not require an exact match between the service requested and the qualifications of the reviewer. We urge CMS to modify the final regulatory text to make this flexibility and plan discretion clear.

M. Part C and Part D Midyear Benefit Changes and Part D Incorrect Collections of Premiums and Cost Sharing (§§ 422.254, 423.265, 423.293, 423.294)

CMS proposes to codify its longstanding prohibition of midyear benefit changes for MA and Part D. Additionally, CMS proposes to require Part D sponsors to: (i) refund incorrect collections of premiums and cost sharing, and (ii) recover underpayments of premiums and cost sharing.

Discussion and Recommendations:

Given that the COVID-19 PHE declaration may end in 2023, certain COVID-19-related waivers and flexibilities may also end at that time. **We recommend that CMS permit plans that have made mid-year benefit changes in 2023 to extend those changes through the end of the contract year.** This approach would ensure that enrollees do not lose a benefit during the plan year and enable plans to continue their efforts to ensure that enrollees have access to their benefits and necessary care.

N. Clarify Language Related to Submission of a Valid Application (§§ 422.502 and 423.503)

CMS proposes to codify that it does not evaluate or issue a notice of determination when an entity submits a substantially incomplete application. CMS also proposes to codify the definition of a substantially incomplete application as one that does not include responsive materials to one or more sections of its MA or Part D application.

Discussion and Recommendations:

AHIP supports codifying the definition of a substantially incomplete application. However, the proposed language does not make clear what constitutes a plan's good faith efforts to provide all required documentation. **We ask CMS to provide additional clarity on what evidence is acceptable to demonstrate that the plan has made best efforts to provide all necessary documentation.**

O. Updating Translation Standards for Required Materials and Content (§§ 422.2267 and 423.2267)

CMS proposes to require MA organizations and Part D sponsors to provide materials to enrollees on a standing basis in any non-English language that is the primary language of at least 5 percent of the individuals in a PBP service area and in accessible formats on request. CMS also proposes to extend this translation requirement to SNP enrollee individualized plans of care. In addition, the proposal would require that FIDE SNPs, HIDE SNPs, and applicable integrated plans translate all Medicare materials that would require translation into any languages required by their capitated Medicaid managed care contract in addition to language(s) required by the Medicare standard. CMS solicits feedback on the scope of this requirement, specifically whether other types of D-SNP plans should be required to meet this requirement as well.

Discussion and Recommendations:

We strongly support CMS' goal to ensure access to important information and materials for Medicare enrollees who have limited English proficiency or need auxiliary aids or services. This proposal applies to a broad range of written beneficiary materials. We have heard concerns about individual cases where it may be difficult to translate and provide a document to a beneficiary under tight timelines (e.g., braille translations could take several weeks). For those circumstances, the plan uses alternative means (e.g., verbal) to communicate the information with their beneficiary to not only meet timeliness standards, but also to appropriately balance the need for quick communication with the beneficiary. **We recommend CMS ensure that the requirement included in the final rule provides plans with flexibility and supports their best efforts to provide translated materials timely and ability to use alternative arrangements when needed to meet timeliness standards. Given the concerns raised above, we also ask CMS to establish a workgroup comprised of plans and other stakeholders that can come up with options for meeting this objective while balancing the need to communicate with beneficiaries quickly in certain circumstances.**

We support the concept of making SNP member care plans accessible to all members but as proposed, we are concerned with both the length of time translation of care plans could take as well as the potentially high costs of translation on a standing basis. Based on figures provided in CMS' Special Needs Plan Comprehensive Report for January 2023, the average SNP enrolls over 4,000 members; and in D-SNPs, the average is 5,825. Instead of requiring each care plan be translated on a standing basis, we believe it would be appropriate and more cost-effective to have a care team member verbally review the care plan in the member's chosen language following updates to the care plan. This approach would have the added benefit of improving member understanding and adherence to the care plan as they would have a team member to review the plan with them and the opportunity to ask questions. Following such a review, if the member requested written translation, the plan could then be required to translate the care plan into the member's requested language. **We urge CMS to modify its proposal to permit SNPs to have a care team member verbally review the care plan in the member's chosen language. If after**

such review the member requests translation, the plan should be required to translate the care plan into the requested language.

P. Medicare Advantage (MA) and Part D Marketing (Subpart V of Parts 422 and 423)

CMS proposes numerous changes related to the content of advertisements and other marketing encounters; new plan oversight rules relating to agents and brokers; and other new marketing rules, including new limits on scheduling of meetings. A number of those proposals and AHIP's comments are highlighted below.

Discussion and Recommendations:

America's older adults and people with disabilities deserve MA plans that continue to deliver better services, better access to care, and better value. And as they make choices about their coverage, Medicare enrollees should be protected from bad actors who engage in misleading advertising and marketing tactics. They should have clear, accurate, easy-to-understand information about MA plans to help them select the coverage option that best meets their needs. Open and honest information about their plans is essential to MA's ability to deliver high levels of satisfaction to enrollees. The industry is committed to ensuring truth in advertising and marketing practices.

Accordingly, AHIP and our members generally support CMS' proposals, which, when added to the robust oversight regime already in place, would protect beneficiaries from misleading advertising and reduce consumer confusion and abrasion.

We are concerned however that several of CMS' marketing related proposals could adversely impact beneficiaries and the resources they rely upon to make the right plan choice to best meet their health care and other needs. Several proposals also do not adequately account for needed implementation time. In addition to complying with state licensing and other requirements, agents and brokers are required to be trained and tested annually on Medicare program rules and regulations and on the specific plan benefits they sell. As members of their local communities, agents can also help plans connect with diverse Medicare populations, including racial and ethnic minorities, to ensure that they have the information and resources they need to inform their Medicare coverage selections. Proposals that unnecessarily limit or impose barriers on access to agents and brokers may prevent consumers from getting educated on critical information they need to make informed decisions. In addition, certain proposals, including those relating to marketing materials, will require the release of more detailed sub-regulatory guidance and may require training and implementation steps that will be difficult to complete if the final rule applied them to marketing for the 2024 plan year.

We have the following specific comments and recommendations on these and certain other proposals:

- Separation of education events from marketing. CMS proposes several changes to the marketing rules which are intended to separate educational events from marketing events. Specifically, CMS proposes to: reinstate the prohibition on accepting Scope of Appointment (SOA) cards or the collection of beneficiary contact information at educational events; prohibit MA plans and agents from setting up future marketing appointments at educational events; prohibit marketing events from taking place within 12 hours of an educational event in the same location; and prohibit personal marketing appointments from taking place until after 48 hours have passed since the time the SOA was completed by the beneficiary.

  CMS explains that these changes would help to "alleviate the pressure a beneficiary may feel to stay for a marketing event and will protect beneficiaries from undue pressures to enroll in a plan for which they may not be interested or a plan that does not best meet their health care needs."[82] We are concerned that these proposed changes would have the opposite effect; they could deprive Medicare enrollees the ability to have in-person interactions and conversations, which studies suggest Medicare enrollees strongly prefer.[83]

  We also are concerned that de-linking education events from marketing could adversely impact dual eligible individuals and result in health inequities. Our members have shared that a higher share of dual eligible individuals enroll through face-to-face encounters with agents and brokers. At the same time, they often face unique challenges such as lack of access to transportation services and technology that makes it difficult to schedule multiple meetings; it is critical that they have access to information and resources in one interaction. The proposed 12-hour wait time after an educational event and 48-hour wait time after completion of an SOA could therefore impose absolute barriers on attending a subsequent meeting, potentially limiting their ability to choose a plan that best meets their health care and other needs. The wait times could also adversely impact beneficiaries who need to make a plan selection but are facing an immediate enrollment deadline. **For these reasons, we strongly recommend that CMS not adopt its proposals that would separate educational events from marketing, including the provisions that prohibit marketing events from taking place within 12 hours of the educational event in the same location; and personal marketing appointments from taking place until after 48 hours have passed from the completion of the SOA. If CMS does finalize its proposal to require a 48-hour wait time**

[82] 87 FR 79452 at page 79530.
[83] Rivera-Hernandez M., Blackwood K.L., Mercedes M., Moody K.A. "Seniors Don't Use Medicare.Gov: How Do Eligible Beneficiaries Obtain Information about Medicare Advantage Plans in the United States?" BMC Health Services Research 21, 146, February 2021; Shupei, Yuan, Syed A. Hussain, et. Al. "What do they like? Communication Preferences and Patterns of Older Adults in the United States. The role of technology, Educational Gerontology, 42:3, 163-174, 2016.

after completion of an SOA, we urge the agency to permit plans to add an opt-out choice on the form if the beneficiary wishes or needs to meet with the agent sooner than 48 hours.

- Timelines. In general, CMS does not explicitly indicate the effective date for these proposed changes in marketing rules, which suggests the intent would be for those proposals to apply for the marketing period for plan year 2024. However, plans must have access to all necessary marketing guidance and sufficient lead time to implement changes for CY 2024. In order for plans to meet this deadline, CMS would have to issue the final rule and provide MA plans with any required sub-regulatory operational guidance by early May 2023 at the latest**.** This would include sub-regulatory guidance for the new third-party marketing organization (TPMO) related requirements (e.g., disclaimers, submission of marketing materials directly to CMS, waivers that apply to EGWPs). CMS also indicates that it would provide more detailed sub-regulatory guidance on questions and areas that would have to be covered during the pre-enrollment discussion with an enrollee. MA plans will also need time to assess the changes in order to develop advertising materials and submit them to CMS for approval; and for agent/brokers to obtain training and modify their processes to reflect the numerous provisions in the proposed rule. Given the breadth and scope of the proposed changes, we are concerned about the timing of these changes, especially if CMS is considering a CY 2024 (Fall 2023 Annual Enrollment Period (AEP)) effective date. **If CMS is unable to issue the final rule and required sub-regulatory guidance by April/May 2023, we recommend that CMS delay the effective date to CY 2025 (Fall 2024 AEP).**

- Agent/Broker oversight. CMS proposes to require MA plans to establish and implement an oversight program that monitors agent and broker activities, identifies non-compliance with CMS requirements, and requires plan reporting of non-compliance to CMS. In the preamble, CMS explains that an acceptable oversight program includes: "the review of internal grievances, 1–800–MEDICARE complaints, random samplings of past audio calls, listening to sales/marketing/ enrollment calls in real-time, secretly shopping in-person education and sales events, and secretly shopping web-based education and sales events."[84] In addition, CMS notes that plans should be able to identify non-compliant agents and brokers through these activities and would be expected to "quickly act, such as [pursuing] tailored training or disciplinary measures, based on the specific issues for each agent or broker"[85] and also report the agent or broker non-compliance to CMS.[86] AHIP members have already taken steps to improve oversight of agent and broker activities including implementing activities described above.

[84] 87 FR 79452 at page 79534.
[85] Id.
[86] Id.

We appreciate CMS not proposing overly prescriptive requirements in regulation for MA plans to implement. We anticipate there are a number of clarifying questions that CMS will receive through the public comment process that should be addressed to ensure common understanding and consistent application. For example, we ask CMS to clarify whether reporting of agent/broker noncompliance would be limited to significant and/or repeated noncompliance actions. We also reiterate our previous recommendation that CMS not hold a MA plan liable for a non-compliant activity of a TPMO or other entity with whom the MA plan does not contract (directly or through a sub-contract). Finally, we continue to recommend that CMS establish a forum for engagement with AHIP, MA plans, the States, agents and brokers, and other TPMOs, and beneficiary advocates to discuss and address marketing-related concerns.

Q. Changes to an Approved Formulary (§§ 423.4, 423.100, 423.104, 423.120, and 423.128)

In subsection Q.2.b.(3), CMS proposes new flexibility for Part D plans to make midyear formulary changes for certain drugs. Specifically, under this proposal Part D sponsors would be allowed to immediately substitute: (1) a new interchangeable biological product for its corresponding reference product; (2) a new unbranded biological product for its corresponding brand name biological product; and (3) a new authorized generic for its corresponding brand name equivalent.

Discussion and Recommendations:

AHIP and its members have long championed the use of generic versions of small molecule drugs as an alternative to more expensive brand/originator versions when they become available. Indeed, since the enactment of the Hatch-Waxman Act, nearly 90% of all drugs dispensed in the Medicare program are generics.[87] The ability of Part D plans to use well-tested formulary management and negotiating tools, including the promotion of cost-effective and clinically appropriate generics, has been critical in plans' ability to keep Part D premiums steady despite exorbitant launch prices for new drugs and out-of-control drug price increases on existing medicines. While the dynamics of the biologic/biosimilars large molecule drug market are more complex, the prospect of growing numbers of interchangeable and biosimilar versions of brand biologics presents new opportunities for patients to obtain greater access to these expensive, but highly effective medicines. **Accordingly, we appreciate and support CMS' efforts to provide plan sponsors with the flexibility to quickly make formulary changes regarding these follow-on biologics.** This additional flexibility provides Part D plans with additional means to promote innovation, patient safety and cost effectiveness for consumers and taxpayers.

R. Part D Medication Therapy Management (MTM) Program (§ 423.153(d))

[87] https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar19_medpac_ch14_sec.pdf.

In general, Part D's statutory provisions impose certain requirements relating to MTM programs. For example, sponsors are required to target those Part D enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to meet a cost threshold for covered Part D drugs established by the Secretary. To address its concerns that MTM is not being utilized to the fullest benefit for the broadest eligible patient populations in Medicare, CMS proposes several changes to the program's targeting criteria:

- CMS subregulatory guidance identifies 9 chronic disease targets for MTM programs, and current regulations provide plans flexibility in choosing which diseases to target. Under the proposal, Part D sponsors would be required to include all core chronic diseases in their targeting criteria. CMS would also codify the current 9 core chronic diseases in regulation and add HIV/AIDS for a total of 10 core chronic diseases.

- CMS would reduce the maximum number of covered Part D drugs a sponsor may require for MTM Program eligibility from 8 to 5 drugs while also mandating sponsors include all Part D maintenance drugs.

- Under its current methodology, the cost threshold for covered drugs is $4,935 in 2023. CMS would revise the cost threshold methodology based on the average annual cost of 5 generic Part D drugs (e.g., $1,004 in 2020).

Discussion and Recommendations:

AHIP and our members have long supported the use of MTM programs in Part D. Medication use in the Medicare population is significant, with patients currently averaging 54 prescriptions per member annually,[88] with >50% of beneficiaries 65 and older taking four or more prescription drugs daily.[89] The need to manage these treatments is a critically important task undertaken by plan sponsors and their contracted Pharmacy Benefit Managers (PBMs) to prevent adverse events and promote effective care. Accordingly, we appreciate CMS interest in expanding beneficiary enrollment in MTM programs.

However, we have the following significant concerns with the proposed changes to the MTM program criteria:

- As a threshold issue, CMS cites reports that only 9% of Medicare Part D enrollees are currently participating in MTM programs. CMS estimates that the proposed changes would

[88] https://www.cbo.gov/publication/57772#:~:text=Use%20of%20prescription%20drugs%20among,year%E2%80%94a%2013%20percent%20increase.
[89] https://www.kff.org/health-reform/issue-brief/data-note-prescription-drugs-and-older-adults/.

increase MTM enrollment to 23%, close to its 2005 projection of 25% MTM enrollment. But the fact that MTM program enrollment rates do not match original projections does not, in our opinion, justify the expansion of eligibility criteria. More critically, **focusing on the fact 9% of Part D enrollees are in MTM programs fails to account that other Part D enrollees receive medication care management through other means.**

+ Plans offer a variety of services, which can range from activities like screening for drug interactions through claims adjudication to more direct enrollee engagement through UM tools, wellness checks, etc. As part of this, plans may employ physicians, pharmacists, nurses, and other clinical experts in-house to engage patients on managing their medications—especially when specialty and other high-cost or complex drugs are involved. Those activities can accomplish the same care quality and safety aims of the formal MTM program for patients outside the current eligibility criteria—and at potentially significantly lower costs.

+ Contracted physicians and pharmacists also conduct regular outreach on patient therapy adherence consistent with clinical standards of care and their provider contracts with plan sponsors.

+ We are concerned that enhanced MTM eligibility could generate overlapping outreach efforts that could overwhelm beneficiaries, including patients with cognition issues, to the point where it discourages patients from participating in similar activities with plans, physicians and pharmacies that have a record of success. Beneficiaries cannot be helped by MTM programs or other plan outreach efforts if they request to be placed on "do not contact" lists in response to these changes.

- In addition, the proposed rule does not offer clear evidence suggesting increased enrollment in the MTM program will improve patient care outcomes. Prior analyses in fact have raised questions about the level of benefits and savings under the MTM program.[90] **We believe that before proposing to expand MTM program eligibility, CMS should provide an updated analysis that evaluates the effectiveness and costs of MTM programs and in comparison to the other non-MTM program-specific plan interventions/care management efforts noted above that may target the same (or similar) populations, before determining to expand MTM eligibility.**

- As noted, CMS estimates that the proposed changes would result in significant increases in enrollment. The agency also estimates that costs would increase by $336M annually, although CMS acknowledges that not all costs involved can be quantified due to the nature of

[90] https://innovation.cms.gov/data-and-reports/2022/mtm-fourth-evalrept.

administering these programs. While there is concern among our members that this estimate undercounts—perhaps significantly—those projected enrollment and cost burdens, even if those projections were to be proven accurate, **we have serious concerns with CMS proposing to increase plan MTM costs by 64% in a single plan year, including the need for rapid increases in staffing and administrative infrastructure, at the same time plans are gearing up to devote significant resources to implementing major program changes resulting from the recently enacted IRA**. In addition, CMS changes relating to pharmacy negotiated prices also take effect in 2024; we have noted our serious concerns with the impact of such changes as well. The combined impacts of these changes could further increase premium pressures and government costs.

- AHIP members have also shared their concerns that it would be difficult—if not impossible—to find enough pharmacists and other clinicians qualified to implement the proposed MTM program expansion mandate. While plans may seek to contract with outside vendors to help meet the added demand, a 2024 effective date would provide plans with limited time to adequately assess the quality of services to be provided so they can ensure high-quality services for patients and avoid abrasion, including potentially negative impacts on Star Ratings scores.

Accordingly, AHIP strongly recommends CMS withdraw these proposed changes and instead conduct additional research of MTM and alternative methods, and provide the results for public review and comment, so stakeholders can better assess the implications of the changes. Subsequently, those findings should drive future engagement with stakeholders—clinicians, plan sponsors, beneficiary advocates, etc.—on how to revise eligibility criteria and/or other program changes going forward. **However, if CMS chooses to finalize this proposal, we urge the proposed changes not be made effective for 2024, and that they be phased in over time to help mitigate potentially significant premium increases—especially in concert with pending IRA-mandated Medicare Part D changes to be implemented in the very near future.**

W. Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act (§§ 422.326I, 423.360(c), (§ 401.305(a)(2))

CMS proposes to revise the definition of when an MA plan or Part D sponsor has identified an overpayment by removing a reference to "reasonable diligence" and replace with language that gives the terms "knowing" and "knowingly" the same meaning given those terms in the False Claims Act.

Discussion and Recommendations:

AHIP supports this proposal.

IV. Strengthening Current Medicare Advantage and Medicare Prescription Drug Benefit Program Policies

A. Amending the Definition of Severe or Disabling Chronic Condition; Defining C-SNPs and Plan Types; and Codifying List of Chronic Conditions (§ 422.2)

CMS proposes a number of codifications and changes relating to "chronic condition special needs plans" (C-SNPs). For example:

- CMS would modify the definition of special needs individual to reflect a statutory change in the Bipartisan Budget Act of 2018 to the definition of a severe or disabling chronic condition.

- CMS would codify the list of chronic conditions that meet the statutory definition by including (with some modifications) conditions previously provided through sub-regulatory guidance and adding additional categories recommended by a panel of clinical advisors. Those new conditions would include conditions relating to obesity and related conditions, chronic gastrointestinal disease, and post-organ transplantation care and immunodeficiency and immunosuppressive disorders. Moreover, the proposal would add as chronic conditions certain functional needs that may be similar even if the underlying disease or chronic condition may differ. CMS provides the following examples: conditions that may cause cognitive impairment; conditions that may cause similar functional challenges and require similar services such as spinal cord injuries; chronic conditions that impair vision, hearing (deafness), taste, touch, and smell; and conditions that require continued therapy services in order for individuals to maintain or retain functioning. CMS also requests input on whether MA organizations require further guidance related to the functional needs categories.

- CMS would codify current guidance regarding MA plans' ability to offer C-SNPs focused on single or multiple chronic conditions. For C-SNPs that restrict enrollment to individuals with multiple commonly co-morbid and clinically-linked conditions (CMCLC), CMS would codify the currently approved set of five CMCLC and add three additional groupings recommended by the clinical advisor panel. CMS would also clarify that CMCLC C-SNPs may enroll eligible individuals who have only one of the qualifying conditions listed in the approved groupings.

Discussion and Recommendations:

We appreciate that CMS is proposing to modify, clarify and expand the current list of 15 chronic conditions to 22 conditions beginning in 2025. We believe this adjustment is appropriate and in keeping with developments in standards of care. As part of this proposal, we support including functional categories as chronic conditions so that individuals with similar kinds of functional

impairments can benefit from targeted models of care even though their underlying diagnoses may vary.

In terms of CMS' request for input on more guidance that may be needed on the new functional categories, **we suggest that CMS take the approach of reviewing plan proposals for new C-SNPs organized around those functional categories and, based on that experience, determine whether additional guidance is needed**. We note that the acuity or extent of functional impairments across a group of individuals may vary significantly. In that regard, **CMS may wish to consider providing additional guidance on how and the extent to which an individual's level or degree of impairment should be considered as an element of eligibility criteria.**

CMS also requests comments on the proposal to limit the regulatory definition of "severe or disabling chronic condition" to those conditions recommended by the panel of clinical advisors. We believe that it is appropriate to rely on the recommendations of a panel whose members have appropriate expertise and maintain currency with clinical innovation and standards of care.

G. Clinical Trial-Related Provisions (§§ 422.101 and 422.109)

CMS proposes to adopt regulations regarding MA plan coverage of clinical trials covered by Medicare under NCD 310.1 and as part of Category A or B Investigational Device Exemption (IDE) trials. CMS proposes to codify that an MA enrollee's in-network cost sharing must be included in the plan's maximum out-of-pocket calculation. CMS also proposes to specify that MA plans may not require prior authorization for participation in a Medicare-qualified clinical trial not sponsored by the plan (nor create impediments to participation in such a trial).

Discussion and Recommendations:

AHIP and our member plans support Medicare coverage of clinical trial participation for beneficiaries across Medicare's coverage options. We appreciate CMS' efforts to ensure payment and coverage policies do not act as a barrier to such participation. We support the proposed regulations and clarifications relating to MA plan obligations regarding enrollee participation in covered clinical trials, including IDE trials. We encourage CMS to continue providing MA plans with information about clinical trials that qualify for Medicare coverage and MA plan responsibilities related to such trials.

O. Possible End Dates for the SEP for Government Entity-Declared Disaster or Other Emergency (§§ 422.62 and 423.38)

CMS proposes two (2) revisions to the end date(s) for the SEP for a government entity-declared disaster or other emergency. First, in the case of a State or local emergency or disaster where a

specific end date of the emergency or disaster is not declared, the end date for the SEP may also be based on the emergency or disaster order automatically expiring pursuant to a State or local law, if such a law exists. Second, if no end date for the emergency or disaster period is specified, the SEP would end one year after the SEP start date.

Discussion and Recommendations:

AHIP supports the proposed revisions to the end dates for SEPs resulting from State or local emergency or disaster declarations. While SEPs for individuals affected by such disasters are important for protecting enrollees' ability to access care and needed benefits, the lack of clear end dates for SEPs lead to confusion and uncertainty. CMS' proposed specifications for SEP end dates in cases where the emergency or disaster end date is not clearly specified will provide certainty for both enrollees and plans.

AH. Gross Covered Prescription Drug Costs (§423.308)

To address a newly perceived ambiguity regarding interpretation of this term, CMS is proposing to revise its regulatory definition for Gross Covered Prescription Drug Costs (GCPDC) to fully "mirror" the statutory language in §1860D-15(b)(3) of the Social Security Act (SSA) by stripping the words "actually paid" from the regulatory definition in §423.308 in the Code of Federal Regulations (CFR). It is notable that the regulatory definition already mirrored the statutory language, but for the addition of the words "actually paid."

Discussion and Recommendations:

In the preamble, CMS states that this change ". . . would not constitute a change in policy or require a change in operations under Part D, and thus would not place any additional burden or reduce burden on Part D sponsors, nor result in government savings or costs." CMS also briefly notes that the GCPDC definition is incorporated into provisions of the IRA, specifically, those relating to new CMS negotiating authority for certain prescription drugs. While CMS explains at length why the change does not affect the calculation of reinsurance or have other Part D benefit implications, we believe the agency should also explain what, if any, effects the change could have under the IRA provisions such as the selection of drugs for negotiation or other implications. Without such explanation, it can be difficult for stakeholders to fully assess the consequences of the change or provide meaningful comment. **Therefore, we urge CMS to explain the potential effects of this change under the provisions of the IRA.**

V. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (42 CFR 422.162, 422.164, 422.166, 422.260, 423.182, 423.184, and 423.186)

The MA Star Ratings program incentivizes plans to achieve high performance on quality and plays a vital role in helping millions of diverse individuals continue to have access to high-quality, coordinated care, affordable benefit offerings, and options they deserve and rely on. MA plans with Star Ratings of at least 4 stars receive increased funding as an incentive to achieve high performance. In turn, high performing plans use Star Ratings rebate funds to reduce cost-sharing and offer additional benefits to Medicare enrollees. For example, MA plans can offer dental, vision, and hearing aid benefits, as well as other benefits, including those that can address socioeconomic barriers to health. Star Ratings is also one of many factors reflected in the Medicare Plan Finder (MPF) tool to help Medicare enrollees choose between available plans in their service area.

Given the value of the Star Ratings program to MA enrollees, we have serious concerns about the combined impact of the proposed changes to the Star Ratings program that would make it more difficult for MA plans to achieve 4 or more overall Star Ratings. CMS estimates that its proposed changes would save a total of almost $25 billion over 10 years. We offer comments below about specific components of these proposals but we emphasize our general concern that the cumulative impact of the proposed changes could result in reducing additional benefits offered by plans or increasing cost-sharing for Medicare beneficiaries without improving quality of care. Reducing supplemental benefit offerings in particular would run counter to the Administration's health equity goals, as supplemental benefits support plan efforts to advance them.

D. Adding, Updating, and Removing Measures (§§ 422.164 and 423.184)

CMS proposes to make a number of measure-specific and other changes under this Star Ratings proposal:

- Data Collection. CMS proposes to add collection of data through alternative sources or modes of collection to the list of non-substantive measure updates that can be made without rulemaking under existing regulations. For example, if a web mode of survey administration is added to the current mail with telephone follow-up of non-respondents survey administration that is currently used for the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey and the Health Outcomes Survey (HOS), CMS would consider this to be a non-substantive change that could be announced without going through the rulemaking process because, CMS reasons, there would only be a change in the method of collection and not a change in the information collected.

- Parts C & D Measures. CMS proposes to make a number of changes to the measures included in the Parts C and D measure set, including implementing risk adjustments for the three Part D medication adherence measures.

Discussion and Recommendations:

- Data Collection. While we support the addition of alternative modes of data collection to the Star Ratings program requirements, we do not agree that this change is non-substantive. Differing survey modalities have been shown to produce varying results, even when the same survey questions are asked.[91,92] Additionally, survey modality preferences differ by age groups,[93,94] which may also affect the population responding and, therefore, the survey results. We believe adding a web-based data source for the surveys, especially CAHPS, would likely increase the number of respondents which could have a significant impact on the numerator or the denominator and subsequently a plan's performance results. **We therefore recommend that CMS finalize this policy change as a substantive change in accordance with existing Star Ratings rules that cover substantive updates.**

  Parts C & D Measures.

  + Part D Medication Adherence for Diabetes Medication, Medication Adherence for Hypertension (RAS Antagonists), and Medication Adherence for Cholesterol (Statins) measures. CMS proposes to implement risk adjustment for the three Part D medication adherence measures based on sociodemographic status (SDS) characteristics for 2028 Star Ratings. CMS also proposes to implement other changes to these measures, including removing the adjustment for stays in inpatient (IP)/skilled nursing facilities (SNF), starting with the 2026 measurement year (2028 Star Ratings). To prepare for the application of SDS risk adjustment for the medication adherence measures, **AHIP and our members recommend CMS provide more details on the risk adjustment methodology for these measures to allow for additional assessment and input.** For example, information should be provided on whether plans will test against their own population or if vendors will test against the entire Medicare population and give plans the adjustment at the end of the period. Plans need to better understand these and other details to forecast performance and make other adjustments. Several AHIP members have also raised concerns about CMS' plans to remove the adjustment for IP/SNF stays from the medication adherence measures starting with the 2026 measurement year (2028 Star Ratings). CMS indicates that its analysis revealed that this change would have minimal impact on ratings. However, AHIP members are concerned that this change would be

[91] Keeter, S. "*Methods Can Matter: Where Web Surveys Produce Different Results than Phone Interviews.*" PewResearch.org. Available online at: https://www.pewresearch.org/fact-tank/2015/05/14/where-web-surveys-produce-different-results-than-phone-interviews/.
[92] Christensen A, Ekholm O, et. al. "Effect of Survey Mode on Response Patterns: Comparison of Face-to-Face and Self-administered Modes in Health Surveys." Eur J Public Health. 2014.
[93] Palonen M, Kaunonen M, Åstedt-Kurki P. "Exploring How to Increase Response Rates to Surveys of Older People." Nurse Res. 2016.
[94] Gigliotti, L. and Dietsch, A. "Does Age Matter? The Influence of Age on Response Rates in a Mixed-Mode Survey." Human Dimensions of Wildlife. 2014.

impactful. **We also recommend that CMS provide plans with more details on its analysis related to the removal of the IP/SNF stay adjustment prior to finalizing this proposed change.**

+ Part D Concurrent Use of Opioids and Benzodiazepines, Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults, and Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults measures. CMS proposes to add these three Part D measures to the 2026 Star Ratings. These measures are currently on display. AHIP and our members have concerns with CMS' proposal to move these three measures from the display page to Star Ratings for 2026. While we recognize the potential harmful impacts associated with the use of these medication regimens in the Medicare population, we do not support adding these measures to Star Ratings as they may hamper a plan's ability to support appropriate medication use and ensure access to care. We have several concerns. First, we want to ensure that mental health conditions that may impact the use of these medications are appropriately accounted for and note that there are cases where concurrent use may be appropriate, which is not reflected in the measures' specifications. Second, we are concerned that concurrent use, defined under the specifications for these measures, as overlapping days greater than or equal to 30 days in the measurement period, may not provide plans with adequate time to assess whether the benefit of concurrent use outweighs the risk and to coordinate activities with prescribers. Third, some medications included in these measures would require dosage tapering and management of withdrawal symptoms which are clinical practices and patient safety measures that are also not accounted for in the measures' specifications. Finally, we believe CMS should delay the addition of these measures to Star Ratings due to the impact the proposed changes to the Part D Medication Therapy Management (MTM) eligibility requirements could have on plan performance on these measures if finalized. **We urge CMS to delay adding these Part D measures to the Star Ratings until the concerns we and our members have raised are fully considered and addressed.**

E. Measure Weights (§§ 422.166(e) and 423.186(e))

CMS proposes to lower the weight of patient experience/complaints and access measures from 4 to 2 beginning with the 2026 Star Ratings.

Discussion and Recommendations:

For several years, AHIP has recommended that CMS decrease the weight of CAHPS measures used in Star Ratings from 4 to 2. We have raised concerns about the current disproportionate weight for CAHPS measures in comparison to evidence-based clinical quality outcome measures. Reducing the weight of CAHPS measures to "2" would result in these measures being

weighted higher than process measures but not as high as clinical quality outcome measures. In addition, this change is consistent with one of the goals of CMS' Quality Strategy[95] and would align more closely with the weight these types of measures are given in other CMS quality programs. **AHIP agrees with CMS' proposal to lower the weight of CAHPS measures from 4 to 2.**

We also ask CMS to consider the comments submitted by AHIP members on this topic. In addition, we appreciate that CMS continues to work with the Agency for Health Research and Quality (AHRQ) and National Committee for Quality Assurance (NCQA) to research longer-term solutions to improve the CAHPS survey and response rates. Such potential approaches could include reducing the length of the survey; increasing sample size; and revising the questions to better reflect the current health care delivery system, including use of telehealth and non-physician clinicians. Additionally, removing questions from surveys addressing circumstances falling outside of a health insurance provider's control or with low reliability and/or validity would make room on the survey for questions that could be used to measure emerging quality issues and address health equity concerns without increasing the burden on respondents. **We welcome the opportunity to engage with CMS on comprehensive evaluation and field testing of improvements to the CAHPS survey.**

F. Guardrails (§§ 422.166(a)(2)(i) and 423.186(a)(2)(i))

CMS proposes to remove guardrails when determining measure-specific cut points for non-CAHPS measures starting with 2026 Star Rating.

Discussion and Recommendations:

In the preamble, CMS explains that the intent of the guardrails policy is to improve predictability and stability of Star Ratings measure cut points from one year to the next. CMS believes that the combination of the mean resampling and Tukey outlier deletion (set to take effect with 2024 Star Ratings) would provide "sufficient predictability and stability of cut points from one year to the next."[96] In the preamble, CMS explains that the guardrails, which were created in the 2019 final rule, were intended to increase the predictability and stability of cut points because recent experience calculating Star Ratings during the PHE showed that they were unable to keep pace with any unanticipated changes in industry performance. As a result, CMS believes the guardrails policy is no longer necessary. We believe that CMS should not be making a permanent methodological change based on the extraordinary situation experienced during the recent public health emergency. **We do not agree that the current use of mean resampling along with application of the Tukey outlier deletion (set to take effect with 2024 Star**

[95] 83 FR 16440 at page 16521, April 2018.
[96] 87 FR 79452 at page 79626.

Ratings) would be an adequate substitute that increases cut point predictability and stability.

AHIP maintains that setting pre-determined cut points are the most effective way for CMS to improve predictability and stability under the Star Ratings program. Regarding value-based arrangements with providers, setting goals in advance of the measurement period is essential to helping plans and their network providers assess the effectiveness of their efforts to improve quality of care and reduce costs while maintaining high performance and rating levels. Moreover, setting cut points in advance of the measurement period reduces burdens on providers contracting with multiple plans who otherwise may face varying and conflicting quality performance metrics on the same quality measures. Setting cut points in advance of the measurement period would also support several CMS guiding principles for MA Star Ratings, including aligning Star Ratings with the current CMS Quality Strategy, ensuring contracts are treated fairly and equally, driving quality improvement, minimizing unintended consequences, and supporting transparency.[97] We believe that establishment of pre-determined thresholds is the best means to ensure transparency, predictability, stability, and quality improvement.

The use of pre-determined cut points also aligns with principles of quality improvement. The Institute for Healthcare Improvement's (IHI) Model for Improvement is a widely accepted framework for quality improvement programs.[98,99] Setting quality aims and identifying measurement targets is the model's fundamental starting point. For the MA program, measure-specific cut points can serve as quality improvement aims. Additionally, pre-determined cut points could identify "stretch goals" that align with IHI's quality aims best practices to incentivize plans to identify and direct care toward populations experiencing health disparities that require individualized quality improvement solutions. Establishing pre-determined cut points for measures linked to clinical disparities can help plans set goals to aim quality improvement efforts toward populations with unique needs. Use of pre-determined cut points also empowers consumer choice as consumers are increasingly relying on categorical ratings and scores to inform their decisions. With the increasing number of MA plan choices that are available, pre-determined cut points could help clearly and meaningfully communicate the value of each MA plan to the beneficiary. For example, a beneficiary with diabetes may be most interested in choosing a plan with high Star Ratings on diabetes care measures.

We therefore do not support the elimination of the guardrails policy and the introduction of the Tukey outlier deletion (per our prior comments on this issue). Instead, AHIP recommends CMS assess and consider proposing the setting of cut points for Star Ratings

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[97] Id.
[98] Institute for Healthcare Improvement, "Science of Improvement: How to Improve." Available online at: https://www.ihi.org/resources/Pages/HowtoImprove/default.aspx.
[99] Langley, G., Moen, et. al. "The Improvement Guide: A Practical Approach to Enhancing Organizational Performance." 2nd Edition. April 2009.

measures well in advance of the measurement period. As discussed above, pre-determined cut points would enable MA plans and their network providers to better manage their quality care and health equity improvement efforts, allow for greater methodological transparency, and allow plans and their network providers to better understand the goals for each Star Ratings measure.

We also ask CMS to consider the comments submitted by AHIP members on this topic.

G. Health Equity Index Reward (§§ 422.166(f)(3) and 423.186(f)(3))

CMS proposes to use a health equity index (HEI) in the Part C and Part D Star Ratings starting with the 2027 Star Ratings (which would include data from the 2024 and 2025 measurement periods). The HEI adjustment would reward contracts for obtaining high measure-level scores for the subset of their enrollees with specified social risk factors (SRFs). The SRFs included in the HEI would be low-income subsidy or dual eligibility (LIS/DE), or disability. CMS also proposes to eliminate the reward factor after 2026 Star Ratings, contingent on finalizing the addition of the proposed HEI reward.

Discussion and Recommendations:

We appreciate the details CMS has included in the regulation regarding the agency's HEI proposal. **We support the goal of the HEI to further incentivize MA plans to focus on improving care for enrollees with SRFs. However, given the complexity of the proposal, we recommend CMS address questions raised about the HEI, perform additional modeling, and make additional changes as recommended below prior to finalizing and adding it to Star Ratings. We also oppose elimination of the reward factor, which could penalize high-performing plans.**

We have the following specific comments and recommendations about CMS' HEI and reward factor proposals:

- HEI. AHIP members have many questions about the HEI methodology that would need to be addressed before its introduction into Star Ratings. For example, plans need to learn more about the contract level proportions of enrollees with SRFs that would be included in the HEI. In addition, plans need to review the stratified measure performance reported by SRFs that would be included in the HEI. Plans would also appreciate CMS' feedback and analysis on whether the HEI should be treated as an adjustment or separate measure in Star Ratings.

  There are other aspects of the MA program that could impact a plan's HEI result that CMS should also address prior to finalizing this program requirement. For example, in the 2023

MA and Part D rule[100], CMS finalized its proposal to create a pathway for states to require D-SNPs with exclusively aligned enrollment to hold a "D-SNP only" contract starting with plan year 2025. AHIP members have raised concerns about the impact on a plan's HEI result if D-SNP only contracts are compared to non-D-SNP contracts under the proposed HEI reward system. Concerns have also been raised about the impact of the HEI adjustments for contracts that are too small or have other characteristics that would disqualify them for a positive adjustment under the HEI. For example, a plan may have many enrollees with SRFs under a large contract, but the percentage may be too small to make the contract eligible for an HEI adjustment. Furthermore, plans may have contracts with many enrollees with other SRFs that would not be captured by the proposed HEI methodology.

Given these concerns, we urge CMS to delay the introduction of the HEI into Star Ratings. We believe CMS should first address all questions and issues raised about the HEI during this comment period. Next, CMS should pilot test the HEI for at least one performance year and provide plans with confidential feedback reports, and then seek additional public comments prior to finalizing and adding the HEI to Star Ratings. This approach would ensure plans have an opportunity to understand, assess and provide meaningful feedback to CMS to promote accuracy, reliability, and utility of the HEI and its results. **We also ask CMS to consider specific comments about the HEI submitted by AHIP members.**

- Reward Factor. CMS also proposes to eliminate the reward factor after 2026 Star Ratings. In the preamble, CMS explains that the reward factor was added to Star Ratings to provide "additional incentives for high and stable relative performance across measures by discouraging contracts from having a lot of variation in performance across measures."[101] CMS further explains that over time the agency has established additional methodological changes (e.g., addition of Parts C and D quality improvement measures) to incentivize performance improvement across measures and therefore the reward factor is no longer needed. CMS further states that "[t]he removal of the current reward factor is contingent on finalizing the addition of the proposed HEI reward."[102]

  We have significant concerns regarding CMS' proposal to remove the reward factor from Star Ratings. Removal of the reward factor represents a significant change to the program and would result in penalizing consistently high-performing plans. CMS anticipates a 10-year Medicare savings estimate of $5.13 billion with the addition of the HEI and elimination of the reward factor. Star Ratings for high-performing plans with a disproportionate share of enrollees with SRFs could be adversely impacted with the addition of the HEI and elimination of the reward factor. Lower Star Ratings for high-performing

[100] 87 FR 27704, May 9, 2022.
[101] 87 FR 79452 at page 79626.
[102] 87 FR 79452 at page 79627.

plans due to the elimination of the reward factor could also adversely impact Medicare enrollees by reducing additional benefits offered by plans or increasing cost-sharing requirements. **We therefore oppose CMS' proposal to eliminate the reward factor and recommend the agency further analyze the potential adverse impacts of its proposal.**

H. Improvement Measure Hold Harmless (§§ 422.166(g)(1) and 423.186(g)(1))

Under the current improvement measure hold harmless provision, Part C and Part D scores are calculated both with and without the improvement measures, and contracts with 4 or more stars are held harmless from having the highest rating reduced by the addition of the improvement measures. CMS now proposes to modify the Part C and Part D improvement measure hold harmless provision to limit its application to contracts with 5 stars only beginning with the 2026 Star Ratings.

Discussion and Recommendations:

In the preamble, CMS indicates its belief that the hold harmless provision is not needed for contracts with 4 or 4.5 Star Ratings because these plans "still have the potential to increase scores across measures and thus their Star Ratings."[103] With this proposed change, CMS also anticipates a 10-year Medicare savings estimate of $19.53 billion.[104]

Given the variability of Star Ratings cut points year to year, we are very concerned that with the proposed change to the hold harmless policy for the improvement measures, slight differences in performance on a small number of measures could have an inordinately adverse impact on a high-performing plan's overall Star Ratings. We are also concerned that Part D plans will be undergoing significant operational changes due to implementation of IRA provisions, which could lead to more challenges hindering plans' ability to achieve higher Star Ratings that are not necessarily indicative of performance or care quality. Although CMS views this policy change as a way to encourage continued quality improvement, it could result in penalizing high-performing plans. We believe that given the complexity and rigorous nature of the Star Ratings program, achieving and maintaining 4 stars takes tremendous effort and should not be discounted.

We are further concerned that CMS' proposed change to limit the application of the improvement measures' hold harmless policy could adversely impact MA beneficiaries. The existing hold harmless policy has driven quality improvement across measures. MA plans with a Star Rating of at least 4 stars receive increased funding as an incentive to achieve high performance. Plans use these funds to provide additional benefits and reduce beneficiary cost-sharing. Health plans that obtain the quality bonus payment for achieving 4-Stars or higher are

[103] 87 FR 79452 at page 79632.
[104] 87 FR 79452 at page 79702.

able to offer more robust supplemental benefits such as dental, vision, hearing aids, meals, nutrition, transportation, and in-home services and supports. These enhanced benefit offerings are also critical to addressing social drivers of health and advancing health equity. Limiting the offering of these benefits for disadvantaged populations would work against the Administration's health equity goals and could worsen disparities in health outcomes. Changes to the Star Ratings program should support, not take away, vital benefits. **We therefore oppose CMS' proposal to modify the Part C and Part D improvement measure hold harmless provision and urge the agency to not adopt this policy change.**

I. Extreme and Uncontrollable Circumstances (§§ 422.166(i) and 423.186(i))

CMS proposes to modify its extreme and uncontrollable circumstances policy by no longer applying the "60 percent rule" starting with 2026 Star Ratings. The 60 percent rule excludes, for all non-CAHPS measures, the numeric scores for contracts with 60 percent or more of their enrollees living in a FEMA-designated Individual Assistance area when calculating cut points for non-CAHPS measures.

Discussion and Recommendations:

AHIP supports the removal of the "60 percent rule" for extreme and uncontrollable circumstances and recommends CMS adopt this proposal in the final rule.

Other Star Ratings Comments

AHIP has additional comments on other Star Ratings issues for CMS' consideration.

Discussion and Recommendations:

- **Impact of IRA implementation on Star Ratings.** We are concerned about the unanticipated impacts that implementation of IRA provisions will have on certain Star Ratings measures and plan performance. Beneficiary complaints and confusion as well as other factors outside of plan control could impact plan performance on various measures including, but not limited to, survey and administrative measures (e.g., complaints, disenrollment). **We recommend that CMS consider applying a hold harmless policy for 2024 and 2025 Star Ratings years through an interim final rule or other mechanism to ensure that summary and overall Star Ratings for individual plans do not go down if lower performance results are likely due to IRA impacts.**

- **Part D MTM Program Completion Rate for CMR.** CMS is proposing to make significant changes to the Part D MTM program requirements. Included are multiple changes to the enrollee targeting/eligibility criteria to improve access for enrollees CMS asserts could

benefit from these services. Accordingly, any of the changes that CMS finalizes related to the MTM program requirements should be considered as substantive changes under the Star Ratings program rules at §423.184. **We recommend CMS address the impact of these substantive changes to the Part D MTM measure in a future rule for additional stakeholder input prior to finalizing the proposed changes to the MTM program requirements.**

- **Part C and Part D Members Choosing to Leave the Plan Measures.** Several AHIP members have raised concerns about the impact of IRA implementation and other factors that could unfairly impact plan performance on the Part C and Part D Members Choosing to Leave the Plan measures. Under the IRA, Medicare enrollees who take insulin have access to an SEP in 2023 which could impact plan performance for the 2023 measurement year (2025 Star Ratings). Plans should not be penalized for member enrollment changes during this additional SEP, as such election changes have no bearing on the plan's performance but are due solely to statutory changes established by the IRA. There are also circumstances where an enrollee with an existing plan may select another plan under the same MA organization because their care and benefit needs have changed. For example, a member may choose to move to a D-SNP within the same parent organization or move from a PDP to a MA-PD due to changing life circumstances. If a plan assists a beneficiary to move to a product that may be more appropriate for their situation, the change should be excluded from the Members Choosing to Leave the Plan measures. **We ask CMS to review and address the above issues that could impact plan performance on this Part C and Part D measure.**

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Submitter Information

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General Comment

See attached file(s)

Attachments

UHG Comments - MA CY 2024 Policy Changes

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February 13, 2023

Administrator Chiquita Brooks-LaSure
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Department of Health and Human Services
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Washington, DC 20201

Submitted Electronically: www.regulations.gov

Re: Contract Year 2024 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs Proposed Rule (CMS-4201-P)

Dear Administrator Brooks-LaSure,

UnitedHealth Group (UHG) is pleased to respond to the Centers for Medicare and Medicaid Services (CMS) request for comments regarding the Contract Year 2024 Policy and Technical Changes to the Medicare Advantage (MA) and Medicare Prescription Drug Benefit (Part D) Programs Proposed Rule. We are focused on providing all Medicare beneficiaries with stable access to high-quality, affordable care and continuing to facilitate informed consumer decision-making, improving outcomes and quality, and advancing equitable health care. We believe CMS's recent actions will undermine the health care that seniors and individuals with disabilities enrolled in the MA and Part D programs receive. **We are concerned about the combined impact of the changes included in the Proposed Policy Rule, Risk Adjustment Data Validation (RADV) Final Rule, and the proposed 2.3% decrease in overall MA rates for 2024. CMS is making a significant departure from current policy that we believe will drive up premiums and cut benefits for MA beneficiaries.**

UnitedHealth Group is a mission-driven organization dedicated to helping people live healthier lives and helping our health care system work better for everyone through two distinct business platforms - UnitedHealthcare, our health benefits business, and Optum, our health services business. Our workforce of 380,000 people serves the health care needs of 149 million people worldwide, funding and arranging health care on behalf of individuals, employers, and the government. We not only serve as one of the nation's most progressive health care delivery organizations, we also serve people within many of the country's most respected employers, in Medicare serving nearly one in five seniors nationwide, and in Medicaid supporting underserved communities in 32 states and the District of Columbia.

MA delivers significantly lower out-of-pocket costs for beneficiaries and provides more comprehensive and coordinated benefits that work to achieve better health outcomes, while serving a more diverse, lower-income, and clinically complex population compared to Medicare Fee-For-Service (FFS). Beneficiaries also report a 94% satisfaction rate with the MA program.[1] Overall,

[1] Morning Consult, Annual Seniors on Medicare Survey, January 2022. Available at: https://bettermedicarealliance.org/wp-content/uploads/2022/01/BMA_Seniors-on-Medicare-Memo_final3.pdf

research suggests that MA achieves a 12% savings to the health system when combining both beneficiary and government savings.[2] MA has an established track record of delivering better health outcomes for people compared to those in Medicare FFS, with a more than 40% lower rate of avoidable hospitalizations.[3]

UHG's MA offerings are consumer-focused, helping beneficiaries find the best paths of care at the right place and time, while also reducing health care costs through modernized and coordinated clinical programs and resources that address their unique needs. We are driving innovation to promote person-centered care through clinical models focused on value-based care, resulting in 80% of our MA members obtaining services from providers in value-based arrangements. A recent, first-of-its-kind study in *JAMA* found MA patients served by Optum value-based care experienced 18% lower odds of an inpatient admission, 11% lower odds of emergency department (ED) visits, and 44% reduction in hospital admissions for COPD or asthma complications.[4] We are working to advance health equity through innovative programs that proactively identify and treat chronic and acute conditions, as well as address Social Determinants of Health (SDOH). For example, we are striving to better address food and nutritional needs and improve continuity of care by offering 14 meals after each inpatient stay during the plan year.

We appreciate the opportunity to provide feedback on specific policy changes to help CMS build upon the successes of the MA program. As CMS finalizes policies for 2024, UHG recommends the agency prioritize the following specific adjustments:

- Preserve the Improvement Hold Harmless Provision in the Star Ratings Program to ensure benefit stability and continued investments in supplemental benefits focused on addressing SDOH.
- Include both the Health Equity Index and the Reward Factor in the Star Ratings Program until CMS can ensure accuracy on social risk factor data.
- Uphold CMS's longstanding policy regarding when a beneficiary should be considered an inpatient for purposes of correct Medicare billing (the "2-Midnight Rule").[5]
- Maintain the current definition of Gross Covered Prescription Drug Costs to ensure effective implementation of the Inflation Reduction Act.
- Follow the plain language of the Patient Protection and Affordable Care Act and adopt the correct standard that an MA plan or Part D sponsor has “identified” an overpayment once it has determined that the overpayment exists.

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[2] Milliman, Value to the Federal Government of Medicare Advantage, October 2021. Available at: https://bettermedicarealliance.org/publication/milliman-reportvalue-to-the-federal-government-of-medicare-advantage/

[3] Center for Innovation in Medicare Advantage, Positive Outcomes for High-Need, High-Cost Beneficiaries in Medicare Advantage Compared to Traditional FFS Medicare, December 2020. Available at: https://bettermedicarealliance.org/wp-content/uploads/2020/12/BMA-High-Need-Report.pdf

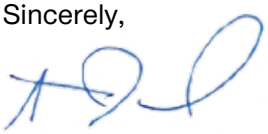
[4] JAMA. Comparison of Care Quality Metrics in 2-Sided Risk Medicare Advantage vs Fee-for-Service Medicare Programs. December 2022. Available at: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2799376?trk=public_post_comment-text

[5] See CMS, 78 FR 50495, 50943 (Aug. 19, 2013) (Final Rule) (discussing the 2-midnight rule as clarification to address "hospital claim errors... due to inappropriate patient status (that is, the services furnished were reasonable and necessary, but should have been furnished on a hospital outpatient, rather than hospital inpatient, basis).

As CMS considers policy changes in MA, we urge CMS to ensure any finalized payment and policymaking does not compromise the access, affordability, comprehensive benefits, and care coordination programs that MA beneficiaries currently receive and depend on as they age.

Attached are UHG's technical comments and recommendations in response to the CMS 2024 MA and Part D Policy Proposed Rule. UHG appreciates this opportunity to provide comments, and if you have any questions, please do not hesitate to contact me.

Sincerely,



Tim Noel, CEO
UnitedHealthcare, Medicare & Retirement

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III. Enhancements to the Medicare Advantage and Medicare Prescription Drug Benefit Programs

A. Health Equity in Medicare Advantage (§§ 422.111, 422.112, and 422.152)

Medicare Advantage Provider Directories (§ 422.111)

UHG supports the proposed codification of current guidance that Medicare Advantage (MA) plans identify the provider's cultural and linguistic capabilities, including languages spoken and access to interpretative services, in their provider directories.

However, UHG requests that CMS reconsider the proposed requirement to identify providers who have a waiver to treat patients with medications for opioid use disorder (MOUD). Recent action by the Drug Enforcement Agency (DEA), as well as pending rulemaking from the DEA and the Substance Abuse and Mental Health Services Administration (SAMHSA) could modify opioid treatment program qualifications and requirements and the special registration and waiver rules for providers engaged in the treatment of opioid use disorders (OUDs). While the scope of the expected changes to provider qualifications and permitting is unknown in the pending guidance, UHG urges CMS to consider delaying additional provider directory requirements targeted at identifying providers with a waiver until further DEA and SAMHSA guidance is issued and there is clarity about the impacted population of providers and portion of plan networks for which this special designation may be required.

B. Behavioral Health in Medicare Advantage (§§ 422.112, 422.113, and 422.116)

Behavioral Health Specialties in Medicare Advantage Networks (§§ 422.112 and 422.116)

UHG opposes CMS's proposal to add prescribers of MOUD to the list of provider-specialty types subject to network adequacy evaluation. As previously discussed, DEA regulation of these specialty providers is currently changing. Additionally, there are data accuracy issues currently with the source MA plans rely on to determine whether a treatment facility, program or provider meets the HHS qualifications for certification as an Opioid Treatment Program (OTP). CMS maintains the list of approved OTPs that plans must use to contract, credential, and conduct business with OTPs. UHG has observed numerous issues with the accuracy and timeliness of the information on the CMS website, which has led to beneficiary and provider complaints and claims denials. Until these data accuracy issues are remediated, MA plans should not have a specific network adequacy standard applied to them because they could inadvertently fail to meet it based on the use of inaccurate data completely out of their control. Accordingly, UHG urges CMS to delay this proposal until the data integrity issues have been adequately addressed.

UHG also has concerns with the proposed time and distance standards and minimum number of in-person providers in each county type proposed for prescribers of MOUD (including MOUD Waivered Providers and OTPs). The proposed standards do not account for the scarcity of these providers. For example, it does not make sense to have the same maximum time standard for social workers

and prescribers of MOUD in the metropolitan category given the material difference in the number of such providers in these categories. UHG urges CMS to reconsider the proposed standards to ensure MA plans can comply with them given the current available workforce that meet the definitions of these categories.

UHG recommends CMS consider modifying the existing specialty provider type of "psychiatrists" to include not just psychiatrists but any qualified provider who can prescribe prescription drugs used to treat behavioral health conditions within the scope of their practice under state law. For example, the category could include advance practice clinicians such as advance practice registered nurses, nurse practitioners, physician assistants, as well as psychologists, who have prescribing authority under their state licensing and scope of practice requirements. We believe broadening this provider type would expand access for beneficiaries and allow them to obtain medications from additional providers with a behavioral health specialty.

Finally, UHG supports the proposal to include the behavioral health specialty types in the list of provider types for which the 10 percent credit to time and distance standards applies and appreciates the recognition of the vital nature of behavioral health telehealth services as a critical tool to meet consumer access and care needs.

Behavioral Health Services in Medicare Advantage (§§ 422.112 and 422.113)

UHG supports the proposal to clarify that the definition of an "emergency medical condition" includes conditions arising from a behavioral health or substance use disorder diagnosis. It is important to note that in the context of behavioral health services, there are services which are designated as "crisis services," and that in some cases these services will be the result of an emergency medical condition and in other cases they will not. As such, UHG cautions against defining "emergency medical condition" with reference to "conditions for which an enrollee may receive behavioral health crisis services." It is our understanding that SAMHSA is leading an interagency work group to collaborate on more clearly defining "crisis services," and this work may impact this proposal and future guidance on this topic.

Medicare Advantage Access to Services: Appointment Wait Time Standards (§ 422.112)

CMS proposes to codify the standards for appointment wait times for primary care services that are currently set forth in the Medicare Managed Care Manual and to extend those standards to behavioral health services. UHG urges CMS to set the requirement for services which are "not emergency or urgently needed" to be 14 calendar days rather than within one week as proposed. A one-week standard for non-emergent care would make it harder for providers to prioritize access for urgently needed care, which commonly requires access within 72 hours. This is especially true in geographic areas with health care work force issues or specialties, like behavioral health, with provider shortages.

To reduce administrative burden and avoid creating standards that would foster disparities across payer types, UHG also supports efforts to reference alternative standards that may already exist and appropriately apply to MA plans. As an example, UHG supports alignment of standards for wait

times across Qualified Health Plans (QHP) and MA plans or consideration of non-payer specific standards such as standards promoted by NCQA.

CMS solicits comment on whether a more flexible approach would be appropriate, such as requiring MA plans to have specific appointment wait time standards in their written internal policies and requiring MA plans to meet the specific appointment wait time limits for routine or non-emergency services only for a significant portion of appointments. UHG supports this approach because access and wait time for any given beneficiary may be influenced by factors beyond the plan's control and believes that CMS's proposed 95 percent standard for compliance is appropriate.

D. Enrollee Notification Requirements for MA Provider Contract Terminations (§§ 422.111 and 422.2267)

CMS proposes adding specific and more stringent beneficiary notification requirements for provider contract terminations that involve behavioral health and primary care providers. Specifically, CMS proposes that plans notify all enrollees who have ever seen a terminating behavioral health or primary care provider, not just enrollees who are seen on a regular basis by the terminating provider, which is the case for other specialty types. While UHG appreciates CMS's commitment to removing barriers to behavioral health services, CMS does not provide any indication that the current notification processes are deficient and causing continuity of care issues for enrollees or dissatisfaction. Indeed, the existing notification processes are consistent with industry standards and practices, and UHG does not believe changes are necessary. Accordingly, UHG recommends CMS only require MA plans to notify eligible enrollees who are assigned to a terminating primary care provider or have seen the behavioral health provider or primary care provider in the past twelve months. Requiring plans to notify all enrollees who have ever received care from the terminating provider without any reasonable "look back" period to identify impacted patients could cause confusion if the enrollee saw the provider for a limited time or a significant length of time in the past.

CMS also proposes requiring MA plans to provide notice to enrollees of a terminating behavioral health or primary care provider 45 calendar days prior to the termination instead of 30 calendar days for other provider types. Adding an additional 15 days to the industry standard 30 days will increase the likelihood of beneficiary and provider abrasion, as often contract negotiations continue through the last month of the contract. Informing beneficiaries their provider is terminating when that might not ultimately happen, can be unnecessarily disruptive and confusing. An earlier notification timeline increases the likelihood that more beneficiaries will be in a situation where they are notified of a contract termination that does not occur and as a result would need to be re-notified that the provider is remaining in network. An earlier and premature notification may also negatively impact the MA plan's ability to successfully negotiate a resolution and provide continuity for its beneficiaries. UHG recommends instead CMS maintain its requirement to notify eligible enrollees 30 calendar days prior to the termination, with the below exceptions:

- When the provider does not notify the MA plan of their intent to terminate with time to provide 30 days of notice.
- When the provider and health plan are in active negotiations.

UHG also opposes CMS's proposal to notify all enrollees who have seen a terminating behavioral health or primary care provider telephonically in addition to sending a written communication via US Mail. CMS has not indicated that the existing notification processes are problematic. Accordingly, adding this duplicative telephonic notification requirement does not seem necessary. In addition, UHG requests that CMS include an option for MA plans to provide the written communication through electronic delivery if the beneficiary has opted into e-delivery. Electronic delivery ensures the beneficiary receives the information in the timeliest manner and through the delivery method elected by the beneficiary as their preference.

Finally, CMS proposes requiring MA plans to include specific content in the provider termination notices, including names and phone numbers of in-network providers the enrollee may access. Providing this information could be confusing to enrollees because they may think that these are the only providers they can access. Similarly, enrollees may mistakenly believe the MA plan recommends these providers based on enrollees' language(s) spoken, location, accessibility, gender, or other factors. UHG recommends that instead of requiring MA plans to include specific names and phone numbers of in-network providers, CMS require the notice contain information on how an enrollee can access the MA plan's online provider directory or request a paper directory from the MA plan.

UHG does support the development of a model notice document by CMS with review and input from stakeholders. UHG recommends CMS consider existing notices of this type required for commercial plans to promote consistency to the greatest extent possible in such notices.

E. Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools (§§ 422.101, 422.112, 422.137, and 422.138)

Taken as a whole, CMS's proposed changes could significantly undercut MA plans' ability to ensure access to medically necessary care while limiting waste, inefficiency, and risk of beneficiary harm from unnecessary and unproven services. The Social Security Act expressly references MA plans' ability to establish utilization management procedures,[6] such as "prior authorization or other review requirements,"[7] intentionally leaving room for innovation in utilization management tools and care management strategies. However, CMS's proposals markedly deviate from Congress' intent in creating Medicare managed care because they substantially limit MA plans' ability to actually manage care.

Utilization management tools are critical to MA plans' ability to ensure access to high quality safe care and maintain high member satisfaction while appropriately managing costs. In 2022, MA-PD plans received an average rating of 4.37 out of 5 when assessed on more than 30 measures across clinical and patient experience areas as part of CMS's robust quality rating system for MA plans.[8]

[6] Social Security Act, § 1852(c)(2)(B).
[7] Social Security Act, §§ 1852(c)(1)(G).
[8] Better Medicare Alliance, State of Medicare Advantage (July 2022), available at: https://bettermedicarealliance.org/wp-content/uploads/2022/07/BMA-State-of-MA-2022-FIN.pdf.

Further, nine in ten seniors agree that Medicare Advantage lets them see the doctors they want on their own terms (88%) and saves them money compared to other coverage options (89%).[9] Nearly all (94%) seniors with MA plans are satisfied with their Medicare Advantage coverage.[10] Through utilization management tools and other flexibilities that Congress built into the role of Coordinated Care Plans, Medicare Advantage provides $32.5 billion annually in additional value to beneficiaries and the federal government and provides all Medicare-covered benefits for 24% less than FFS Medicare.[11]

UHG is committed to providing Medicare Advantage beneficiaries with timely access to high-quality care and continuing investments in technology and processes that streamline coverage reviews, case management, and care coordination. For these reasons, UHG supports many aspects of the proposed rule; however, some of the proposed changes (§§ 422.101, 422.112, and 422.137) contain elements counter-productive to timely and appropriate access, transparency, and quality while simultaneously increasing costs to the Medicare Trust Funds. Detailed comments are set forth below.[12]

Coverage Criteria for Basic Benefits (§ 422.101)

UHG supports codification of longstanding CMS guidance that MA plans must make coverage determinations based on medical necessity, and in making those determinations, may apply internal policies that include coverage criteria that are consistent with and no more restrictive than traditional Medicare. Departing from existing policy, CMS proposes to limit MA plans' ability to use internal coverage criteria.[13] CMS focuses on partial stakeholder feedback and limited findings in the April 2022 OIG report to support its proposal.[14] CMS's rationale does not take into account: (1) the benefits of and need for evidence-based tools when making clinical judgments; (2) prevailing evidence of MA health plan quality; and (3) high enrollee satisfaction.

Requirements Relating to Basic Benefits

[9] Memo to Better Medicare Alliance, Survey Results: Annual Seniors on Medicare Survey (2022), available at: https://bettermedicarealliance.org/wp-content/uploads/2022/01/BMA_Seniors-on-Medicare-Memo_final3.pdf.
[10] Id.
[11] Better Medicare Alliance, State of Medicare Advantage (July 2022), available at: https://bettermedicarealliance.org/wp-content/uploads/2022/07/BMA-State-of-MA-2022-FIN.pdf.
[12] Prior to finalizing any of the proposed changes to §§ 422.101, 422.112, 422.137, and 422.138, CMS must publish a regulatory impact analysis so that stakeholders can better understand the exact changes CMS is purportedly making and provide public comment on them.
[13] Proposed § 422.101(c)(1)(i)(A).
[14] CMS explains that proposed changes at 422.101(b) and (c) are based on certain stakeholder feedback and OIG recommendations. Proposed Rule, 79499. While the OIG report is concerning, it also found that MA plans approve the "vast majority of prior authorization requests and provider payment requests." The report data also showed that nearly 90% of prior authorization denials were appropriate, meaning the treatment or service that was requested was either not in line with evidence-based care, was unnecessary, or even potentially harmful. Additionally, the OIG acknowledged that the results of its case review were subject to the interpretations and clinical judgments of its health care coding experts and physician reviewers. The OIG noted that results would likely have been different under Traditional Medicare. OIG, *Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care*, April 2022.

CMS proposes to amend § 422.101(b)(2) to clarify that MA plans must comply with general coverage and benefit conditions in Traditional Medicare laws, unless superseded by laws applicable to MA plans. The proposed revision also includes references to specific Traditional Medicare regulations that include payment criteria for Part A inpatient admissions, skilled nursing facility (SNF) care, home health services, and inpatient rehabilitation facilities (IRF). CMS also proposes to add subsection (6) to §422.101(b) to allow MA plans to create internal coverage criteria based on widely used treatment guidelines or clinical literature where coverage criteria are not fully established in "applicable Medicare statute, regulation, NCD or LCD." Finally, CMS proposes parameters for medical necessity determinations in §422.101(c), including that MA plans may not deny coverage for basic benefits based on coverage criteria not specified in the section. UHG opposes any interpretation of the new regulatory language that limits an MA plan's ability to adequately assess whether a covered item or service is medically necessary or that would prohibit use of internal coverage criteria when appropriate and consistent with traditional Medicare coverage requirements.

2-Midnight Rule

Specifically, UHG opposes the proposed reference to § 412.3, Part A inpatient admissions, in § 422.101(b)(2) if it is intended to mean that MA plans are limited to the treating physician's presumption that a member requires a two midnight stay as the only criteria for determining whether an inpatient stay is reasonable and necessary. § 412.3 contains CMS's requirements for determining when a beneficiary should be considered an inpatient for purposes of correct Medicare billing (the "2-Midnight Rule").[15] In the Final Rule adopting § 412.3, CMS explained that the 2-Midnight Rule does not determine whether services are "reasonable and necessary"[16] or the appropriate level of care, because "there are no prohibitions against a patient receiving any individual service as either an inpatient or an outpatient, except for those services designated by the... Inpatient-Only list."[17]

CMS should clarify that the treating physician's presumption that an inpatient stay will cross two midnights is not the only criteria for determining whether an inpatient stay was reasonable and necessary. Rather, CMS should make clear that § 412.3 allows for case management review of inpatient admissions based on whether the complex medical factors documented in the medical record support medical necessity of the inpatient admission, regardless of the actual duration of the hospital stay.[18] As further discussed below, this clarification is consistent with MA plans long-

[15] See CMS, 78 FR 50495, 50943 (Aug. 19, 2013) (Final Rule) (discussing the 2-midnight rule as clarification to address "hospital claim errors… due to inappropriate patient status (that is, the services furnished were reasonable and necessary, but should have been furnished on a hospital outpatient, rather than hospital inpatient, basis)." If CMS finalizes proposed § 422.101(b)(2) with reference to § 412.3, CMS should explain the basis for its re-interpretation of the 2-Midnight Rule as a coverage rather than payment rule.

[16] See id. at 50951 ("We note it was not our intent to suggest that a 2-midnight stay was presumptive evidence that the stay at the hospital was necessary; rather, only that if the stay was necessary, it was appropriately provided as an inpatient stay.")

[17] Id. at 50945.

[18] CMS, 78 FR 50495, 50944 (Aug. 19, 2013) (Final Rule) ("…a reasonable expectation of a stay crossing 2 midnights, which is based on complex medical factors and is documented in the medical record, will provide the justification needed to support medical necessity of the inpatient admission, regardless of the actual duration of the hospital stay and whether it ultimately crosses 2 midnights.") Note also, § 412.3(d)(3), with regard to inpatient stays not

standing ability to develop criteria for whether services are reasonable and necessary when Traditional Medicare criteria are not fully established.

"Fully Established" Coverage Criteria

UHG recognizes that MA plans must make coverage determinations consistent with the requirements set forth in Medicare laws and regulations. But even relatively specific coverage requirements in Medicare laws and regulations lack objective criteria outlining the specific clinical information necessary to meet coverage requirements. UHG recommends that CMS revise proposed § 422.101(b)(6) to state: "When coverage criteria are not fully established in applicable NCD and/or LCD, MA organizations may...." This change would clarify that coverage criteria are not "fully established" when found in Medicare statute and regulation alone. Rather, coverage criteria for a particular service may be fully established only if there is also an applicable NCD or LCD (or both).

Even then, as CMS notes, some NCDs and LCDs include flexibility that allows for coverage in circumstances beyond the specific coverage or non-coverage indications that are listed in the NCD or LCD.[19] Likewise, some NCDs and LCDs expressly acknowledge that additional, unspecified coverage criteria may be applied to determine medical necessity in a particular case.[20] In these situations, UHG agrees that Medicare coverage criteria are not fully established and MA plans may also apply internal coverage criteria.

UHG also recommends striking that MA plans "may not deny coverage for basic benefits on coverage criteria not specified in paragraph (b) or (c) of this section."[21] Coverage requirements in Medicare statute and regulation often expressly acknowledge that additional, unspecified criteria need to be applied to determine medical necessity in a particular case. Even substantive requirements for acute hospital and post-acute care, for example, involve inexact standards about "reasonable expectations" and "reasonable and necessary."

To illustrate, IRF services are covered when there is a "reasonable expectation" that the patient meets certain coverage criteria, including that the patient "requires" multiple therapy disciplines and can "reasonably be expected" to benefit from an "intensive" rehabilitation program.[22] CMS guidance explains that "the intensity of therapy provided must be reasonable and necessary under section 1862(a)(1)(A) of the Act and must never exceed the patient's level of need or tolerance, or

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expected to cross two midnights, requires a reasonable and necessary determination on a case-by-case basis using a list of non-exhaustive factors. A similar case by case assessment in the context of stays crossing two midnights is aligned with this provision.

[19] Proposed Rule at 79500. See, e.g., Electrocardiographic Services NCD 20.15 ("Certain uses other than those specified above may be covered if, in the judgment of the local Medicare Administrative Contractor (MAC), such use is medically necessary.").

[20] Proposed Rule at 79502 (discussing Computed Tomography NCD 220.1). NCD 220.1 states that a CT scan must be found reasonable and necessary considering the patient's symptoms and preliminary diagnosis, as well as reasonable and necessary as the initial diagnostic test, if applicable. The NCD does not specify the criteria to be applied to determine whether a CT scan is reasonable and necessary as a diagnostic test or as the initial diagnostic test.

[21] § 422.101(c)((1)(i)(A).

[22] § 412.622(a)(3).

compromise the patient's safety."[23] Given these imprecise requirements, additional coverage criteria are necessary to ensure appropriate and consistent determinations.

Permitting use of internal coverage criteria, as needed, to help support and better define the Medicare coverage criteria in statute, regulation, and NCD or LCD (if applicable) promotes consistent, transparent, and evidence-based clinical decisions.

Medical Necessity Determinations

CMS previously stated: "[T]here is a distinction between the general rule that a health care service is covered under Medicare and the decision that an individual patient fits the clinical criteria necessary for receipt of the service."[24] UHG agrees with this statement.

UHG supports the use of evidence-based clinical appropriateness tools to assist clinical reviewers in applying Traditional Medicare coverage requirements to specific clinical facts and circumstances. When a coverage requirement is expressed in terms other than the presence or absence of specific clinical factors, CMS should encourage the use of national best practices and evidence-based guidelines to identify the relevant clinical information necessary to assist the reviewer in making clinical determinations.

CMS should clarify that use of such tools does not equate to an MA plan applying additional criteria beyond Traditional Medicare, but rather complements and helps interpret existing Medicare requirements. In fact, CMS Medicare review contractors use similar resources to assist in their review decisions. In the FY 2014 IPPS/LTCH PPS Final Rule, CMS explains: "Medicare review contractors must abide by CMS policies in conducting payment determinations, but are permitted to take into account evidence-based guidelines or commercial utilization tools that may aid such a decision."[25] That CMS allows Medicare review contractors to use evidence-based guidelines indicates CMS recognition of such guidelines as an appropriate tool to assist reviewers in determining coverage consistent with Traditional Medicare requirements.

Proposed Standard: Current Evidence in Widely Used Treatment Guidelines and Clinical Literature

UHG supports the revised standard for clinical evidence as provided in 422.101(b)(6) with a clarification—express inclusion of the ability for MA plans to use third-party evidence based clinical criteria. UHG asks CMS to expressly recognize third-party, evidence-based clinical appropriateness guidelines, such as InterQual® criteria, as a source of medical evidence to support the interpretations and clinical judgment of the reviewing professional.

Tools such as InterQual® have been developed to provide objective, evidence-based criteria that align with Medicare requirements for coverage of acute hospital, SNF, home health, and IRF services (among others). Using evidence-based criteria aligned to Medicare coverage guidelines helps MA plans ensure appropriate and consistent decisions about whether services would be covered under Traditional Medicare.

[23] CMS, Medicare Benefit Policy Manual, Ch. 1, § 110.2.2.
[24] CMS, 65 FR 40107, 40207 (June 29, 2000) (Final Rule).
[25] CMS, 78 FR 50495, 50948 (Aug. 19, 2013) (Final Rule).

Proposed Policy Reversal: Managing Care Delivery

UHG opposes CMS reversing longstanding policy to restrict MA plans' ability to manage the provision of services when care can be delivered in more than one way or in more than one type of setting. UHG supports CMS's prior position that the requirement under § 422.101(a) to provide coverage for all Medicare covered services "is not intended to dictate care delivery approaches for a particular service."[26]

UHG questions the discussion in the preamble that Traditional Medicare allows coverage for SNF and IRF when the beneficiary's needs could have been met in a different setting.[27] CMS statements in the proposed rule directly contradict its Medicare Benefit Policy Manual instructions that provide:

> In determining whether the daily skilled care needed by an individual can, as a "practical matter," only be provided in a SNF on an inpatient basis, the A/B MAC (A) considers the individual's physical condition and the availability and feasibility of using more economical alternative facilities or services.[28]
>
> The IRF benefit is not appropriate for patients who have completed their full course of treatment in the referring hospital, but do not require intensive rehabilitation. Medicare benefits are available for such patients in a less-intensive setting.[29]

Medically managing setting of care is essential to making appropriate determinations for acute and post-acute care based on Traditional Medicare coverage requirements. As illustrated by the examples above, CMS has long interpreted "reasonable and necessary" under Section 1862 to contemplate whether alternative settings or types of providers are able to meet the beneficiary's needs.

More recent CMS actions to expand the settings Medicare will provide coverage for services historically only covered in a hospital setting further supports allowing MA plans the ability to manage care to those settings to provide better care for members as well as ease hospital bed and nurse staffing shortages. During the onset and height of the pandemic, CMS took proactive steps to increase hospital capacity by allowing MA plans to approve care provided outside the traditional hospital setting: expanding the availability of telehealth services, allowing acute hospital at home services for members who met criteria for inpatient hospitalization but could be safely treated at home, and updating staffing flexibility to allow ambulatory surgical centers to provide greater inpatient care when needed.[30]

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[26] CMS, 65 FR 40107, 40207 (June 29, 2000) (Final Rule).
[27] See, e.g., Proposed Rule at 79502.
[28] CMS, Medicare Benefit Policy Manual, Ch. 8, § 30.7.
[29] CMS, Medicare Benefit Policy Manual, Ch. 1, § 110.
[30] November 25, 2020: CMS Announces Comprehensive Strategy to Enhance Hospital Capacity Amid COVID-19 Surge (CMS.gov).

This same flexibility is currently being used to help address the influx of hospitalizations stemming from the combination of influenza, COVID-19 and RSV, and has proven to be a significant benefit to both members and providers. CMS's expansion of the settings for beneficiaries to obtain care only underscores the fact that enrollees can obtain the same level of care in different settings. CMS should not now limit MA plans from doing exactly what Congress intended they do, i.e., manage care. Narrowing the longstanding policy allowing medical management of type of setting conflicts with the requirement that MA plans only cover services that are "reasonable and necessary," is inconsistent with recent CMS actions and could impact needed flexibility in care management when our health system is in crisis.

Appropriate Use of Prior Authorization (§ 422.138)

UHG supports proposed § 422.138, including the codification of longstanding guidance that when an MA plan approves a pre-service determination of coverage, the plan cannot later deny coverage or payment of the approved item or service based on medical necessity. But we reiterate our comments to the requirements on basic benefits in proposed § 422.101, because § 422.138 expressly incorporates the standards specified in proposed § 422.101.

Continuity of Care

Access to Services

UHG is committed to providing Medicare beneficiaries with timely access to high-quality care and supports MA plans' ability to use prior authorization and case management to ensure access to medically necessary care. But UHG opposes approving a prior authorization for the duration of a prescribed order or ordered course of treatment when medical necessity can only be determined at a particular point in time. To avoid unintended consequences, UHG urges CMS to narrow its approach which goes far beyond the stated purpose of restricting unreasonable interference with provider care.

Requiring MA plans to cover services for periods of time or units of service beyond what can be determined at the onset of services conflicts with MA plans' obligations to ensure access to medically necessary care and impedes MA plans' ability to manage care through strategies that ensure quality and control unnecessary cost. Providers and patients are not required to design treatment plans according to standards and criteria for Medicare coverage or even evidence-based care guidelines. Even when treatment meets medical necessity coverage criteria upon initial review, the member's condition could change during the prescribed timeframe resulting in medical necessity criteria no longer being met. Given the variability of individual patients' responses to care, predicting length of stay or duration of need at the onset of services is difficult, if not impossible.

Instead, services should be authorized for a defined duration or specific number of visits which enables MA plans to manage cases and collaborate with providers to ensure that member needs are met and to timely facilitate any transitions to alternate levels of care. For instance, during facility bed shortages, this frees up capacity and enables access to inpatient services for patients who might not otherwise be admitted. The proposed rule's requirement to cover services for the duration of the

course of treatment is not necessary to ensure timely member access to medically necessary care.

"Active Course of Treatment"

UHG agrees that MA plans must allow new plan enrollees undergoing an active course of treatment for certain conditions or receiving inpatient care a reasonable transition period within which to request and receive any prior authorization applicable to that course of treatment. However, the proposed rule's definition of "active course of treatment"[31] conflicts with existing regulations. CMS should narrow the definition of "active course of treatment" to align with industry standards, which means: (1) a course of treatment for a serious and complex condition, which includes a condition that is serious enough to require specialized medical treatment to avoid the reasonable possibility of death or permanent harm, or a condition that is life threatening, potentially disabling, degenerative, or congenital, and requires specialized medical care over a prolonged period of time; (2) course of institutional or inpatient care; (3) scheduled nonelective surgery, including related postoperative care; (4) a course of treatment for a pregnancy; and (5) treatment for a terminal illness.

Adopting this definition aligns with industry standards and other federal continuity of care requirements while protecting beneficiaries who are at risk of negative outcomes from potential delays or interruptions in ongoing care.

90-Day Transition of Care

UHG supports efforts to ensure that beneficiaries receiving an active course of treatment experience no delays or disruptions in their treatment when enrolling in a new MA plan. UHG recommends modifying § 422.112(b)(8)(i)(B) to require MA plans to provide continued coverage for an active course of treatment authorized by the member's prior plan for the remainder of the authorized period or units of service. For courses of treatment scheduled or initiated prior to a member's transition date but not reviewed and authorized as medically necessary by the member's prior plan, MA plans should allow a maximum 30-day, as opposed to 90-day, transition period before requiring authorization for the services.

Allowing new members to avoid an initial or re-authorization of services for 90 days could lead to unnecessary and costly utilization without any evidence of member benefit. For new members receiving inpatient services, a 90-day transition would impede an MA plan's ability to conduct case management and coordinate services. To illustrate, concurrent review throughout an inpatient stay assists with successful discharge planning and allows MA plans to manage the length of stay by determining when the member no longer meets acute inpatient criteria and can be safely transferred to a lower level of care. Delaying concurrent review for 90 days could potentially lead to unnecessary resource utilization and lengthy hospitalizations. Applying a maximum of 30 days for a transition period would enable members to continue care while allowing MA plans to ensure the medical necessity of the ongoing services and assist with care coordination.

[31] § 422.112(b)(8)(ii)(B) defines active course of treatment as a course of treatment in which a patient is actively seeing a provider and following the prescribed or ordered course of treatment as outlined by the provider for a particular medical condition.

CMS intends proposed § 422.112(b)(8)(i)(B) to mirror Part D transition requirements, thereby enabling consistency between programs. However, a 90-day minimum transition period significantly exceeds Part D transition requirements at § 423.120, which require providing new members only up to a 30-day supply if requested within 90 days of coverage under a new plan.[32] Moreover, medical services present unique considerations compared to Part D drugs, such as the impact on case management and care coordination. For example, lengthy hospitalizations could result in coverage of custodial care which is not a benefit under Traditional Medicare and longer stays could potentially increase hospital associated infections and patient safety events which could have been prevented if the member had been moved to a lower level of care when acute inpatient care was deemed no longer medically necessary. In the post-acute scenario, prolonged stays when such care is not medically necessary could result in unwarranted exhaustion of members' benefits. Taking these factors into account, a 30-day transition period for new MA members is more aligned to Part D transition requirements.

Mandate Annual Review of Utilization Management (UM) Policies by a UM Committee (§ 422.137)

CMS proposes that an MA plan may not use any UM policies for basic or supplemental benefits unless those policies and procedures have been reviewed and approved by a UM committee. CMS believes that this would ensure that UM policies are reviewed on a timely basis and have the benefit of provider input. CMS states that proposed § 422.137 would establish a UM committee that would operate similar to the Pharmacy and Therapeutics (P&T) committee.

The proposed rule sets up a duplicative and potentially conflicting set of requirements which appears unnecessary. MA plans have existing medical management programs supported by existing medical management policies and procedures. Those policies and procedures are reviewed by existing UM committees and are led by practicing physicians. MA plan medical management programs are subject to NCQA standards[33] and audit. If CMS adopts a UM committee requirement, CMS should deem compliant with such requirements any MA plan that has NCQA health plan accreditation or meets NCQA health plan accreditation requirements. CMS should also clarify how proposed § 422.137 would apply when an MA plan has delegated utilization management functions, including whether and how the requirements of proposed § 422.137 would be shared or divided between the MA plan and its delegate(s).

Effective Date

If CMS finalizes a January 1, 2024, effective date, MA plans will have a relatively short period of time to meet the requirements to establish the new committee as well as to complete the following actions:

[32] A 91-day supply is allowed in long-term care settings.

[33] NCQA surveys include whether an organization satisfies requirements such as: maintains written UM program description that includes specified structural elements; conducts annual review of the UM program; maintains written UM criteria and written policies for appropriately applying the criteria; and senior level physician involvement in implementation, supervision, oversight, and evaluation of the UM program.

- Recruiting of committee members, including clinical specialists, which may be challenging given the substantial time commitment needed from members, and the shortage in many physician specialties.
- Drafting and execution of Independent Contractor agreements for purposes of committee membership.
- Reviewing potential conflicts of interest, including time to address and resolve such conflicts where possible.
- Implementing a process to re-review existing UM policies and procedures.

For these reasons, if CMS proceeds to finalize this requirement as proposed, CMS should delay the effective date to at least January 1, 2025.

UM Committee Membership

If CMS finalizes the rule as proposed, UHG generally supports a requirement for the UM committee to include a majority of members who are practicing physicians, including members representing various clinical specialties. UHG's existing committees consist of practicing physicians with licenses in various specialties using their medical license to conduct UM and other clinical and medical management related work for the MA plans.

UHG also generally supports a requirement that the participation of physicians on the Committee who are board-certified through the Board of Medical Specialists or ABMS. UHG recognizes the benefit of including other types of providers or other health care professionals in fields such as physical therapy, chiropractic care and integrative medicine, who have formal training and active certification in their specialty area.

However, proposed § 422.137(c) and (d) again sets up potentially duplicative and conflicting requirements and mismatches clinical subject matter expertise with responsibilities for medical management programs and regulatory compliance. UHG opposes combining review of medical management programs and policies with review of clinical criteria into a single committee. UHG has two separate committees to handle these substantive areas and UHG's robust committee structure is consistent and compliant with NCQA standards. Medical management processes and coverage criteria require different clinical subject matter expertise and are more effectively managed by two separate committees. Further, UM committee responsibilities should not include determinations of compliance with specific MA organization regulatory requirements.

UHG supports permitting MA plans to use one UM committee to serve multiple MA plans to reduce the administrative burden. Additionally, one UM committee increases transparency and consistency.[34]

Additional Areas for Consideration and Comment

[34] Service on P&T and UM Committees is a substantial time commitment. Individuals that accept this responsibility are often recognized experts in their specialty field and have significant clinical responsibilities. With several competing demands on their time, it may be challenging for these clinical leaders to serve on both P&T as well as UM Committee meetings as the proposed rule suggests.

Termination of Services in Post-Acute Care

UHG supports authorizing post-acute treatment in discrete increments to allow MA plans to assess members needs and progress to ensure ongoing medical necessity of care. UHG also supports MA plans' ability to immediately issue a new termination of services when a Quality Improvement Organization (QIO) reinstates coverage due to administrative reasons and not because the QIO has determined continued services are medically necessary. When QIO reinstatement is based on the medical necessity of continued skilled services, however, a new termination should not be issued until the MA plan has reassessed the member's skilled needs.

Authorizing Treatment in Discrete Increments

As CMS notes in the proposed rule, federal regulation outlines criteria for termination of services from home health agencies (HHAs), SNFs, and comprehensive outpatient rehabilitation facilities (CORFs) at 42 CFR § 422.624. The regulation explicitly acknowledges termination of coverage at the end of a course of treatment preauthorized in a "discrete increment."[35] Prior authorization in discrete increments allows MA plans to ensure ongoing medical necessity. Each incremental review serves as an opportunity to assess the member's needs and discuss the member's progress, while working toward a comprehensive discharge plan. Authorizing treatment in discrete increments is appropriate for specific services and is a critical tool for MA plans to ensure quality of care and appropriate utilization.

Given the variability of individual patients' responses to care, predicting length of stay or duration of need at the onset of services is difficult. Requiring MA plans to cover services for periods of time or units of service beyond what can be determined medically necessary at the time of the request conflicts with MA plans' obligations to ensure access to medically necessary care and impedes MA plans' ability to manage care through strategies that ensure quality and control unnecessary cost.

Timing of Termination of Services following QIO Reinstatement

CMS requests comment on whether, when coverage is reinstated based on a QIO decision, the enrollee should have more than the 2-day period from the date of the termination of services notice before coverage can be terminated again by the MA plan. CMS should distinguish between coverage reinstatements based on administrative reasons and reinstatements based on medical necessity determinations. UHG supports MA plans' ability to immediately issue a new termination when the QIO overturn is due to administrative reasons, such as when an incomplete or incorrect Notice of Medicare Non-Coverage (NOMNC) is issued or when insufficient information is submitted to the QIO for review. In such cases, the QIO does not reinstate based on a review that continued skilled services are medically necessary; therefore, a new NOMNC should be issued immediately with sufficient information provided to the QIO for review to validate the need for continued services. Where services are reinstated based on medical necessity for continued skilled intervention, MA plans should not issue a new termination until the plan has time to receive incremental updates and reassess the ongoing needs of the member, which in general takes at least five days.

[35] § 422.624(a)(2).

Gold Carding

UHG agrees that gold carding programs have the potential to be an effective tool for simplifying the prior authorization experience for care providers that consistently demonstrate adherence to evidence-based care. Currently, there is significant variability in gold carding programs in terms of the items and services that are covered and provider qualifications for participation. This variation causes confusion for providers and complicates implementation, tracking and claims payment for payers. In practice, gold carding presents complex issues, including ensuring patient safety, supporting program integrity, and promoting access to high-quality, lower cost care. Given the complexities, UHG suggests CMS works closely with stakeholders on any future gold carding efforts to best address consistency and alignment of programs across markets.

Addressing Vulnerabilities that can lead to Manual Review Errors and System Errors

UHG's compliance program has extensive measures and controls in place to improve claim processing accuracy and to monitor for manual review errors and system errors, including but not limited to, adhering to NCQA system control standards for both UM systems and appeals systems. Additionally, UHG supports increasing automation of prior authorization to decrease manual errors while increasing transparency, reducing decision-making delays, and simplifying the process.

F. Request for Comment on the Rewards and Incentives Program Regulations for Part C Enrollees (§ 422.134 and Subpart V)

We appreciate CMS's request for comments on potential Reward and Incentive (R&I) program revisions to clarify the definition of "cash equivalent" as the term is used in § 422.134. CMS notes that it intends to incorporate the OIG definition of "cash equivalent," which includes "gift cards offered by large retailers or online vendors that sell a wide variety of items (for example, big box stores)."

Since the inception of the MA R&I programs, CMS has allowed plans to offer rewards incentives to beneficiaries, including gift cards, provided they are not offered "in the form of cash or monetary rebates, including reduced cost-sharing or premiums" and, consistent with statutory prohibitions, they are not "redeemable for cash."[36] The guidance has otherwise encouraged plans that offer rewards in the form of gift cards to offer a choice of cards to beneficiaries to account for differences in enrollees' preference and accessibility of retailers.

In 2021, CMS finalized its rewards regulation adding a new restriction on "cash equivalents," to prohibit not only rewards items that can be "converted to cash," like a check, but also items that "can be used like cash, such as a general-purpose debit card." As CMS notes, the 2021 final rule did not mention gift cards from big box stores or discuss them in relation to the prohibition on cash equivalents in § 422.134(d)(2)(i). While CMS stated in rule commentary that it intended to adopt OIG's definition of "cash equivalents," the final rule did not specify a prohibition on big box retailer gift cards, but instead stated it would be permissible for plans to offer a card "that can be redeemed only at specific retailers or retail chains or for a specific category of items or services."[37]

[36] Section 100.5 Permissible Rewards and Incentives, Managed Care Manual (2016).
[37] § 422.134.

UHG urges CMS not to incorporate the OIG's restrictive definition of "cash equivalents," including big box retailer gift cards into the MA rewards program regulation. The OIG commentary cited by CMS regarding cash equivalents and big box retailer gift cards was not made in the context of rewards and incentive programs and should not be applied in a categorical manner for the MA program. Many of the OIG comments regarding cash equivalents relate to requirements applicable to regulatory safe harbors protecting items or services and in-kind supports provided to patients to promote access to care and care management.[38] To meet the requirements of the safe harbors, an item or service or in-kind support offered to a patient must facilitate access to care or care management. For example, transportation to a medical appointment or a gift card for healthy food purchases or a smoking cessation program might be permissible, but movie tickets would not because a movie ticket does not itself facilitate access to care. In that context, the OIG stated that offering gift cards to big box retailers would not qualify for safe harbor protection because the card would not be limited to promoting patient's access to care but could instead be diverted and used for purposes unrelated to accessing care.

Those OIG concerns are not applicable in the context of a program designed to provide rewards and incentives to enrollees in exchange for completing defined health-related activities. Unlike the items and services described in the OIG safe harbors, MA plan rewards and incentives are not intended to provide the means for enrollees to access a health-related activity; they are instead intended to reward enrollee completion of health-related activities. The purpose is to provide items that have sufficient value to enrollees to encourage their active participation in maintaining their health. In addition, CMS regulations specify detailed requirements for rewards programs, including a requirement that reward items may not have a value that exceeds the value of the health-related activity. In this context, the OIG's stated concern around diversion of funds to impermissible purposes or a concern that an enrollee may be rewarded too much or have too many options for using the rewards they earn is not applicable.

Indeed, the OIG commentary on the in-kind support safe harbor pointed out that while cash equivalents are not specifically protected by the access to care safe harbor, that does not mean that all programs offering them are per se unlawful. Rather, the specific circumstances of the programs would require further analysis.[39] The OIG offered several examples of incentives in conjunction with government-sponsored programs, including those overseen by CMS, noting that adherence to the requirements of these programs would be relevant factors in assessing them. OIG further acknowledged that such government-administered programs may or may not meet all requirements of the regulatory safe harbor, but that the safe harbor is there to protect qualifying supports furnished outside of a program administered and monitored by CMS.[40]

As a practical matter, UHG is also concerned that the OIG definition of cash equivalent is too vague, and its application would lead to arbitrary and inequitable results. Requiring that plans avoid gift cards to "big box" retailers that sell "a wide variety of items" without any further direction leaves plans to guess at how many items a retailer can offer without being considered a "big box," and

[38] See § 1001.952(ee) and § 1003.110(6); 85 FR 77684, 77789-77793 December 2, 2020; 81 FR 88368, December 7, 2016.
[39] 85 FR 77684 at 77791.
[40] 85 FR 77684 at 77792-93.

conversely, how many items and services a plan must therefore exclude from their retailer gift cards to be permitted. Prohibiting "big box" retailer gift cards while allowing gift cards for several specific retailers also creates arbitrary results. It would be permissible to provide gift cards covering a wide variety of consumer goods if they are offered in the form of individual retailer gift cards that each individually sell more limited categories of items and services, but potentially impermissible to provide a gift card to one or two larger retailers that offer the same scope of items and services under one roof. Big box retailers such as Walmart and Amazon may be a primary source of retail goods in less affluent or rural communities, and so categorically prohibiting them in MA rewards programs may have a disparate impact on marginalized communities and create equity concerns.

Rather than defining cash equivalent in terms of the scope of items that can be purchased, or arbitrary definitions of big box retailers, UHG recommends that CMS propose a clarifying definition of permissible reward items for public comment that would more clearly define the types of transactions CMS views as harmful in the context of a beneficiary health incentive and reward programs and require that plans exclude those types of purchases from their program. For example, consistent with the statutory prohibition on offering items in the form of cash or monetary rebates, CMS could require that plans ensure that their cards exclude banking, ATM and any other cash transactions. Similarly, CMS might consider restrictions on specified purchases for items that CMS views as inconsistent with the purpose of a beneficiary health incentive program, such as alcohol, tobacco, or firearms.

If CMS decides to make further revisions to the rewards regulation, UHG asks that CMS publish the specific proposal and allow further industry comment before making it final. UHG also asks that CMS provide an effective date that allows plans adequate time to make the changes and communicate them to beneficiaries before the plan year in which the changes will go into effect.

H. Review of Medical Necessity Decisions by a Physician or Other Health Care Professional with Expertise in the Field of Medicine Appropriate to the Requested Service and Technical Correction to Effectuation Requirements for Standard Payment Reconsiderations (§§ 422.566, 422.590, and 422.629)

UHG supports the proposed change to § 422.566(d) and § 422.629(k)(3) linking the experience of the reviewing professional to the requested service on initial medical necessity reviews where there is a denial or a partial denial. UHG is dedicated to enhancing overall decision-making and the quality of reviews conducted by plans. We agree with CMS's acknowledgment that the reviewing professional does not, in all cases, need to be the same specialty or subspecialty as the treating provider due to resource limitations in specialized areas of medicine. We note that in some cases, reviewing professionals may have even greater expertise than the ordering physicians (e.g., internal medicine doctor vs. family nurse practitioner). Allowing flexibility in the specialty of the reviewer enables MA plans to route cases to an appropriate reviewer more quickly and streamlines reviews and clinical decisioning.

N. Clarify Language Related to Submission of a Valid Application (§422.502 and § 423.503)

CMS proposes to codify its authority to decline to consider a substantially incomplete application for a new or expanded Part C or D contract. CMS further proposes to codify the definition of a substantially incomplete application as one that does not include responsive materials to one or more sections of the MA or Part D application in the form and manner published annually by CMS. One example CMS provided of an incomplete MA application is "Failure to upload either a state license or documentation of a state licensure application before the CMS application due date."

UHC recommends that CMS issue specific guidance to clarify what constitutes an acceptable form of "documentation of a state licensure application" to be provided to CMS in the event a state license has been applied for, but not yet obtained, before the CMS application due date.

O. Updating Translation Standards for Required Materials and Content (§§ 422.2267 and 423.2267)

Standing Request for Translated Materials and Materials in Accessible Formats Using Auxiliary Aids and Services

CMS proposes to require that MA and Part D plans provide materials to beneficiaries in non-English languages and/or in an accessible format using auxiliary aids and services "on a standing basis" as long as a beneficiary remains enrolled in the plan or until the beneficiary requests that the plan provide required materials in a different manner. UHG notes that when beneficiaries request that a particular communication be provided in an alternative language or format, it does not necessarily mean that a beneficiary desires all communications in that language or format. Accordingly, UHG suggests CMS revise this requirement to allow the beneficiary the option to request a one-time alternate language or format communication or to request ongoing communications in the desired alternate language or format.

UHG also requests flexibility in the way MA plans can meet the beneficiary's request for an alternate format or language. For example, in time sensitive communications a fulfillment in Braille for a visually impaired beneficiary would take longer than a direct call or a conversation with an advocate. Finally, UHG requests CMS delay implementation of this proposal to at least the 2025 plan year to allow MA plans sufficient time to implement the requirement for all impacted communications. While a particular beneficiary may not receive a large variety of communications, ensuring availability of all plan communications in a variety of languages and formats will be a substantial undertaking.

Require FIDE SNPs, HIDE SNPs, and Applicable Integrated Plans to Translate Materials into the Medicare Translation Standard Plus Additional Medicaid Languages

UHG opposes CMS's proposal to require FIDE SNPs, HIDE SNPs, and applicable integrated plans (AIPs) to translate all required Medicare materials into any languages required by the Medicaid translation standard specified through their capitated Medicaid managed care contract in addition to the language(s) required by the Medicare translation standard at § 422.2267(a)(2). The number of languages an MA plan would need to account for in its communications is unsustainable, and the languages selected at the state level often do not meet the five percent threshold that is incorporated into the Medicare translation standard. Accordingly, UHG requests that CMS specify that the five percent threshold applies at the state level as well.

Alternatively, UHG requests that CMS specify that translation into state-required alternate languages apply to annual required communications only. This would ensure beneficiaries receive their benefit information in their selected language while retaining the option to request translated transactional communications as needed. CMS could permit the states to specify in the State Medicaid Agency Contract (SMAC) the documents the state requires to have translated into specific languages.

If CMS finalizes the translation requirement as proposed, UHG requests that CMS or the relevant state provide the translated templates for any required communications and CMS provide flexibility to meet the enrollee's needs using methods other than documents sent via US Mail. UHG estimates that industry cost to implement the requirements as proposed would significantly exceed the combined $12.5 million estimate CMS has noted. While the annual required materials could be plan-specific and the financial impact could be somewhat limited, the transactional communications are not plan-specific, so all of them would have to be translated to meet the proposed requirement. There will also be significant ongoing cost to maintain translated communications after the initial implementation.

P. Medicare Advantage and Part D Marketing (Subpart V of Parts 422 and 423)

Requirement for Multi-Carrier TPMO Materials Submission

CMS proposes requiring TPMOs to submit to CMS any material that the TPMO develops for multiple MA plans and Part D sponsors that meets the definition of marketing and that TPMOs receive prior approval, from each MA plan or Part D sponsor, of the material being submitted on their behalf. UHG recommends CMS maintain the current system that allows TPMOs to file materials in the Health Plan Management System (HPMS) and have MA plans decide whether to approve them through HPMS by opting-in or out when the materials are filed. The increased administrative work effort and resources to get approval of materials from MA plans outside of the HPMS portal seems counterproductive to increased program efficiency and could substantially delay getting necessary information to beneficiaries in a timely manner to make their plan selections.

Reducing TPMO Recording Scope

CMS proposes limiting the scope of calls that must be recorded by TPMOs to only those calls regarding sales, marketing, and enrollment instead of the current requirement to record all calls. UHG supports the proposed narrowing of the required TPMO call recording scope, and we recommend this change be effective immediately upon final publication of the final rule. UHG additionally requests that, upon implementation of the recording scope reduction, TPMOs not be required to retain previously recorded calls that fall outside the scope of marketing, sales, and enrollment.

TPMO Disclaimer

UHG believes CMS should revise the proposed TPMO disclaimer to more accurately reflect the role of a TPMO. The language in the proposed regulation and the disclaimer refers to TPMOs that "sell" for MA plans/Part D sponsors and "offer" plans. In practice, TPMOs do not offer plans and those

conducting only lead generation may not even distribute or sell plans. To capture the scope of TPMO types and activities more accurately, UHG suggests using broader terminology, changing "we do not offer every plan available" to "we do not represent every plan available." Further, UHG similarly suggests revising references to "sells" in 422.2267(41)(i) and 423.2267(41)(i), as not all TPMOs engage in the activity of selling.

UHG also has concerns with CMS's proposal to modify the TPMO disclaimer to require all TPMOs to list the names of the MA plans or Part D sponsors with which they contract in the applicable service area. Requiring TPMOs to list all represented plans may result in lengthy lists that may overwhelm and confuse beneficiaries. Additionally, given the nature of general advertising in the market (e.g., broad national/multi-service area ads), it is not feasible to list only those plans that are offered to all beneficiaries in the viewing area. UHG therefore recommends CMS either exclude the disclaimer on national and multi-service area ads or modify it to state that "Any information we provide is limited to those plans we represent in your area, which may include (listing)." Alternatively, UHG asks CMS allow MA plans to provide beneficiaries a link on digital and printed marketing and communication materials to a listing of all MA plans in their service area, as providing each MA plan name on written materials may not be feasible with material space/character constraints.

To the extent it is important to ensure further transparency regarding the scope of plans available, UHG recommends CMS consider requiring TPMOs make a disclaimer verbally during a TPMO's telephone call with a beneficiary. For example, CMS could require that TPMOs disclose the plans they represent in the consumer's service area at the beginning of any marketing or lead generation call with a beneficiary. That said, knowing the beneficiary's service area to read the appropriate disclaimer with all the names of the MA plans in the beneficiary's service area may not be achievable within the first 60 seconds of the call, so additional time and flexibility may be needed.

Prohibiting TPMOs from Distributing Personal Beneficiary Data to Other TPMOs

CMS proposes prohibiting a TPMO from distributing personal beneficiary data collected by that TPMO to another TPMO. UHG agrees that the practice of TPMOs selling or otherwise distributing a lead to multiple other TPMOs may result in unwanted outreach from multiple entities/individuals resulting in beneficiary confusion and abrasion. However, UHG believes that lead generation and distribution, if done in a controlled and exclusive way, is in the best interests of beneficiaries by giving them access to information about all the plans available to them. The proposed language would have the effect of eliminating arrangements between entities that generate leads only and entities that sell MA/Part D plans (i.e., licensed agents/agencies), as a TPMO is defined to include both lead generation entities as well as licensed insurance agents/agencies. To address CMS's concerns but maintain some flexibility for plans, UHG proposes the below changes to CMS's proposed language:

> "Personal beneficiary data obtained by a TPMO may only be distributed to, or used by, a TPMO and its representatives (e.g., a licensed insurance agency and its licensed agents representing the agency) as set forth below. In each instance where a TPMO obtains a beneficiary's data, the beneficiary's data may be shared with only one other TPMO (and its representatives) or an MA plan/Part D sponsor (properly covered by the consent to contact). If a TPMO obtains a beneficiary's data and uses it to contact that beneficiary, that beneficiary's data may not be distributed to other TPMOs or an MA plan/Part D sponsor. If a

TPMO distributes a beneficiary's data to another TPMO, it may not later use it to contact that beneficiary. For the purposes of the restrictions outlined in this section, an enrollment submitted to an MA plan or Part D sponsor by a TPMO does not constitute an instance of sharing of personal beneficiary data."

General Communications Materials and Activity Requirements

CMS proposes to further restrict the use of superlatives by prohibiting them unless sources of documentation or data supportive of the superlative are also referenced in the material. UHG supports CMS's requirement to the extent it is only requiring plans to provide citations to the substantiating supporting data as it would not be feasible to include the sources themselves in all marketing materials.

In addition, CMS proposes to require that the documentation or data supportive of the superlative reflect data, reports, studies or other documentation that has been published in either the current or prior contract year. UHG is concerned that a recent publication date is not necessarily reflective of recently sourced data. For example, one could publish documentation in 2022 based on data from 2015. UHG also notes that plans frequently utilize internal data that is not always publicly published. Accordingly, UHG recommends replacing "documentation that has been published" with either "documentation that is applicable to either the current contract year or prior contract year" or "documentation that is based on either the current contract year or prior contract year."

CMS also proposes placing limits around the use of the Medicare name, logo, and Medicare card to reduce concerns about misleading marketing activities and documents. UHG supports the clarifying restrictions on the use of the Medicare name, Medicare card or other Federal Government issued information to prevent uses that are likely to mislead a consumer into believing that they are interacting with a government entity or receiving an official government communication. The examples that CMS provides in the commentary to the proposed rule make clear various ways that the use of the Medicare name and government imagery (such as official looking seals, flags, eagles and government buildings) may be misleading to beneficiaries. Another example of misleading use may be the use of the Medicare name in a URL without other private branding or description. Conversely, we understand that it would be permissible to use the Medicare name and/or card images in a manner that accurately conveys to the consumer the nature of Medicare products that are being offered (for example, using Medicare and/or Medicaid card imagery in a material to convey the context that the plan is offered to Medicare and Medicaid-eligible beneficiaries as long as it is clear through prominent use of commercial branding and other language that the entity providing the products is a private commercial entity, such an MA plan or Part D plan sponsor).

Advertising Benefits in a Service Area Where those Benefits are not Available

CMS proposes adding a new restriction which prohibits MA plans from advertising benefits not available in a service area, unless doing so is unavoidable in a local market. UHG requests further clarification on the definition of "unavoidable" in this context and recommends CMS provide examples in the Medicare Communications and Marketing Guidelines (MCMG) or in a HPMS memo if no MCMG updates are planned for 2024. For example, we would consider national advertising, where the scale of the communication is broad and delivered through channels that cannot be

locally tailored as "unavoidably" advertising benefits that may not be available in a particular local market. This includes both television and digital communications, including display advertising.

CMS should also allow for flexibility in national advertising to the extent the benefits promoted are available to most beneficiaries in most service areas. Given the variation in plan benefits at a local level, a general representation of the average benefits or benefits available to the majority should be allowed in national or regional advertising and would ensure that the benefits promoted would be available to most of the Medicare eligible audience within the plan footprint. UHG proposes modifications to this requirement to read: "benefits that are not available to beneficiaries in most of the MA plan's service areas where the marketing appears, unless unavoidable..."

Beneficiary Contact Information

Generally, UHG supports efforts to protect beneficiaries from inappropriate sales pressures. However, we are concerned that CMS's proposals regarding limits on collecting beneficiary contact information at educational events and requiring a 48-hour delay between form collection and a personal marketing appointment, will inhibit beneficiaries' timely access to agent resources as well as their ability to enroll when election or coverage deadlines are nearing.

Beneficiary Opt-Out

CMS proposes a new requirement for each MA plan and Part D sponsor that reaches out to beneficiaries regarding plan business, to provide notice to all beneficiaries whom the plan contacts at least once annually, in writing, of the individual's ability to opt out of future calls regarding plan business. This would apply regardless of the plan's intent to contact the beneficiary again. Currently, plans are only required to provide this notice once, and not annually. UHG requests CMS confirm that the scope of activity impacted by this proposed revision is calls for "plan business" as described in the regulation (i.e., calls to discuss other products/services offered by the MA plan or Part D sponsor). It should not impact informational calls from the plan with information regarding the beneficiary's current plan.

Prohibiting Acceptance or Collection of SOA Cards or Beneficiary Contact Information at Educational Events

CMS proposes reinstating the prohibition on accepting Scope of Appointment forms (SOAs) and Business Reply Cards (BRCs) at educational events. UHG recommends that CMS not implement a complete restriction, as it may result in a significant reduction in educational events, potentially reducing health literacy and beneficiary access to information. UHG recommends CMS consider mitigating concerns regarding beneficiary pressure via less restrictive means. For example, by prohibiting the distribution of SOA/BRCs during the educational event but allowing access after the educational event concludes and requiring that the agent read a standardized statement or script that announces the availability of the SOA/BRCs while clearly noting that beneficiaries have no obligation to provide information.

Prohibiting Marketing Events from Taking Place within 12 Hours of an Educational Event in the Same Location

CMS proposes prohibiting marketing events from taking place within 12 hours of an educational event in the same location, defined as the entire building or adjacent buildings. UHG recommends that CMS consider clarifying that the prohibition on sales and marketing events within 12 hours of one another in the same location applies to a single agent conducting multiple events in the same location. In other words, it should not prohibit an agent from hosting a sales event in a location where another agent had held an educational event within 12 hours. Agents will largely be unable to determine when other agents have scheduled events. UHG also recommends that CMS consider reducing the proposed wait time between events to a one hour minimum. A reduced wait time of an hour still relieves beneficiaries of pressures to remain for the sales event, but also allows the convenience of educational and sales event occurring at the same location during the same day.

Prohibiting Personal Marketing Appointments from Taking Place until 48 hours after SOA Completion

CMS proposes codifying previous marketing guidance by prohibiting personal marketing appointments from taking place until 48 hours have passed after the SOA was completed by the beneficiary. UHG opposes this approach, as the 48-hour requirement without any exceptions may jeopardize a beneficiary's timely access to agent resources as well as their ability to enroll when election/coverage deadlines are nearing. Such delays will eliminate a beneficiary's ability to engage with an agent on a schedule that best fits their needs, even when the beneficiary initiates the discussion with inbound calls and walk-in appointments.

Beneficiaries that have transportation challenges or may have engaged friends or family members to accompany them may also be burdened with a need to leave and reschedule transportation and personal assistance. Engaging additional people in the process is common; for example, in Special Needs Plans (SNPs) 85 percent of beneficiaries have responsible parties gather the information on plan options and ultimately make the plan selection on behalf of the beneficiary. Unlike other MA plans, most SNP beneficiaries have this built-in added layer of protection from any alleged undue pressure and MA plans should be able to meet with the beneficiary's responsible party to the extent the responsible party can meet shortly after submission of the contact forms.

A 48-hour SOA wait may also be difficult for beneficiaries that choose to meet with multiple agents before making an enrollment decision. The current proposal will also significantly alter the operating structure of call centers that do not primarily operate on a pre-scheduled appointment basis.

The potential for beneficiary barriers to information and access is compounded when considering the combined effect of the SOA/BRC collection prohibition, 48-hours SOA waiting period, and 12-hour educational/marketing event delay. For example, a beneficiary who attends an educational event will not only have to separately contact the agent to set up an appointment rather than doing so at the event, but they must then also wait 48 hours from the time that appointment is set up until they can meet with an agent.

For these reasons, UHG recommends CMS not finalize the proposal to require an SOA 48 hours prior to personal marketing appointments. If CMS believes a 48-hour waiting period is essential, we recommend that CMS require an SOA 48 hours prior to personal marketing appointments "when practicable," and note the circumstances where such an exception to the 48-hour delay would be permissible, consistent with previous iterations of the CMS Medicare Marketing Guidelines.

Recommended exceptions to the 48-hour SOA delay include: beneficiary-initiated inbound calls, walk-in appointments, and proximity to election period deadlines (e.g., close of the Annual Enrollment Period (AEP)).

Establishing a 6-month Scope of Appointment (SOA) Expiration Date, unless Beneficiary has Renewed

CMS proposes modifying current regulations to limit the validity of SOAs and BRCs to six months. UHG recommends setting the auto-expiration date of SOAs and BRCs at nine months to ensure that permission to contact does not expire before the beneficiary's election period ends. Beneficiaries often engage with agents in advance of their election period eligibility. For example, a beneficiary on Original Medicare may engage an agent in January, but not qualify for an enrollment period until the AEP. A nine-month SOA/BRC expiration date would allow the agent to outreach and engage with the beneficiary during the AEP.

UHG also requests an exception to the expiration date for 5-star SNP plans, as these plans permit an individual to change plans throughout the year. As an example, this flexibility would be valuable for ISNP plan beneficiaries in a medical situation that changes suddenly. If a beneficiary is moved to an Assisted Living or Nursing Home setting as the result of a life changing experience, they can more easily shop for a new plan.

UHG also notes that the language of (c)(3)(iii)(A) as proposed is confusing as it includes SOAs, BRCs and requests to receive additional information, but only the SOAs document the scope of conversation. UHG recommends separating the limitations related to SOAs and those related to BRCs and requests to receive additional information. We suggest language under (c)(3), which is specific to personal marketing appointments, addressing the limits related to Scope of Appointment. Specifically, we recommend (c)(3)(iii)(A) to read as follows:

> "Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary and documented by the plan in a Scope of Appointment, which is valid the earlier of when the appointment is held or nine months following the date of beneficiary's signature date."

Separately, regarding § 422.2264(a) and § 423.2264(a), which address unsolicited contact and circumstances where contact is permissible, we propose adding a new (a)(4) as follows:

> "Consent to contact a beneficiary documented in a business reply card or request to receive additional information, excepting contact covered by and addressed in paragraph (c)(3) of this section, expires and is no longer valid nine months following the receipt of the consent to contact."

Requiring Plans to Establish Oversight Plan Monitoring Agent and Broker Activities

UHG recommends that CMS incorporate 'agent/broker' non-compliance reporting requirements into sub-regulatory guidance and provide plans with an opportunity to discuss reporting details with CMS Account Managers (timing, content, frequency, etc.). This discussion opportunity will allow for a cooperative reporting design that both meets CMS objectives and plan capability.

R. Part D Medication Therapy Management (MTM) Program (§ 423.153(d))

UHG supports efforts to increase access and eligibility for beneficiaries who suffer from chronic diseases and reducing variability of MTM eligibility criteria across plans.

Multiple Chronic Diseases

While UHG is generally supportive of CMS's proposal to codify the core chronic disease conditions so that there is alignment across all plans in MTM eligibility, UHG encourages CMS to revise the list of core chronic diseases and limit it to only those diseases that a pharmacist without specialized training could provide the most benefit to a beneficiary when completing a comprehensive medication review (CMR) and optimize the beneficiary's drug therapy.

UHG recommends that CMS consider removing several of the current core chronic diseases because they (a) require pharmacists with specialized training and experience to optimize outcomes; (b) require additional lab work or data points that are not easily accessible to the plan MTM pharmacist (in a call center or retail pharmacy) to either make strong clinical recommendations or assess if current therapy is safe and appropriately dosage adjusted for the beneficiary; and (c) may not directly provide benefit to a beneficiary and would be better handled via care/disease management programs involving interdisciplinary teams.

Specifically, UHG recommends CMS remove the following conditions from the core chronic disease list because the MTM pharmacists are not in the best position to positively impact a beneficiary's care with a CMR and routine targeted medication review assessments:

- **Mental health (including other chronic/disabling mental health conditions).** Generally, only pharmacists with specialized training and expertise in this chronic disease category can influence and/or improve beneficiary outcomes. Without specialized training such as board certification or residency training in mental health, an MTM pharmacist may not be equipped to provide the specialized care that is needed for these beneficiaries. In addition, when working with enrollees who have a mental health disease or condition, having an ancillary pharmacist who has not previously worked with an enrollee, make recommendations on drug therapy without knowing the enrollee's medical and drug history may cause disruption in the enrollee's treatment/therapy–which is already a complex condition to address and one that frequently involves input from other treating providers, such as a physician, a therapist and/or a counselor.
- **End-stage renal disease (ESRD).** A plan's MTM pharmacists (in call centers and retail pharmacy settings) may not have all the necessary data points, such as lab values, to make meaningful clinical recommendations around current therapy, gaps in care and/or any potential adjustments to therapy. Without lab values like BUN, Serum Creatinine, magnesium, potassium, calcium, and hematocrit/hemoglobin levels for example, the value the MTM pharmacist provides in a drug review may be less impactful. In addition, patients with ESRD are usually managed by interdisciplinary teams including a pharmacist who would be in the best position to make clinical recommendations (outside of MTM program) as part of the standard care that the ESRD beneficiary receives. The medication review done by the enrollee's care team is likely not captured as part of this MTM program and

CMS would not see that data; since these enrollees are likely already getting their medications reviewed by their care team, it may be confusing and duplicative to complete another CMR as part of this MTM program.

- **Alzheimer's disease.** The plan's MTM pharmacist may not be able to complete an interactive CMR with the beneficiary due to declining cognitive impairment. UHG believes this type] of review should be done outside of the MTM program where the beneficiary would best be served by an interdisciplinary care team, including a pharmacist, who can make recommendations around appropriate prescribing and current drug therapy based on their ongoing monitoring and intervention of the beneficiary's condition. UHG believes beneficiaries with Alzheimer's are better served by the beneficiary's care team, especially if the beneficiary is living in a setting where they are not managing their own medications and there are caregivers and/or a health care team that is responsible for overseeing their medication therapy.

As discussed above, UHG believes that there are certain chronic diseases where the most effective mechanism for managing the disease is through an interdisciplinary care team because the needs of the beneficiary require specialized training and/or additional care coordination. Because the MTM services provided under the MTM program are not the most effective mechanism for managing these types of specialized, complex diseases, UHG does not support adding HIV/AIDS or cancer to the list of core chronic diseases. UHG does support CMS's proposal to codify dyslipidemia as a core disease to include both chronically high (hyperlipidemia) and low (hypolipidemia) lipid levels, as well as CMS's proposal to change to specify only chronic congestive heart failure as a core disease.

To address CMS's concerns over the decline in MTM eligibility, UHG recommends CMS consider only including the following diseases on the core chronic disease list with a minimum requirement that the beneficiary have at least three out of the nine core conditions:

1. Bone disease-arthritis:
    - Osteoporosis
    - Osteoarthritis
    - Rheumatoid arthritis
2. Chronic congestive heart failure (CHF)
3. Diabetes
4. Dyslipidemia
5. Hypertension
6. Respiratory Disease limited to the following:
    - Asthma
    - Chronic obstructive pulmonary disease (COPD)

UHG believes that developing an MTM policy that includes these chronic diseases will help ensure alignment in MTM eligibility across plans, that the appropriate beneficiaries are targeted for enrollment and have access to the MTM program, and that MTM services are provided where they have the most value and/or benefit to the beneficiaries.

UHG recommends that to the extent CMS codifies a chronic disease list that it provides greater specificity in the definitions for each disease. Specifically, UHG asks that CMS clarify how "other

chronic lung disorders" are defined under respiratory disease and how "chronic/disabling mental health conditions" are defined under mental health.

Multiple Part D Drugs

UHG supports CMS's proposal to require that plans rely on a standardized source for the purpose of identifying maintenance drugs, such as Medi-Span or First Databank (FDB) if plans have the discretion to determine which to use.

UHG does not support CMS's proposal to decrease the number of Part D drugs a plan may require for an enrollee to be eligible for MTM from eight to five. A typical enrollee with three or more chronic diseases takes between seven and ten medications. For this reason, while changing the number of targeted medications to five would result in the inclusion of more enrollees, it is not the targeted population of enrollees that the MTM program is designed to benefit. UHG recommends that CMS maintain the number of Part D drugs at eight to ensure that the focus of the MTM program continues to be on enrollees who have more complex drug regimens and who are at the most risk of medication therapy problems.

Annual Cost Threshold

CMS proposes revising the method for calculating the eligibility cost threshold to be commensurate with the average annual cost of five generic drugs. UHG supports CMS's proposal to codify a drug spend threshold, but as discussed above, UHC does not support decreasing the maximum number of Part D drugs from eight to five and recommends that if CMS codifies a drug spend threshold, that it set the average annual price to eight generic drugs.

Clarifications

UHG requests clarification that CMS will continue to allow plans to require that an enrollee have a minimum of three chronic conditions out of the total number of targeted core conditions to be eligible for MTM.

Effective Date

CMS is proposing several substantial changes to the MTM program which will take time for plans to properly implement. If CMS finalizes the changes as proposed, UHG recommends that CMS delay the change to on or after January 1, 2026, to allow plans an adequate amount of time to enhance their systems and software to support the criteria changes and the potential increase in volume of enrollees, to hire and onboard additional administrative support and clinical staff, onboard new vendors to support the CMR volumes, and to provide clinical training on new core conditions.

V. Limitation on PDP Contracts Held by Subsidiaries of the Same Parent (§ 423.272)

UHC appreciates CMS's intent to provide more meaningful competition and provide a level playing field for Part D plans. There are currently only three plan benefit packages in a region; however,

there may be multiple contracts that require operational considerations upon consolidation (e.g., service area expansion, financial settlements, etc.). If CMS finalizes guidance as proposed, UHG recommends providing more than two bid cycles as a transition period for plans to consolidate contracts between plans. Specifically, UHG recommends a minimum of three bid cycles to ensure proper implementation.

W. Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act (§§ 422.326(c), 423.360(c), (§401.305(a)(2))

In the proposed rule, CMS proposes to amend the standard for when an MA plan or Part D sponsor has "identified" an overpayment. *See* 87 Fed. Reg. 79,452, 79559-60 (Dec. 27, 2022); *see also id*. at 79,455-56; *id*. at 79,699; *id*. at 79,719. Specifically, CMS "propose[s] to remove the existing standard and adopt, by reference, the False Claims Act [FCA] definition of 'knowing' and 'knowingly.' Under the proposed rule, an MA plan or Part D sponsor has identified an overpayment if it has actual knowledge of the existence of the overpayment or *acts in reckless disregard or deliberate ignorance* of the overpayment." *Id*. at 79,559-60 (emphasis added). UHG respectfully submits that the Notice's proposal to adopt the FCA standard is contrary to the statute's plain language and drafting history and would also render unlawful the rule's separate definition of "overpayment." In addition, as a policy matter, it would cause numerous practical problems that would massively outweigh any potential benefits. Instead of CMS's proposal, UHG recommends that CMS follow the plain language of the statute and adopt the following actual knowledge standard: an MA plan or Part D sponsor has "identified" an overpayment once it has determined that the overpayment exists. This definition is consistent with the statute, is workable for MA plans, and comports with the recent decision of the U.S. Court of Appeals for the District of Columbia Circuit concerning the same subject.

The Patient Protection and Affordable Care Act (the "Act"), Pub. L. No. 111-148, 124 Stat. 119 (2010), imposed an obligation on all entities that receive payments from federal healthcare programs to report and return overpayments that such entities identify on their own. The Act defines "overpayment" as "any funds that a person receives or retains under [Medicare or Medicaid] to which the person, after applicable reconciliation, is not entitled." 42 U.S.C. § 1320a-7k(d)(4)(B). And it requires that any "overpayment . . . be reported and returned [within] 60 days after the date on which the overpayment was *identified*." *Id*. § 1320a-7k(d)(2) (emphasis added). The Act provides no definition of the term "identified," which triggers the 60-day clock.

In 2014, CMS promulgated a rule that MA plans were deemed to have "identified" an overpayment under the Act when "the MA organization has determined, or *should have determined through the exercise of reasonable diligence*, that the MA organization has received an overpayment." *See* Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 29,844, 29,923 (May 23, 2014) (emphasis added). UHG brought suit under the Administrative Procedure Act, challenging CMS's newly promulgated definition of "identified." *See UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 182 (D.D.C. 2018), *rev'd in part on other grounds sub nom. UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. 2021). The D.C. District Court vacated this provision because CMS had adopted too strict a definition of "identified" and, "[n]ot being Congress, CMS has no legislative authority to apply more stringent standards to impose FCA consequences through regulation." *Id*. at 190-91. CMS did not appeal that aspect of the D.C. District Court's decision. CMS now proposes to

replace that vacated standard with the FCA standard, which extends beyond actual knowledge to include "reckless disregard or deliberate ignorance." That proposal is flawed for at least four reasons.

First, CMS's proposal is contrary to the plain text of the Act. The Act provides that the 60-day clock starts running on the date an overpayment "was identified." 42 U.S.C. § 1320a-7k(d)(2). The statutory phrase "was identified" unambiguously indicates actual knowledge, not reckless disregard or deliberate ignorance. *See Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984) (requiring "giv[ing] effect to the unambiguously expressed intent of Congress"). To "identify" is to "establish," "indicate," or "determine" the identity of something. *See, e.g.*, Identify, *New Oxford American Dictionary* (3d ed. 2010) ("to establish or indicate who or what (someone or something) is"); Identify, *Webster's II New Collegiate Dictionary* (3d ed. 2005) ("to establish the identity of" or "to determine" the classification of); *see also* Identify, *Merriam-Webster Dictionary* (2023), https://www.merriam-webster.com/dictionary/identify. No one would think, nor does any dictionary suggest, that something has been "identified" if it merely *should have been* established, proved, or determined. A witness has not "identified" a suspect just because she should have recognized him but recklessly did not. Similarly, an overpayment has not been "identified" until an MA plan has actually determined that it exists. The proposed definition flouts the plain, unambiguous meaning of the statutory text.

Second, even if the statutory text had any ambiguity, CMS's interpretation is unreasonable, because it adopts a standard Congress already considered and rejected. *See Chevron*, 467 U.S. at 844-45. The legislative history shows that Congress intended "identify" to require something *more* than mere recklessness or deliberate ignorance. The initial version of the statute introduced in the U.S. House of Representatives in 2009 included a provision that an overpayment had to be reported within 60 days after it was *known*. H.R. 3200, 111th Cong. § 1641 (as introduced by the House, July 14, 2009). It specified that the meaning of "known" would be the same as the FCA's knowledge standard, which includes recklessness and deliberate ignorance. *See* 31 U.S.C. § 3729(b)(1). If Congress wanted to adopt the FCA's knowledge standard, then it would have stopped right there. But Congress instead adopted the Senate version of the bill, which substituted "identified" for "known." Pub. L. No. 111-148, § 6402(a), 124 Stat. at 755 (enacting H.R. 3590, 111th Cong. (2010)).

The drafting history thus makes clear that Congress affirmatively chose to adopt a standard *different* from the FCA standard. And as the D.C. District Court has already held in striking down the Rule's prior "reasonable diligence" standard, Congress plainly did not wish for "identify" to embody a liability standard lower than the FCA's knowledge standard. *See* 330 F. Supp. 3d at 191. The only remaining option, consistent with the plain language, is that Congress instead intended the *more* demanding standard of actual knowledge. That legislative choice should be controlling. *INS v. Cardoza-Fonseca*, 480 U.S. 421, 442-43 (1987) ("Few principles of statutory construction are more compelling than the proposition that Congress does not intend *sub silentio* to enact statutory language that it has earlier discarded in favor of other language." (citation omitted)). In short, even if the term "identified" were ambiguous, the one meaning it *cannot* possibly have is the precise recklessness/deliberate indifference standard that Congress already considered and rejected. CMS's proposal would impermissibly nullify Congress's choice.

Indeed, in *UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. 2021), the D.C. Circuit read the term "identified" in precisely this proper way. There, the court made clear—consistent with the Act's

plain language and legislative history—that it understood the term "identified" as an actual knowledge standard: "the Rule only requires insurers to refund amounts they know were overpayments, *i.e.*, payments they *are aware* lack support in a beneficiary's medical records. That limited scope does not impose a self-auditing mandate." *Id.* at 884 (emphasis added). As the court repeatedly phrased it, the rule applies only to diagnostic code errors that an MA plan "*discovers*." *Id.* at 870.[41] "Aware" and "discover" is language of actual knowledge. *See* Discover, *Merriam-Webster Dictionary* ("to obtain sight or knowledge of for the first time" or "to find out").

Third, that understanding of the meaning of "identified"—that the overpayment obligation applied only to the return of actually known overpayments, i.e., overpayments that an MA plan is "aware" of and has "discovered"—was the critical underpinning for the D.C. Circuit's opinion upholding CMS's Overpayment Rule against the challenge that it violated the Act's actuarial equivalence requirement. There, the challengers had argued that CMS's definition of "overpayment" violated the statutory requirement of "actuarial equivalence," because it deemed all unsupported codes from MA plans to be "overpayments," regardless of the rate of unsupported codes in CMS's own data, which is used to set the MA payment rates. 16 F.4th at 882-84. The D.C. Circuit reasoned that CMS's overpayment definition did not violate the actuarial equivalence requirement, however, because while that requirement may apply at the larger population level, it does not apply to individual codes that an MA plan *discovers* are incorrect. *Id.* at 870-71, 886-87.[42] As the court reasoned, CMS's stringent definition of "overpayment" was permissible because it applied only to the "limited scope" of payments that MA plans "*are aware* lack support." *Id.* at 884.

In opposing certiorari in the same case, the U.S. Solicitor General's office likewise repeatedly defended the Rule's definition of overpayment on the ground that it applied only to diagnoses which the insurer "discovers" or "determines" are unsupported.[43] And CMS also recently expressed the same view in a new RADV rule, stating "Nor does this rule change the longstanding obligation of an

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[41] *See also, e.g.*, *UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867, 877-78 (D.C. Cir. 2021), *cert. denied*, 142 S. Ct. 2851 (2022) ("[I]nsurers are required to refund payments based on *unsupported diagnoses that they themselves discover through the course of their business*." (emphasis added)); *id.* at 882-83 (referring to CMS "recouping overpayments pursuant to the [Overpayment] Rule for codes that a Medicare Advantage insurer reported to CMS *but later discovered* were unsupported by beneficiaries' medical records." (emphasis added)).

[42] The court made clear that it was not reaching the issue whether CMS's overpayment rule would violate actuarial equivalence if it were implemented at the population level, as in the RADV context. *See* 16 F.4th at 892-93 & n.1.

[43] *See also, e.g.*, *UnitedHealthcare Insurance Co., et al. v. Becerra*, U.S. Br. in Opp. at I (U.S. No. 21-1140) ("Consistent with longstanding Medicare rules, the Overpayment Rule provides that *when an insurer discovers* that a previously submitted diagnosis is not supported by the beneficiary's medical record, the associated payment is an 'overpayment' subject to the 60-day return requirement and other procedural measures." (emphasis added)); *id.* at 5 ("If upon conducting an internal review of submitted diagnosis codes, *the plan sponsor determines* that any . . . diagnosis codes that have been submitted do not meet risk adjustment submission requirements, the plan sponsor is responsible for deleting the submitted . . . diagnosis codes as soon as possible." (emphasis added; citation omitted)); *id.* at 24-25 ("Thus, petitioners have not demonstrated that requiring Medicare Advantage insurers to *also* account for overreporting, *when discovered*, will lead to improper underpayment." (emphasis added)); *id.* at 27-28 ("As explained above, CMS has long required that, if a submitted diagnosis *is discovered to be invalid*, insurers must return any resulting payment." (emphasis added; citation omitted)); *id.* at 30-31 ("As explained, CMS has long required that Medicare Advantage insurers return payments for diagnoses *that are discovered* to be unsupported by medical-record documentation." (emphasis added; citation omitted)); *id.* at 33 ("The Overpayment Rule is consistent with insurers' longstanding obligation to refund payments for *diagnoses discovered* to be unsupported by medical-record documentation." (emphasis added)).

insurer to refund payments to CMS *if it learns* that a diagnosis lacks support in the beneficiary's medical record."[44] The repeated characterized of "identified" as requiring actual knowledge—by the D.C. Circuit, the Office of the Solicitor General, and CMS itself—is no accident. Rather, it is the only standard that is workable in a system where there is a widely acknowledged known high rate of diagnostic coding errors by providers across the industry and no freestanding audit obligation imposed on MA plans. In that context, CMS's proposed extension of "identified" to include recklessness/deliberate ignorance would cut out the critical underpinning that led the D.C. Circuit to uphold the Rule in the first place.

Fourth, the proposed FCA standard would also be difficult to administer and follow as a practical matter. The purpose of the statutory term "identified" is to pinpoint the moment in time at which failure to return an overpayment triggers liability under the FCA. The penalties under the FCA, a fraud statute, are severe: treble damages, statutory penalties, and even potential exclusion from the Medicare program. Given the potential severity of the consequences of failing to return an overpayment on time—and the fact that those consequences flow from *inaction*, not from affirmative conduct—it is critical that MA plans be able to determine with certainty when the 60-day clock starts to run. A plan can have little doubt about when it *actually* identified an overpayment, but the point at which it *would* have identified an overpayment had it not exhibited reckless disregard or deliberate ignorance will be anything but clear. That ambiguity will have particularly stark impact in the MA program, where there is often uncertainty as to whether a plan has been overpaid, and thus would result in further uncertainly about when the 60-day clock begins. The proposed standard would unsettle MA plans longstanding business expectations, and threaten the long-term viability of the program. At a minimum, it would launch endless disputes about how far MA plans must go toward removing errors to avoid being deemed reckless in disregarding them.

Instead of adopting the FCA standard, UHG recommends that CMS adopt the actual knowledge standard dictated by the plain language of the statute: an MA plan or Part D sponsor has identified an overpayment when it has determined that an overpayment exists. "It is a basic tenet that regulations, in order to be valid, must be consistent with the *statute* under which they are promulgated." *Decker v. Nw. Envtl. Def. Ctr.*, 568 U.S. 597, 609 (2013) (emphasis added) (citation omitted). Here, the statute sets forth an *actual* knowledge standard, and CMS should abide by that standard instead of the FCA's recklessness/deliberate ignorance standard it is now proposing.

IV. Strengthening Current Medicare Advantage and Medicare Prescription Drug Benefit Program Policies

U. Shortages of Formulary Drug Products During a Plan Year (§ 423.120)

UHG understands CMS's concerns over drug shortages and the potential disruption that it can have on Part D enrollees' current therapies. UHG recognizes the challenges enrollees face when they do not have access to their current medications and must switch to another drug. UHG agrees with

[44] *See* CMS, Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021, at 25 (Jan. 30, 2023).

CMS that enrollees should have coverage for a therapeutically equivalent or interchangeable non-formulary alternatives but recommends that CMS continue to allow plans to have the flexibility to require enrollees meet the formulary exception requirements in certain circumstances.

CMS proposes that Part D plans permit enrollees to obtain coverage for a therapeutically equivalent drug or interchangeable biological product for the duration of the shortage without requiring those enrollees to satisfy formulary exception, prior authorization, or step therapy requirements, as applicable. UHG recommends that CMS allow plans the flexibility to require that enrollees request an exception if the alternative drug/medication is non-formulary (NF) or a prior authorization/step therapy (PA/ST) review if the alternative drug/medication has a utilization management (UM) requirement to ensure appropriate Part D utilization. With this flexibility, plans could verify that the drug continues to be in shortage and the PA team would be able to review and identify the most appropriate alternative course of treatment given an enrollee's specific medical condition. A drug that is in shortage may have multiple indications with different therapeutic alternatives depending on the enrollee's diagnosis. The plan may not always have the complete medical history or record for the enrollee. If a drug recall or shortage is extended to the class level, the selection of alternatives would become even more broad, making it exponentially more complex to manage to ensure continuity of care and adherence to CMS guidance of medically accepted indications. The exception or authorization would then be put in place until the end of the year. Allowing this flexibility would ensure that enrollees receive a review of their adjusted therapy and continuity of treatment throughout the plan year.

UHG has concerns with CMS's proposal to have plans allow pharmacies to utilize the Dispense as Written 8 (DAW8) code to specify that an equivalent brand product is being dispensed due to unavailability of any generic formulary products. Plans do not have the ability to know whether the DAW8 is being used by pharmacies beyond the duration of the generic drug's shortage and would not have any recourse or ability to audit the usage of DAW8 by pharmacies for fraud, waste and abuse.

AA. Part D Proposed Automatic Shipment Requirements (§ 423.505)

UHG supports ensuring consistent and reliable access to Part D drugs for enrollees and supports CMS's proposal to codify its current auto-ship policies. Specifically, UHG supports CMS's proposals for Part D plans to require their network pharmacies that offer auto-ship services to:

- Provide automatic shipments only to Part D enrollees that opt-in, on a drug-by-drug basis, after an initial fill.
- Provide a minimum of two shipping reminders prior to each shipment.
- Refund any cost sharing paid by the Part D enrollee and reverse the claim when the enrollee reports the shipment is not needed or wanted, reverse the claim, and delete the PDE.
- Discontinue auto-ship services when a Part D enrollee requests to opt-out or when notified that a Part D enrollee has entered a skilled nursing facility or elected hospice coverage.

UHG recommends that CMS consider allowing only one shipping reminder by a Part D plan's network pharmacies when an enrollee is receiving an automatic shipment of prescriptions that are for a 30-day supply. UHG believes one successful reminder to an enrollee is sufficient between 30-day supply shipments. UHG also encourages CMS to consider issuing model language for the

shipping reminders that Part D plans can share with their network pharmacies to ensure the notifications that enrollees receive are consistent.

Refund Policy

UHG recommends CMS not finalize the refund policy as proposed. UHG understands CMS's desire to ensure that enrollees are protected from potential cost, safety risks, and the inconvenience of unwanted or unneeded prescriptions being filled. However, given the required shipment reminders, unique enrollee circumstances, and the potential for fraud, waste, and abuse if the enrollee is not required to return the medication, UHG believes that the best way to ensure enrollees are protected from unneeded and/or unwanted shipments is at the network pharmacy level. UHC encourages CMS to allow plan network pharmacies the flexibility to create their own refund policies since they are in the best position to collaborate with the enrollee on the appropriateness and safety of the auto-ship services and to determine the circumstances under which an enrollee is entitled to a cost share refund.

Discontinuation

UHG supports CMS's proposal to require plans to discontinue auto-ship services if an enrollee requests to opt-out and when the network pharmacy receives notification that an enrollee has entered a skilled nursing facility (SNF) or elected hospice. UHG has concerns, though, with using information through data systems, such as the MARx system, to discontinue auto-ship services because it does not provide real-time data. If network pharmacies are required to discontinue auto-ship services based on data that is not real-time, there is potential for disruption of care delivery and coordination. For example, there may be a situation where a network pharmacy receives information through the data system that an enrollee has entered a SNF, but by the time it is received, the enrollee has already left the SNF and returned to accessing care through a community center. In this situation, if the network pharmacy were to discontinue the enrollee's auto-ship, the enrollee may experience a disruption in therapy. Since notification through a data system may not be timely, UHG recommends that CMS only require discontinuation of auto-ship services when notification is received from the enrollee or the enrollee's authorized representative that the enrollee has entered a SNF or elected hospice.

AC. Application of 2-Year Ban on Reentering the Part D Program Following Non-Renewal (§§ 423.507 and 423.508)

UHG understands CMS's intent in promoting stability at the Part D plan (PDP) region level. However, UHG has concerns that prohibiting plans from being able to offer a new PDP contract for two years in a region where the Part D sponsor terminated a contract limits the number of alternative PDP choices that are available to enrollees and decreases enrollees' access to benefits.

UHG supports exempting new Employer Group Waiver Plan PDPs from the two-year ban and encourages CMS to consider other exemptions, such as for any PDPs that are included as part of an acquisition by a Part D sponsor.

AD. Crosswalk Requirements for Prescription Drug Plans (§ 423.530)

Provisions included in the recently passed Inflation Reduction Act (IRA) are substantially changing the Part D program. As a result of IRA-related changes, plans will need to consider the impacts on their formulary design, benefits, and network strategy and what changes they may want to make in order to continue to provide attractive and innovative Part D plan offerings to beneficiaries. Due to the year-to-year variability that will likely occur as a result of the IRA changes going into effect over the next several years, UHG recommends that CMS continue to provide plans with flexibility to make changes and that it not implement its proposed restrictions on existing PDP crosswalk practices. Maintaining the existing crosswalk practices will allow plans to provide beneficiaries with sustainable and affordable plans. UHG also recommends that CMS consider the impact that the IRA-related changes may have on plan premiums and national averages from one year to the next and that it not rely solely on a "current versus projected" comparison of premiums as a criteria for cross walking.

If CMS finalizes its proposed crosswalk changes, UHG strongly recommends that CMS delay the implementation of these requirements until after Calendar Year 2026 to allow plans the ability to assess and amend any required benefit changes.

AH. Gross Covered Prescription Drug Costs (§423.308)

At §423.308, CMS previously defined the term "gross covered prescription drug costs" (GCPDC) to include those costs "actually paid" by the plan, or as CMS further clarified, "costs actually incurred by the plan that are net of direct and indirect remuneration (DIR), including discounts, rebates, or other price concessions typically received and applied after the point of sale." At the time this regulatory definition was finalized, it was specifically related to the calculation of Part D reinsurance amounts. In this proposed rule, CMS notes that the concept of GCPDC is now relevant in another context – IRA changes made to the Social Security Act. Given this new context, CMS proposes to amend the definition of GCPDC by removing the phrase "actually paid." Removing this term "clarifies that GCPDC are not net of all [DIR]." CMS further elaborates that this change will not impact the calculation of Part D reinsurance amounts.

UHG strongly disagrees with this proposed change and recommends the agency not include it in the final rule. While we appreciate the analysis CMS provides on why this change would not impact the calculation of reinsurance payments, the proposed rule fails to provide even a cursory regulatory impact analysis of how this change might impact other dynamics of the Part D program, or implementation of the new drug negotiation program for which CMS says the change is needed. Stakeholders cannot adequately provide feedback on proposed changes if agencies do not outline their rationale and intent in making them or provide an evaluation of the quantitative and qualitative benefits and costs. In this instance, CMS has alluded to the idea that removing the phrase "actually paid" from the definition of GCPDP will impact the implementation of the IRA's drug negotiation provisions, but CMS has not described what policy goal this change is meant to achieve.

As we describe below, we believe this change could have far reaching consequences for the relationship between plans and manufacturers in their negotiations outside of new provisions added by the IRA. If UHG is correct and CMS implements the proposed change it will have violated the Administrative Procedure Act by not adequately apprising "interested parties of the issues to be

addressed in the proposed rule with sufficient clarity and specificity to allow them to participate in the rulemaking in a meaningful and informed manner."[45]

Given the clarification that the removal of "actually paid" means GCPDC are not net of all DIR, we are left to deduce that CMS's intent may be to create its list of drugs eligible for negotiation under the IRA based on gross spending. UHG would strongly disagree with this approach for the reasons below but would need additional information from CMS in order to provide more thorough feedback.[46]

The intent of the IRA's drug negotiation program was for Medicare to negotiate a select number of drugs that had been on the market for a significant amount of time and lacked competition. Implicit in the concept of competition in the prescription drug market is whether pharmacy benefit managers (PBMs) can negotiate rebates off gross price from pharmaceutical manufacturers on behalf of Part D plan clients. If CMS selects drugs based on gross spending, rather than net, it could capture products for which PBMs already negotiate significant savings – even if those products lack generic or biosimilar competition.

Based on an OptumRx analysis of the CMS Part D Dashboard and estimated national rebates based on OptumRx's understanding of the market, we created an illustrative model to show how drug selection changes if the list of negotiation-eligible products is made based on gross or net prices. When using gross prices, five products are selected whose net prices today are lower than the statutory ceiling prices established by the IRA (compared to three when using net prices). This dynamic represents an additional $800 million in savings in the first year alone that CMS could generate by constructing the list of negotiation-eligible products based on net prices (assuming that every product's negotiated price is the statutory maximum). Constructing the list based on gross prices would make it very difficult for CMS to negotiate a Maximum Fair Price that is lower than the net price PBMs already have. In this way, the IRA's drug negotiation program would simply replace PBMs' private market competition with government negotiation – but without correcting the market failure the IRA was envisioned to address.

V. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System

UHG supports efforts to ensure all people receive equitable, high quality and value-based care and believes progress can be made on those goals through the Star Ratings Program. However, the Quality Rating System proposals, in aggregate, would ultimately have a negative impact on beneficiaries' access to care and benefits, and may unravel and delay advances in health equity such as transportation benefits or utilities support for those with SDOH barriers. UHG believes its recommendations will help CMS more effectively improve quality and advance health equity by

[45] *Am.Md. Ass'n v. United States,* 887 F.2d 760, 767 (7th Circ. 1989).

[46] In addition to implications around how the IRA's drug negotiation program would be implemented, this change could also impact other parts of the Part D program not discussed in the proposed rule and result in CMS violating the Non-Interference Clause and conflicting with Congress' ratification of the definition of GCPDC when it enacted the IRA.

preventing the unraveling of recent and proposed advancements in health equity, continuing integration and alignment of quality into the care journey, accelerating innovation in care and beneficiary benefits and mitigating changes that may adversely affect beneficiary safety. UHG highlights five of its recommendations below:

- UHG opposes CMS's proposed changes to the Improvement Hold Harmless Provision.
- UHG supports the addition of the Health Equity Index (HEI) but recommends CMS phase in the replacement of the Reward Factor with the HEI, keeping both the reward factor and HEI until the 2029 Star Ratings, to allow time for the HEI to be further refined and improved.
- UHG supports the expansion of the age range for the Part C Star Rating colorectal cancer screening measure to include 45- to 49-year-old beneficiaries.
- UHG does not support risk-adjusting the Part D medication adherence measures for sociodemographic status (SDS).
- UHG also does not support the addition of Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (POLY-ACH), Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults (POLY-CNS) and Concurrent Use of Opioids and Benzodiazepines (COB) measures to the Star Ratings as currently defined.

D. Adding, Updating, and Removing Measures (§§ 422.164 and 423.184)

Kidney Disease Monitoring

UHG supports the removal of Diabetes Care – Kidney Disease Monitoring and Medication Reconciliation Post-Discharge and the additions of Care for Older Adults – Functional Status Assessment and Kidney Health Evaluation for Patients with Diabetes, which aligns with the National Kidney Foundation recommendations.

We request clarification from CMS that it will include both the stand-alone Medication Reconciliation Post-Discharge and the composite Transitions of Care measure (which includes the Medication Reconciliation Post-Discharge measure) in the 2024 and 2025 Star Ratings program.

Colorectal Cancer Screening

UHG supports the expansion of the age range for Colorectal Cancer Screening to include 45- to 49-year-old beneficiaries. We recognize the importance of promoting these screenings for this age group and believe MA plans should cover them in alignment with recommendations set forth by the U.S. Preventive Services Task Force (USPSTF) and subsequently adopted by NCQA. The USPSTF recommended screening adults ages 45 and older who had no signs or symptoms of colorectal cancer and were at average risk for colorectal cancer. Beyond colonoscopy, certain colorectal cancer screening tests were part of that recommendation. At the time of the age range adjustment, the CMS NCD 210.3 Colorectal Cancer Screening Tests did not yet reflect this adjustment, causing confusion for providers regarding what would or would not be covered. In the future, we propose that CMS adjust or publish traditional CMS coverage criteria consistent with the timing for applying new or updated quality standards to MA plans.

Part D Measures – Polypharmacy and Concurrent Use of Opioids and Benzodiazepines

UHG does not support the proposed additions of Concurrent Use of Opioids and Benzodiazepines (COB), Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH), and Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults (Poly-CNS) in their current forms because they do not distinguish between inappropriate and appropriate polypharmacy. The premise of these measures appears to be that concurrent overlapping therapy for 30 or more days of two or more anticholinergic medications, three or more CNS medications, or the combination of opioids and benzodiazepines is always inappropriate. However, for measures to be truly effective and not cause undue harm to patients, CMS needs to make a distinction between inappropriate polypharmacy (the use of unnecessary or excessive medication) and appropriate polypharmacy with the clinical goal of managing multiple comorbid conditions in the same patient.[47]

The current definitions of these measures make no allowances for:

- Beneficiaries with clinical chronic conditions who require this combination of medications because they are medically necessary. For example, a beneficiary with schizophrenia will likely need to be on an antipsychotic (on the Poly-CNS and Poly-ACH drug list), a mood stabilizer like divalproex (on the Poly-CNS drug list) or an antidepressant (on the Poly-CNS and Poly-ACH list), and if they also have other comorbid conditions like overactive bladder they may need to be on an antimuscarinic (Poly-ACH drug), all of which may be clinically appropriate.
- Beneficiaries who have been clinically stable on combinations of medications long-term who cannot be appropriately deprescribed therapy within the 30-day overlap period that places beneficiaries in the numerator.
- Dosage reductions while not discontinuing medications completely.
- Prescriptions written and filled for at least 30 days even though the beneficiary may not necessarily be taking the medication or was asked to keep it on hand if needed.
- The fact that most of the medications listed within the drug lists for the Poly-ACH, Poly-CNS, and the COB measure have no good therapeutic alternatives and would result in indexing a beneficiary into the numerator for at least one of these measures (e.g., a Medicare beneficiary on a benzodiazepine for anxiety may get switched over to a SSRI which is also considered inappropriate for a 65 year old plus patient and is on the Poly-ACH and Poly-CNS drug list).
- Common medications used to treat behavioral health conditions such as anxiety, depression, or psychosis are listed on both the Poly-CNS and Poly-ACH medication list. The somewhat duplicative measures will place beneficiaries at risk of not having access to common behavioral health therapies that are medically indicated.

UHG agrees inappropriate polypharmacy is a clinical concern and must be addressed to keep Medicare beneficiaries safe. However, UHG predicts if the measures are implemented in their current state, they will lead to beneficiaries being at risk of not having access to medically appropriate therapies where therapeutic necessity is documented and monitored against each diagnosis. As such, UHG recommends CMS:

[47] Hughes, Carmel. "Appropriate and Inappropriate Polypharmacy—Choosing the Right Strategy." *British Journal of Clinical Pharmacology*, 9 Nov. 2020, 10.1111/bcp.14589. Accessed 4 Dec. 2020.

- Work with the Pharmacy Quality Alliance (PQA), the measure steward, to look for more effective ways of measuring inappropriate polypharmacy and make a distinction between appropriate and inappropriate use. UHG recommends that CMS and PQA consider having these measures apply only to the disease states where the highest risk of adverse events has been documented with this combination of therapies. For instance, there are known risks and limited benefits for enrollees with Alzheimer's Disease and dementia to being on three or more CNS active medications and a combination of opioids and benzodiazepines.[48] The National Institute of Aging (NIA) has developed a Deprescribing Research Network whose goal is use deprescribing to improve the quality of care in older adults. PQA could work with the NIA to understand what measures would be impactful to ensure the measures are not causing undue harm to beneficiaries.
- Extend the concurrent overlap days to at least 120 days (or more) to ensure that health plans and prescribers can work with beneficiaries and caregivers to come up with realistic plans around deprescribing, dosage reduction, and tapering therapy and that only beneficiaries who are on the concurrent medications long-term are included in the numerator of the measure.[49] [50] [51]
- Should CMS finalize inclusion of the poly-pharmacy measures, we recommend including only one of them in the Star Ratings program due to the overlap of the drug list across multiple measures as well to minimize potential undue harm.

Part D – Medication Adherence

Risk Adjustment for Sociodemographic Status

UHG does not support CMS's proposal to implement risk adjustment based on sociodemographic status (SDS) to the Part D medication adherence measures. There should be one set of medication adherence standards by which plans are measured; risk adjusting for SDS will effectively create multiple standards. Risk adjustment based on SDS also adds further complexity to an increasingly complex Star Ratings program without sufficient increased benefit to quality measurement. CMS even acknowledges this increased complexity. CMS says it intends to incorporate the SDS risk adjustment to the medication adherence measures reported by CMS to Part D sponsors only in the last monthly patient safety report for the measurement year because of the time commitment involved with implementing the SDS risk adjustment to the patient safety reports.

CMS should not finalize this proposal, or any of the changes to the pharmacy adherence measures, before making available additional information on the proposed methodology and allowing plans to provide comments, including: (1) whether it would be an enrollee-level adjustment to the Percent Days Covered calculation or a plan-rate adjustment at the measure level; (2) the calculated changes to the Categorical Adjustment Index (CAI); (3) updated patient safety-reports that incorporate each of the changes; and (4) relevant coefficients consistent with the information CMS provides for the CAHPS case-mix adjustment each year.

[48] The dangers of polypharmacy and the case for deprescribing in older adults | National Institute on Aging (nih.gov).
[49] Clinical Review: Recommendations for the Tapering of Benzodiazepines (uhcprovider.com).
[50] Going Off Antidepressants - Harvard Health Publishing - Harvard Health.
[51] A Method for Tapering Antipsychotic Treatment That May Minimize the Risk of Relapse - PMC (nih.gov).

Inpatient and Skilled Nursing Facility Adjustments

UHG does not support removing the existing adjustments for inpatient (IP) and skilled nursing facility (SNF) stays. CMS began the IP stays adjustment in 2011 and expanded that adjustment to SNF stays in 2013 to account for the time the Part D plan was not responsible for prescription drug coverage. Because skilled stays are covered under Part A, there would be no Part D claim, and without the adjustments the beneficiary would inaccurately be counted as non-adherent even if the beneficiary was adhering to the medication. CMS claims that the IP/SNF stay adjustment has a "very minimal" impact to the distribution of measure rates, but this does not consider the disparate impact on certain populations such as beneficiaries in ISNPs. Prior to finalizing this proposal, UHG requests CMS make available additional information supporting its claim that this will have minimal impact.

In addition to SDS risk adjustment and the proposed removal of the adjustment for IP and SNF stays, CMS also proposed a change from member-years adjustment to continuous enrollment for the medication adherence measures. CMS also contends that the above changes will be finalized independently of one another, but UHG disagrees with that position. In order to better evaluate their impact, CMS should provide plans with the information and data discussed above and provide additional time for plans to provide feedback on the proposed changes.

E. Measure Weights (§§ 422.166(e) and 423.186(e))

UHG supports reducing the Patient Experience/Complaints and Access measures weight to two beginning with the 2026 Star Ratings. UHG agrees with CMS that the weight reduction appropriately accounts for the value this measure category contributes to achieving high quality care and better aligns the total contribution of patient experience and outcome measures within the Star Ratings program.

UHG supports adding a question to the CAHPS survey related to whether enrollees' personal doctors dismiss symptoms that are important to them but does not support adding this as a measure to the display page, as it is a measurement of providers rather than plans.

F. Guardrails (§§ 422.166(a)(2)(i) and 423.186(a)(2)(i))

UHG supports the retirement of guardrails in the 2026 Star Ratings. However, during the transition to outlier removal in the 2024 Star Ratings, guardrails should be applied to the 2024 cut points from the actual 2023 cut points with mean resampling and not the adjusted outlier removal cut points. As stated by CMS, the outlier removal methodology is meant to stabilize cut points; however, applying the guardrails from adjusted outlier removal cut points can have undue and substantial movement while removing consistency year over year counter to the intention of creating stability. We propose that guardrails should be used to ease the transition to outlier removal cut points.

G. Health Equity Index Reward (§§ 422.166(f)(3) and 423.186(f)(3))

UHG supports the addition of the Health Equity Index Reward to the Star Ratings program but has several recommendations to further strengthen the calculation as well as reward MA plans for high

and improved performance for beneficiaries with social risk factors (SRFs) while minimizing unintended consequences of changing existing framework.

To strengthen the impact of the HEI goals, UHG recommends the following changes:

1. Include both the HEI and Reward Factor through SY29

UHG requests that CMS phase in the replacement of the Reward Factor with the HEI, keeping both the reward factor and HEI until the 2029 Star Ratings, to allow time for the HEI to be refined and improved. If the reward factor were removed and HEI were in place today, millions of beneficiaries could be negatively impacted since their plans would not qualify for HEI and likely have limited ability to provide tailored benefits (for example, transportation or utility benefits) for individuals with SRFs. A phased approach would give plans time to enroll beneficiaries with SRFs. This could be particularly challenging for plans in states that require or request that MA parent organizations have state specific contracts for DSNP products and the corresponding phase out of DSNP look-alike plans. It also allows for reporting of HEI scores and measure thresholds for a couple of years prior to implementation, giving baselines for goal setting and allowing for a more stable environment as the HEI Reward evolves and ideally aligns with other quality organizations such as NCQA on health equity strategies such as Health Equity Accreditation and Health Equity Accreditation Plus. Aligned goals, populations, and strategies would enable providers and plans to advance health equity at greater scale and more efficiently.

2. Add an improvement and/or disparity measurement to the HEI to effectively incentivize quality improvement for individuals with SRF and improve health equity.

The HEI looks within group differences, which is an important metric to consider when trying to improve quality for enrollees with SRFs. This effectively compares members with SRFs amongst themselves as opposed to incentivizing improvement of health outcomes of members with SRFs compared to members without SRFs or general improvement across measures. UHG wants to improve health outcomes of these members holistically and recommends the HEI incentivize overall improvement relative to members without SRFs and general improvement overall. The HEI as proposed does not explicitly reward plans for disparity reduction between enrollees with SRFs and enrollees without SRFs, nor does it reward improvement for enrollees with SRFs. These are especially important given the HEI looks at just two SRFs and does not consider intersecting and overlapping SRFs. Without the ability to capture improvement or disparity reduction, similar to the Medicare Health Equity Summary Score (HESS) from the CMS Office of Minority Health, plans servicing the most underserved populations may be disadvantaged. As such, UHG recommends that contract measures be scored on within-group scores, based on reduction of disparity between members with SRFs and without, and general improvement for members with SRF. The contract measure would receive the highest of the three to allow three paths toward a positive HEI.

We acknowledge this would alter the HEI scores from current modeling. However, CMS stated that in simulations on removing the Reward Factor and replacing it with the HEI, just seven contracts, or 1.7% gained one-half star on the overall rating and 54% of contracts lost one-half star. With these changes, the HEI could be a powerful replacement for the Reward Factor and incent plans for both

absolute performance on enrollees with SRFs, but also encourage plans for both disparity reduction and continuous improvement to improve quality scores for the most underserved enrollees.

3. Provide additional details around calculation

UHG appreciates the details CMS provided about the HEI, but the proposed rule did not provide all the requisite information to allow MA plans to perform a complete evaluation of the HEI and the expected impacts. Specifically, UHG requests CMS provide responses to the following questions:

- What are the expected measure level performance thresholds for each of the thirds at a measure level?
- Given CMS is combining multiple years of data, how does CMS intend to calculate and apply the trend for multiple years of data?
- How will measure reliability be calculated?
- If a contract does not meet the minimum share of enrollees with SRFs, will that contract's score be included in the measure level thirds calculation?

H. Improvement Measure Hold Harmless (§§ 422.166(g)(1) and 423.186(g)(1))

UHG recommends CMS not finalize the proposed change to the Improvement Hold Harmless provision. This change would have a disproportionately negative impact on the Star Ratings of plans with beneficiaries who have SRFs. Indeed, it would dwarf any positive impacts of the Health Equity Index reward and Categorical Adjustment Index combined, undoing much of the progress the Star Ratings system has made to appropriately incentivize quality health care for members with SRFs and advance health equity. For example, had it been implemented in the 2023 Star Ratings, the improvement measure hold harmless proposal would have prevented DSNPs across the industry serving 766,000 beneficiaries (17 percent of MA DSNP membership) from reaching four stars. If this change is made, MA plans may not be able to provide critical supplemental benefits designed specifically to address Social Determinants of Health such as food, over-the-counter medications, transportation and utility support.

The proposed change would also penalize contracts that provide high quality care and experience to their enrollees year over year. The improvement measure as it exists today includes situations in which it is mathematically impossible to achieve the statistically significant improvement level due to a contract's high performance on measures. For example, a perfect Call Center measure score two years in a row would result in an adverse measure improvement score ("no significant change"), penalizing high performance plans for perfect performance. It is true that a 4-star contract may have measures in which there is room for improvement, however, it may also have others at 5 stars. While there is an existing measure level hold harmless if the measure is at 5 stars each year, this is characterized by a 0 rather than a 1 in the technical calculation. The existing hold harmless provision for 4 stars plan allows these high performing contracts to be measured without artificially low improvement measures that are not measuring what they were intended to.

While we oppose CMS's proposed changes to the improvement measure hold harmless, we recommend the following changes to the extent CMS moves forward with them:

- If a measure receives 5 stars in two consecutive years, CMS should score them as statistically significant improvement to acknowledge ceilings on measure performance.
- Reduce the weighting of the Improvement Measures back to 3 or combine the Part C and Part D improvement measures into a single measure (similar to the duplicated measures Complaints about the Health/Drug Plan and Enrollees Choosing to Leave the Plan) to balance overall improvement incentives with general performance for a program that has driven quality improvements and innovative benefits to a diverse population and specifically those with social determinants of health (SDOH) and SRF challenges.
- Raise the Hold Harmless threshold, but only to 4.5 instead of 5.
- Phase in the change, raising the threshold to 4.5 for two years before increasing to 5.

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PUBLIC SUBMISSION

Docket: CMS-2022-0191
Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024

Comment On: CMS-2022-0191-0001
Medicare Program: Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, etc.

Document: CMS-2022-0191-0658
Comment on CMS-2022-0191-0001

Submitter Information

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Organization: CVS Health

General Comment

See attached file(s)

Attachments

CVSH 2024 MA and Part D Comment Letter 2.13.23 FINAL

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Submitted electronically via www.regulations.gov

February 13, 2023

The Honorable Xavier Becerra
Secretary, Department of Health and Human Services

Chiquita Brooks-LaSure
Administrator, Centers for Medicare & Medicaid Services

U.S. Department of Health and Human Services
Attention: CMS-4201-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program and Medicare Prescription Drug Benefit Program (CMS-4201-P)

Dear Secretary Becerra and Administrator Brooks-LaSure:

CVS Health appreciates the opportunity to respond to the Medicare Advantage (MA) program and Medicare Prescription Drug Benefit (Part D) proposed rule,[1] published in the Federal Register on December 27, 2022.

CVS Health serves millions of people through our local presence, digital channels, and our nearly 300,000 dedicated colleagues – including more than 40,000 physicians, pharmacists, nurses and nurse practitioners. Our unique health care model gives us an unparalleled perspective on how systems can be better designed to help consumers navigate the health care system – and their personal health care – by improving access, lowering costs, and being a trusted partner for every meaningful moment of health. And we do it all with heart, each and every day.

We appreciate CMS' efforts to enhance beneficiaries' experience with MA and Part D. For years, Medicare Advantage Organizations (MAOs) and Part D Plan Sponsors (PDPs) have been leading the way in combining population-level health management with person-centered care coordination, reduced cost-sharing, and supplemental benefits and innovative programs to address medical and social risk factors and gaps in care.

[1] CMS, Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications, 87 Fed. Reg. 79452 (Dec. 27, 2022).

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MA, PDP and MA-PD plans have, and will continue to offer high-value options to the Medicare population by[2]:

- **Providing affordable coverage to beneficiaries**
  - 98% of MA beneficiaries have access to at least one $0 premium MA plan with prescription drug coverage[3]
  - On average, MA beneficiaries report spending $1,965 less in out-of-pocket costs than those in Traditional Medicare[4]
  - MA beneficiaries receive cost protections not available in Traditional Medicare such as a $7,550 maximum out-of-pocket limit in 2022[5]
  - Beneficiaries in MA-Part D plans have experienced 15% lower combined medical and prescription drug costs compared to Traditional Medicare beneficiaries[6]

- **Offering benefits that support person-centered care[7]**
  - 99.9% of MA plans offer at least one supplemental benefit at no extra cost to the beneficiary
  - Over 90% of MA plans offer vision, hearing, dental, or fitness/wellness benefits, with most plans now offering all four benefits

[2] Seshamani M., Fowler E., Brooks La-Sure, C. "Building On The CMS Strategic Vision: Working Together For A Stronger Medicare", Health Affairs Forefront, January 11, 2022. DOI: 10.1377/forefront.20220110.198444.

[3] 2022 State of Medicare Advantage Report. Better Medicare Alliance. Jul 2022. https://bettermedicarealliance.org/wp-content/uploads/2022/07/BMA-State-of-MA-2022-FIN.pdf.

[4] Medicare Advantage Outperforms Traditional Medicare on Cost Protections for Low- and Modest-Income Populations. ATI Advisory. Apr 2022. https://bettermedicarealliance.org/wp-content/uploads/2022/04/BMA-Medicare-Advantage-Cost-Protections-Data-Brief_FINv2.pdf.

[5] Freed, M., Biniek, J.F., Damico, A., Neuman, T. Medicare Advantage in 2022: Premiums, Out-of-Pocket Limits, Cost Sharing, Supplemental Benefits, Prior Authorization, Star Ratings. Kaiser Family Foundation. Aug 25 2022. https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-premiums-out-of-pocket-limits-cost-sharing-supplemental-benefits-prior-authorization-and-star-ratings/.

[6] Positive Outcomes for High-Need, High-Cost Beneficiaries in Medicare Advantage Compared to Traditional Fee-For-Service Medicare. Avalere Health. Dec 2020. https://bettermedicarealliance.org/wp-content/uploads/2020/12/BMA-High-Need-Report.pdf.

[7] 2022 State of Medicare Advantage Report. Better Medicare Alliance. Jul 2022. https://bettermedicarealliance.org/wp-content/uploads/2022/07/BMA-State-of-MA-2022-FIN.pdf.

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- The number of MA plans offering expanded benefits such as access to meal and nutrition benefits, transportation, caregiver support, and telehealth grew by 43% in 2022.[8]

- **Driving high-quality outcomes and satisfaction**
  - Based on encounter and claims data from 2015 to 2017, when compared to Traditional Medicare beneficiaries, MA beneficiaries experienced:[9]
    - 43% lower rate of potentially avoidable hospitalizations
    - 57% lower rate of avoidable hospitalizations for acute conditions for beneficiaries with major complex chronic conditions
    - 41% higher utilization of primary care services and outpatient follow-up care for beneficiaries with major complex chronic conditions
  - In 2022, 90% of MA beneficiaries were enrolled in a 4 Star or above plan and nearly 27% were enrolled in a 5 Star plan[10]
  - In a 2022 survey of 2,800 MA enrollees, 88% stated that they were satisfied with their coverage, with 63% stating they were "very satisfied"[11]

- **Advancing access to care for minority and high-need populations[12]**
  - 99.7% of Medicare beneficiaries now have access to at least one MA plan
  - 33.7% of MA beneficiaries identify as racial and ethnic minorities compared to 16% of Traditional Medicare beneficiaries
  - 52.7% of MA beneficiaries live below 200% of the federal poverty level compared to 38.3% of Traditional Medicare beneficiaries
  - 30.3% of End-Stage Renal Disease beneficiaries are now enrolled in an MA plan

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[8] Murphy-Barron, C., Buzby, E. Review of Contract Year Medicare Advantage supplemental healthcare benefit offerings. Milliman. Last accessed Aug 30 2022. https://bettermedicarealliance.org/wp-content/uploads/2021/11/Milliman-Issue-Brief-CY-2022-MA-Supplemental-Benefits_20211115112.pdf.

[9] Positive Outcomes for High-Need, High-Cost Beneficiaries in Medicare Advantage Compared to Traditional Fee-For-Service Medicare. Avalere Health. Dec 2020. https://bettermedicarealliance.org/wp-content/uploads/2020/12/BMA-High-Need-Report.pdf.

[10] 2022 State of Medicare Advantage Report. Better Medicare Alliance. Jul 2022. https://bettermedicarealliance.org/wp-content/uploads/2022/07/BMA-State-of-MA-2022-FIN.pdf.

[11] Spotlight on Medicare Advantage: An eHealth Survey. eHealth. Jun 2022. https://news.ehealthinsurance.com/_ir/68/20225/Spotlight_On_Medicare_Advantage_eHealth_Survey_June2022.pdf.

[12] 2022 State of Medicare Advantage Report. Better Medicare Alliance. Jul 2022. https://bettermedicarealliance.org/wp-content/uploads/2022/07/BMA-State-of-MA-2022-FIN.pdf.

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In 2022, more than 28 million beneficiaries (48% of the eligible Medicare population) were enrolled in an MA plan and it is anticipated that enrollment will increase as more seniors recognize the value of MA.[13] The 2022 Medicare Trustees Report projects that half of all Medicare-eligible beneficiaries will be enrolled in MA by 2026, with MA beneficiaries making up over 52% of the total Medicare population by 2030.[14] As more individuals choose MA, PDP, and MA-PD plans we believe that it is of the utmost importance that CMS promote stable payment and policies that allow plans to provide consistent value and high-quality benefits to the growing Medicare population.

In this Proposed Rule, CMS proposes several significant changes to advance health equity, address concerns with prior authorization, and eliminate deceptive marketing practices. We support the goals of many of these proposals, including:

- **Star Ratings:** Reducing the weight of patient experience/complaints and access measures from 4 to 2 to place greater emphasis on clinical outcome measures and better align with the weighting used under other CMS quality reporting programs. We recommend that CMS implement this policy for 2025 Star Ratings.
- **Health Equity:** Requiring that MAOs ensure that services are provided in a culturally competent manner to all enrollees and have a quality improvement program in place to reduce health disparities.
- **Marketing:** Requiring MAOs to have an oversight plan in place for reporting non-compliant sales agent activity to CMS and prohibiting unsolicited contact not initiated by a potential enrollee, including unscheduled door-to-door interactions.
- **Behavioral Health:** Allowing new behavioral health specialty types (Clinical Psychologists, Licensed Clinical Social Workers, and Prescribers of Medication for Opioid Use Disorder) to be eligible for the 10-percentage point telehealth credit in meeting network adequacy requirements, especially in light of ongoing workforce shortages.
- **Part D:** Expanding PDP flexibility to include interchangeable biologics, unbranded biological products and authorized generics to an approved formulary to provide beneficiaries with access to a new lower cost alternative as soon as possible.

However, when taking all proposals under this rule into consideration for the 2024 plan year, we are concerned CMS has not provided sufficient implementation time to plans. Throughout our comments, we describe how CMS' proposals, if finalized as proposed, will have an impact on current processes to help CMS better understand the cost and staffing impact to plans. With any change in CMS policy, CVS Health is committed to ensuring that we have the right staffing, expertise, processes, and infrastructure to support full

[13] Freed, M., Biniek, J. F., Damico, A., Neuman, T. Medicare Advantage in 2022: Enrollment Update and Key Trends. Kaiser Family Foundation. Aug 25 2022. https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-enrollment-update-and-key-trends/.

[14] 2022 Annual Report of the Boards of Trustees to the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. See https://www.cms.gov/files/document/2022-medicare-trustees-report.pdf.

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compliance with CMS' requirements while maintaining a positive experience for our beneficiaries.

We are also concerned that CMS has not adequately considered the associated costs of implementing all policies. In the Regulatory Impact Analysis of this Proposed Rule, CMS acknowledges that there are proposals where the agency is unable to fully quantify the impact.

All Medicare and Medicaid plans must have actuarially sound rates. It takes time to understand new requirements and incorporate them into our plan design, so they can be adequately accounted for in our bids. Given all that CMS' is putting forward in this proposed rule, we urge CMS to carefully reconsider the magnitude of some of the changes it is proposing and to consider delaying or modifying certain proposals to support effective plan implementation. **Based on CMS' own analysis, the year-to-year expected average change in revenue between the 2023 Final Rate Notice and the proposed 2024 Advance Notice is a swing of -7.27% (last year CMS increased MA payments by 5% from 2022 to 2023, and now for 2024 CMS is cutting MA payment by -2.27% relative to 2023).** [15]

Aside from the costs of implementation, CVS Health is concerned that several proposals have the potential to disrupt plan stability and negatively impact the beneficiary experience without further clarification or reconsideration by CMS. Our most significant concerns focus on the following areas:

- **Star Ratings:** Modifying the hold harmless policy for the Health Plan Quality Improvement and Drug Plan Quality Improvement measures to apply only to 5-Star plans would effectively penalize contracts with 4 and 4.5 Stars when CMS considers 4 Stars to be reflective of Above Average performance. We are also concerned that the proposed removal of guardrails when determining measure-specific-thresholds for non-Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures will increase volatility in the Star Ratings program when more stability is needed. We believe that further improvements can be made to the Star Ratings program to better incentivize improvements in the clinical care of all beneficiaries, reduce volatility, and better capture the patient experience.
- **Prior Authorization/Utilization Management:** We are concerned that without additional clarification and implementation time, these proposals have the potential to negatively impact MAO's ability to ensure that beneficiaries receive safe, effective, high-value care. While we recognize CMS' intention of ensuring that MA beneficiaries have access to Medicare basic benefits, we request that the agency consider the challenges of these policies if finalized as proposed.
- **Revision of the "Gross Covered Prescription Drug Costs" Definition:** By revising the definition to exclude all direct and indirect remuneration, including manufacturer rebates received after point-of-sale, the proposed definition will disincentivize

[15] Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. https://www.cms.gov/files/document/2024-advance-notice.pdf.

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manufacturers from providing such rebates, which will have a major negative impact on the Part D program and government costs.

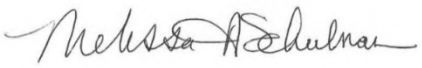
- **Medication Therapy Management (MTM) Program:** CMS should not move ahead with expansion of the MTM program in Part D as evidence supporting its effectiveness is currently limited. We support the goals of reducing medication errors, optimizing therapeutic outcomes and promoting consistent and equitable access to MTM services and offer CMS several suggestions on how to consider future expansion of an evidence-based program.
- **Marketing:** While we strongly support the intent of the marketing proposals and CMS oversight over deceptive marketing practices by plans, agents, and brokers, we are concerned that codifying waiting time standards and new requirements for advertising without further clarification or flexibility from CMS may have the unintended effect of creating a negative beneficiary experience.

As CMS considers comments to this Proposed Rule, we recommend that the agency continue working with MAOs, PDPs, and other stakeholders to further understand the impact of these changes and to focus on those policies that will definitively strengthen the MA and Part D programs for the millions of beneficiaries they serve.

A more detailed discussion of our recommendations is provided in the attached Appendix. Where additional subregulatory guidance is needed, we encourage CMS to announce formally in the Final Rule that it will use enforcement discretion as the agency develops further guidance and plans work toward these proposals.

Thank you for considering our recommendations and comments. CVS Health is committed to working with CMS as it formulates rules and policies that advance affordable, cost-effective care that provides beneficiaries with innovative choices of coverage that meets consumer needs. We welcome any follow-up questions you may have.

Sincerely,



Melissa Schulman
Senior Vice President, Government & Public Affairs
CVS Health

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Appendix

Specific Comments on Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications Proposed Rule

I. Medication Therapy Management (MTM) Program (§ 423.153)

CMS is proposing changes to the MTM program targeting criteria to expand access to MTM services and to promote consistent and equitable access. These changes include requiring plan sponsors to target all core chronic diseases identified by CMS, lowering the maximum number of covered Part D drugs that may be required from 8 to 5 drugs and requiring that all Part D maintenance drugs be included in a sponsor's targeting criteria and lowering the cost threshold to be commensurate with the average annual cost of 5 generic drugs. CMS states that these changes would result in more Part D enrollees becoming eligible for MTM services and would also better align MTM eligibility criteria with statutory goals to reduce medication errors and optimize therapeutic outcomes for beneficiaries with multiple chronic conditions and taking multiple Part D drugs, while maintaining a reasonable cost criterion.

CVS Health supports CMS goals of reducing medication errors, optimizing therapeutic outcomes and promoting consistent and equitable access to MTM services. However, we have significant concerns that the proposed changes will not achieve these goals, but will instead simply vastly expand the program, dramatically increasing enrollment and cost with little or no proven benefit to members. CMS estimates that enrollment will more than double from 9% to 23% of Part D members. However, based on our initial analysis, Aetna's MA-PD plan MTM targeting will increase approximately tenfold, and across our PBM book of business the increase varies dramatically from between 15 to 60%, depending on the member population and type of plan. The increased costs would similarly be greater by orders of magnitude compared to CMS's estimate. For example, our preliminary estimate of the increased cost of targeting alone would be enormous—nearly $50 million for Aetna's MAPD plan population alone. This does not include the increased medication reviews, reports and other MTM services that would have to be similarly increased exponentially. Extrapolating this cost across the entire Part D population would easily dwarf CMS' cost estimate of a $336 million.

In simulating a subset of Medicare MAPD plans, we found the *average* qualification rate under the proposed NPRM targeting criteria was 25%; however, additional analysis at a contract level yielded a significant variation in the qualification rate with a range between 16% to 57%. Influencing these rates was the plan type, with DSNPs qualifying greater than 45% of their membership. The administrative cost will likely be unevenly spread and highly variable based on beneficiary demographic information.

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As noted above, the uneven distribution based on plan type unfairly burdens those plans with higher qualification rates and therefore increased administrative costs. The significant increase in the cost of providing MTM may result in increase in premiums.

We also believe CMS underestimates the time for a pharmacist or other qualified health care professional to complete the Comprehensive Medication Review (CMR). While the average CMR conversation with the enrollee may take 20-40 minutes, the pharmacist or other healthcare professional spends additional time reviewing the case before the conversation with the enrollee and preparing the post CMR materials. A better estimate of the time involved, and thus the cost, is 60 minutes per CMR conducted.

While some increase in cost may be justified based on evidence that increased enrollment will result in improved outcomes, CMS provides no such evidence. Even today at current enrollment levels, there has been little to no evidence that MTM programs are effective in reducing medication errors and improving health outcomes. While CMS postulates that published studies indicate that MTM services "may generate overall medical savings, for example, through reduced adverse outcomes including reduced hospitalizations and readmissions, outpatient encounters, or nursing home admissions," it goes on to acknowledge that it is, "unable to generate reliable savings estimates from the published studies due to limitations in potential study design, including the lack of a control group and numerous intervening variables."

Instead of simply ramping up enrollment in a program that is yet to demonstrate its effectiveness, a better approach would be to revisit the current MTM program to make changes that better integrate with the medical benefit, such as allowing direct reimbursement to pharmacists involved in the member's medical care team for their cognitive clinical services. While some changes may require the help of Congress, a retooling of the MTM program along these lines is more likely to achieve the end-goal of substantial, longitudinal medication management and improved outcomes than simply expanding the MTM program alone. The only sure outcome of the proposed changes will be to increase Part D program costs and premiums drastically at a time when these are already expected to increase due to finalization of the CMS rule on pharmacy price concessions and changes due to the Inflation Reduction Act of 2022.

MTM qualification criteria are designed to identify patients who would derive the greatest benefit from a CMR and ongoing Targeted Medication Reviews (TMRs). Targeting criteria currently allows plans the flexibility to tailor their chronic conditions to meet the needs of their population and those beneficiaries with complicated medication regimens and the most expensive drug therapies.

We agree with standardizing qualification criteria across all plans by removing a plan's ability to only target specific conditions; however, we caution against overly broad criteria that captures beneficiaries who are not likely to benefit from services. Codifying the current nine chronic conditions and adding HIV/AIDS would prevent plans from unfairly manipulating their targeting criteria for the purpose of decreasing their Star measure

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denominator. Within the required conditions, we would recommend allowing plans the flexibility to select one condition each under the Mental Health, Lung Conditions, and Bone Disease categories to continue tailoring to the needs of their populations.

We do not recommend adding Cancer as a chronic condition. This category does not lend itself to meaningful clinical interventions by an MTM provider. Beneficiaries under the current qualification criteria who are subsequently taking oncology drug(s) would still benefit from the MTM consultation as a review for side effects, safety, and potential drug-drug interactions.

We do not recommend decreasing the maintenance medications from 8 to 5 because beneficiaries who participate in the MTM program should be those with higher pill burden and complicated medication regimens.

We do not recommend decreasing the cost threshold to align with annual generic medication costs because that would target beneficiaries who would not benefit from a CMR consultation regarding cost savings opportunities.

Finally, if CMS does move ahead with its proposed changes to the MTM program, changes of this magnitude would constitute a substantial change to the MTM Star measure, including changing the targeted population and measurement. Historically, when significant changes have been made to other Star measures, these measures have moved to the Display Measure page for two (2) years.

Because the proposed changes impact all aspects of the targeting algorithm, it will be difficult to assess the impact of this targeting on the number of CMRs the plans will be able to complete. The expanded enrollment will include types of enrollees not previously targeted and for whom plans do not have the experience to understand how and if this new population of beneficiaries will engage in a CMR.

Increasing qualification will result in plans needing more total CMRs to achieve a 4- or 5-Star rating. Combined with the potential increased cost, increasing the number of enrollees targeted will have an impact on the percent of CMRs completed. In the proposed rule section on MTM costs, CMS notes that it expects 36.5% of enrollees to decline a CMR. This expectation is not consistent with the CMR completion rates for the 4 and 5 star cut points.

Recommendations:

- **CMS should not move ahead with expansion of the MTM program unless and until there is evidence supporting its effectiveness in achieving its intended goals, in which case any expansion should be more measured, particularly in light of the wide variation in potential impact**
- **If CMS moves forward with some or all of the proposed targeting changes, move CMR completion to a Display Measure for 2 years due to the significant change in targeting and thus impact on CMR completion rates**

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- **Delay change in targeting**
- **Recommend only expanding the conditions targeted to all 10 proposed core conditions to see if that improves MTM engagement. Allow the plans some flexibility in how they target within broad therapeutic categories such as bone disease/arthritis or respiratory diseases, such as allowing plans to select specific conditions within these broad categories, so that the targeting isn't overly broad.**
- **Suggest a Stakeholder meeting to brainstorm potential improvements in MTM program**

II. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System ("Star Ratings") (§§ 422.162, 422.164, 422.166, 422.260, 423.182, 423.184, and 423.186)

We support CMS' efforts to create a resilient, high-value health care system that promotes quality outcomes, safety, equity, and accessibility for all individuals. However, as we have previously drawn to CMS' attention, tweaking cut points and guardrails do not and cannot address the larger methodological issues raised by CMS' benchmark-based Star Ratings program. Inherent in the current model is volatile and unpredictable scores. We continue to believe that CMS should consider alternative models to measure performance and would welcome the opportunity to work with CMS in developing alternatives that reward plans that provide quality, safe, equitable and accessible benefits. For example, CMS could move toward a set of measures with defined excellence standards (i.e., 4- and 5-star thresholds) for long-tenured measures backed by years of clinical data, experience, and best practices.

Our comments on specific proposals follow.

A. Reducing the weight of patient experience/complaints and access measures to further align the Part C and Part D Quality Rating System with other CMS quality programs

CMS proposes to lower the measure weight of the of patient experience/complaints and access measures from 4 times to 2 times for 2026 Star Ratings (2024 measurement period). CMS believes that reducing the weighting to 2 for this category of measures would align the patient experience/complaints and access measures more closely with the CMS Quality Strategy and other quality programs. CMS also recognizes that high-value care does not always align with patient experiences of care, further justifying this change.

CVS Health strongly supports reducing this measure weight to 2 times due to the unbalanced impact of the increased weighting of surveyed patient access and experience measures versus reflecting better health outcomes. However, CMS does not explain why this change should be delayed to 2026. We do not believe that CMS should wait until 2026 to make this change—this is a proposal that CMS should adopt for the 2025 Star Ratings (2023 measurement).

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As shared in prior comment letters and other correspondence, the current weighting combined with relatively tight measure-level cut points creates a volatile outcome where relatively minor changes in member perspective year-to-year can significantly move the star ratings and create significant hardships and instability for millions of members as benefit plans in the following year must be significantly reduced in order to submit an actuarially sound bid. Benefit reductions taken due to lower CAHPS scores typically impact an additional year of Star Ratings as benefit reductions triggered by lower star ratings impact beneficiary perspectives on overall rating of health plan, ease of getting needed care, and other care access measures. Delaying this change will just multiply how many beneficiaries are impacted.

Therefore, it is CVS Health's position that CMS should adopt this proposal for the 2025 Star Ratings (2023 measurement).

- **Recommendation: CMS should finalize reducing the weight of patient experience/complaints and access measures to 2 times, but should implement this change one year earlier, for the 2025 Star Ratings.**

B. Removing guardrails when determining measure-specific cut points for non-Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures.

CMS proposes to remove guardrails for non-CAHPS measures, as it believes that the guardrails are no longer necessary due to adding the Tukey outlier deletion to the hierarchical clustering methodology to improve the predictability and stability of cut points, which will be implemented for the 2024 Star Ratings.

CVS Health opposes this proposal. As CMS notes in the preamble, the intent of guardrails was to improve predictability and stability of cut points year over year. CVS Health has previously commented on our concern with drastic movement of cut points and we believe that removing these guardrails is premature and may lead to further volatility.

Tukey's fences primarily remove the lower-end outliers, causing unpredictable movement of cut points in an upward direction outside of industry average movement. The current clustering methodology is inconsistent and does not provide the necessary stability, with or without Tukey and guardrails, that is needed. For example, cut points for MAPD Diabetes adherence moved over 2 times the industry average for 2022 Star Ratings, showcasing that the existing clustering algorithm is not consistently aligned with industry performance. Implementation of Tukey's without guardrails would further increase the cut points outside of industry average performance and further exacerbate this phenomenon.

In the alternative, CVS Health would support CMS removing the guardrails after it determines, for established measures, what truly reflects quality performance and produce set cut point(s) based on that data. For example, the current adherence measures are mature, and performance has begun to consolidate across the industry. There is an

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opportunity for the establishment of set static cut points for these and other mature measures based on clinical and operational measurement guidelines. Setting these cut points would reduce uncertainty and volatility, while incentivizing performance improvement across core clinical measures of the Star Ratings program. CVS Health recommends the following measures for consideration and welcomes further conversation with CMS on this alternative proposal:

- **Breast cancer screening**
- **Colorectal cancer screening**
- **Osteoporosis Management in Women who had a Fracture**
- **Diabetes Care – Eye Exam**
- **Diabetes Care – Blood Sugar Controlled**
- **Medication Adherence for Diabetes Medications (formerly Part D Medication Adherence for Oral Diabetes Medications)**
- **Medication Adherence for Hypertension (RAS antagonists) (formerly Part D Medication Adherence for Hypertension (ACE or ARB))**
- **Medication Adherence for Cholesterol (Statins) (formerly Part D Medication Adherence for Cholesterol (Statins))**

For new measures or measures that demonstrate instability over time, CVS Health encourages CMS to continue to explore other classification methods such as Isolation Forest, DBSCAN, or k-means clustering and engage a Technical Expert Panel to review and reconsider long-term solutions and implications of varying methods for Star Ratings assignment.

- **Recommendation: Do not finalize the proposal to remove guardrails. If CMS finalizes this proposal, the agency should provide static measure cut points for the clinical measures listed above that have been in the program for over a decade and therefore have reached established standards of excellence supported by CMS data.**

C. Modifying the hold harmless policy for the Health Plan Quality Improvement and Drug Plan Quality Improvement measures.

CMS proposes to revise its current policy and apply its current hold harmless provision—which relates to two quality improvement measures and is applied to 4+ Star contracts—only to 5 Star contracts. CMS reasons that the hold harmless provision for the highest rating is not needed for 4- and 4.5-star contracts because they still have the potential to increase scores across measures and thus their Star Ratings.

CVS Health does not support this proposal. CMS considers 4 Star contracts to be reflective of Above Average performance. CMS' proposal would effectively penalize plans that have achieved what is recognized as high-quality performance. This proposal would disproportionately disadvantage larger contracts that already face challenges reaching above 4.5 Stars due to the size and diversity of needs in the populations they serve.

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Moreover, we are concerned that continued volatility in Star Ratings cut points and future policy changes impacting measures (e.g., IRA implementation and the impact on Part D measures) could make it increasingly difficult for plans to reach 5 Stars.

- **Recommendation: Do not finalize this proposal and maintain the hold harmless policy for contracts with 4 Stars and above.**

D. Creating the Health Equity Index (HEI) Rewards.

CMS proposes to reward plans that achieve high scores for enrollees with certain social risk factors. Currently, social risk factors are addressed by on adjusting for the average within-contract disparities in performance through the Categorical Adjustment Index (CAI), in order to not penalize or reward health and drug plans for factors that are difficult for plans to control. However, CMS notes that the CAI does not incentivize contracts to focus on reducing disparities. CMS has therefore developed the HEI to improve health equity by incentivizing MA, cost plan, and PDP contracts to perform well among enrollees with specified social risk factors. CMS further notes that the HEI does not replace the CAI and CMS does not propose to change the current CAI with the implementation of the HEI.

CVS Health supports CMS' desire to reward contracts that are successful with enrollees with social risk factors. We are committed to advancing health equity for our customers, colleagues, clients and communities by improving trust, health care access and quality of health for every population we serve. We recognize that it is critical to understand the challenges of our members with social risk factors in order to assist them with their health.

CVS Health is strongly committed to addressing health care disparities. For example, CVS Health has a platform that includes tools to help employers with Aetna plans track the impacts of the social determinants on their healthcare costs, provide valuable information to CVS to evaluate what interventions may be most useful to specific populations, as well as funding for affordable housing, and community outreach programs to assist with activities of daily living such as healthy eating, financial literacy and health information navigation. CVS Health is increasing its investments and working with clients to create health equity strategies for members with certain conditions that disproportionately affect patients of color and working with local community organizations and advocacy groups to ensure those facing health inequities have access to the resources and care they need. CVS Health has also launched Health Zones, a new nationwide initiative of concentrated local investments design to reduce health disparities and advance health equity in high-risk communities across the country. These are just a few examples of CVS Health's commitment to advance health equity.

However, we are concerned that the HEI reward will in practice duplicate, replace or adjust the CAI. In our experience the CAI has not delivered equity across plans; plans with higher proportions of dual eligible or LIS enrollees have lower average Star Ratings than those with lower proportions of those same beneficiaries. This HEI proposal does not appear to address this fundamental issue, but instead may result in some adjustment on the margins.

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We need more information from CMS to be able to respond to this proposal thoughtfully and completely. We understand that CMS intends to calculate measure-level scores for each contract among enrollees with the included social risk factors over the two most recent measurement years and that CMS has proposed reliability and contract size standards. We request CMS provide additional information regarding the methodology, the reward and the alternative reward structures that CMS is considering. We note that the results of this new measure are largely unknown and there is the potential for a negative impact to plans that do not meet the threshold. Therefore, similar to the information provided for Tukey's outlier calculations earlier this year, we request that CMS consider providing simulations to health plans to assess the impact of these ratings. This will allow plans to identify strengths and opportunities to better understand how to help their members with social risk factors. We also recommend modeling side-by-side HEI data with Reward Factor for 2+ years to understand impact to Star Ratings. In addition, we recommend adding as a display page component for two years in a similar fashion to how substantive measure-level changes are treated.

Recommendations:

- **CVS Health supports continued work toward the adoption of a methodology that would reward plans for work towards advancing heath equity. However, we oppose implementation of the HEI as proposed until further testing can be done to ensure that it will not result in unintended disproportionate impacts.**
- **Additionally, we do not support CMS' proposal to remove the reward factor and replace it with the HEI.**
- **We request additional information from CMS regarding the methodology, the reward and the alternative reward structures that CMS is considering.**
- **CMS should provide simulations to health plans (similar to the information provided for Tukey's outlier calculations).**
- **CMS should also model the HEI data with the Reward Factor for at least 2 years and add a display page component for two years (like substantive measure-level changes are treated).**

E. Removing the 60 percent rule for the adjustment for extreme and uncontrollable circumstances (adjustment for disasters).

Currently CMS excludes certain affected contracts from non-CAHPS measures during certain extreme and uncontrollable circumstances (the 60 percent rule) to ensure that the impact of those circumstances does not have an impact on cut points or reward factors for other contracts. Further analysis by CMS has revealed this rule can have an unintended adverse effect when the extreme and uncontrollable circumstances affect nearly all contracts (such as with the COVID public health emergency). CMS proposes, beginning with the 2026 Star Ratings, to remove the 60 percent rule.

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- **Recommendation: Finalize the proposal to remove the 60 percent rule for contracts impacted by extreme and uncontrollable circumstances.**

F. Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR)

As discussed earlier in our comments, CMS proposes significant changes to the MTM program targeting criteria to expand access to MTM services and promote consistent and equitable access. These changes will drastically increase enrollment in these programs. If CMS finalizes the changes to the MTM program as proposed, we recommend that CMS also move the MTM Program Completion Rate for Comprehensive Medication Review to a display measure for the 2026Star Ratings. This would ensure that plans are not unintentionally penalized on this measure due to the significant changes to the program.

- **Recommendation: If CMS finalizes the policy changes to MTM enrollment, move the MTM Program Completion Rate for CMR to the display page for 2 years due to substantive measure change.**

G. Medication Adherence for Diabetes Medications, Medication Adherence for Hypertension (RAS antagonists) and Medication Adherence for Statin Medications

CMS proposes to use risk adjustment based on socio-economic status for adherence measures, to apply continuous enrollment (CE) instead of member-years adjustment in the 2024 measurement year (MY), and no longer adjust for stays in inpatient settings and skilled nursing facilities beginning with the 2026 MY.

CVS Health needs additional information and analysis to weigh in on this recommendation. It remains unclear how CMS will account for medications distributed during an inpatient hospital or skilled nursing facility stay within the new measurement as the Part D benefit is not utilized during these stays. With cut points and industry performance consolidating recently, a handful of inpatient members that appear non-adherent due to these stays could impact a plan's performance for these measures and negatively impact a plan's ability to receive quality bonus payment.

In addition, display page results are available several months later than the Star Ratings, therefore, CVS Health recommends a minimum of three years on the display page to allow for adequate review and impact assessments for these heavily weighted measures.

CVS Health supports the change to continuous enrollment instead of member years as established relationships with members and health plans are crucial to success in these measures.

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CVSH requests additional information regarding how the new measurement criteria will be compared to prior years within the Drug Plan Quality Improvement measure upon year of implementation.

- **Recommendation: Do not finalize risk adjustment changes to these two measures until additional information on the methodologies can be provided to plans and concerns around medications distributed within inpatient settings can be properly addressed**

H. Polypharmacy Measures

CMS proposes to move the Part D Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults, and the Part D Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults measure from display measures to the Star Ratings. We are concerned about this change. It is unclear what the goal of including these measures is and we continue to believe it would be inappropriate to include Polypharmacy measures in future Star Ratings. There are instances when polypharmacy, or concurrent drug use, is clinically appropriate, but plan sponsors are not fully positioned to differentiate clinically inappropriate polypharmacy. Additionally, plan sponsors have little influence over the provider practice pattern of prescribing medications concurrently. As a result, a plan's performance on the polypharmacy measures would largely be outside of its control. If CMS wants to include these measures in the program in future years, one alternative could be to redesign the measure to only assess new starts, as this would provide a baseline for the measurement of further risk or decline.

- **Recommendation: Maintain the polypharmacy measures as display measures only.**

I. Concurrent Use of Opioids and Benzodiazepines

CMS proposes to add the Concurrent Use of Opioids and Benzodiazepines (COB) to the 2026 Star Ratings because CMS believes that this measure will help plans identify enrollees who are at risk. CMS also noted that the overall rates for the COB measure (on the display page) have improved slightly year over year.

CVS Health does not support this proposal. Plans have minimal ability to impact this measure as it depends on physician behavior. An additional concern is the methodology, since new members and those changing plans will appear as initial fills when they are not actually initial fills.

- **Recommendation: Do not include the COB measure in future Star Ratings.**

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III. Prior Authorization and Utilization Management Requirements (§§ 422.101, 422.112, 422.137, 422.138, and 422.202)

CMS proposes that coordinated care plans may only use prior authorization to confirm the presence of diagnoses or other medical criteria and/or ensure that an item or service is medically necessary based on standards in the proposed rule. We would emphasize that a study of Aetna's Medicare Advantage population showed that the majority of medical necessity denials were driven by Medicare's coverage rules (85%), not unnecessary barriers erected by plans.[16] Thus, we believe that some of CMS' proposals are misplaced and discuss this further in our comments to the proposals in this section.

To begin, CVS Health believes that prior authorization and utilization management are important tools to ensure enrollees receive medically necessary care. CMS has recognized this same value, implementing prior authorization and pre-claim review for select hospital outpatient services, ambulance transport, and DMEPOS items under Medicare fee-for-service.

That being said, we support efforts to make the prior authorization and utilization management process more streamlined and efficient for plans, providers, and patients. We support the move toward electronic prior authorization (ePA) and believe that it can resolve many of the issues that have been recently discussed related to prior authorization. For example, there is concern that prior authorization leads to delays in care; however, some prior authorization delays are a result of the plan receiving insufficient information from the provider. In some cases, this may result in an initial denial that is later overturned once sufficient information is submitted. We recognize that providers may be frustrated when asked for additional information. Electronic prior authorization can be designed so the initial provider request cannot be submitted until all of the necessary information is obtained. This means that a single request is handled once, instead of multiple times by the provider and the plan. Electronic prior authorization would be a more effective, less disruptive and less costly solution to prior authorization concerns.

CVS Health is also working on comments to the Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule (CMS-0057-P) which if finalized, would go into effect in 2026. That rule would set interoperability standards for MAOs that would support the efficient exchange of information between plans, providers, and patients that is central to many proposals of this proposed rule.

- **Recommendation: We encourage CMS to consider delaying implementation of proposals under this rule until at least 2026 to align with the effective date of the interoperability rule. This would ensure that plans have sufficient time to ensure that the technical, staffing, and resource infrastructure is in place to effectively support the changes under this proposed rule.**

[16] Schwartz, Chen, Jagmin, et. al,, Coverage Denials: Government and Private Insurer Policies for Medical Necessity in Medicare, *Health Affairs* 41, No. 1 (January 2022).

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A. Limiting Utilization Management and Prior Authorization

CMS proposes that coordinated care plans may only use prior authorization to confirm the presence of diagnoses or other medical criteria and/or ensure that an item or service is medically necessary based on standards in the proposed rule.

CMS also proposes to require MA Plans to comply with national coverage determinations (NCD), local coverage determinations (LCD), and general coverage and benefit conditions included in Traditional Medicare statutes and regulations as interpreted by CMS. As CMS says, "In other words, an MA plan would not be permitted to deny coverage of a Medicare covered item or service based on internal, proprietary, or external clinical criteria not found in Traditional Medicare coverage policies." However, MA organizations may create internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available to CMS, enrollees, and providers if there are no established coverage criteria.

CVS Health appreciates CMS' efforts to ensure that Medicare beneficiaries receive all the benefits to which they are entitled and to receive those benefits without undue delay or trouble. However, when items and service are not already subject to an NCD or LCD, CMS' proposal will limit MA plans' ability to be effective stewards of federal dollars—the Medicare Trust Fund—and lead to unnecessary services and costs to beneficiaries because the proposal would prevent MA plans from reviewing certain items and services before they are received. Even if plans cannot review items and services beforehand, MA plans are required to ensure that the items and services are medically necessary, including whether the items and services were reasonably necessary based on the enrollee's medical; without prior review, inappropriate services can only be denied post-service. This means that the provider will not receive compensation for items and services already provided; providers may be reluctant to contract with MA plans as a result. Fewer providers in MA plans means fewer options for beneficiaries, possibly delayed care and network adequacy issues at a time when CMS is working to strengthen patient access through reduced wait times and additional network adequacy standards. Importantly, the Medicare beneficiary may also have received, and paid cost-sharing for, inappropriate or unnecessary care.

In fact, in a study of Medicare Advantage beneficiaries in Aetna plans (between 2014 and 2019), over 5 million claims were denied (over $416 million dollars in claims) **post-**service as a result of Medicare's medical necessity criteria. Of the services denied because of Aetna's rules, the most common reason for the denial was that the services were experimental/investigational or without proven efficacy. As the study notes, coverage policies can provide "nuanced incentives based on evidence-based determinations of medical necessity."[17] There is every reason to believe that the amount of medically **un**necessary services received would increase if MA plans are limited in the utilization

[17] Id.

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management processes they may employ to ensure that services are medically necessary **before** they are received.

MA prior authorization and other pre-service medical management requirements are designed by MA plans when NCD and LCDs do not apply, in order to ensure quality, safety, and appropriateness under a managed care model. While Medicare may cover spinal surgery in certain circumstances, best medical practice and the most conservative and safe approach based on clinical evidence may be to try physical therapy before surgery. Based on our understanding of this proposed rule, MA plans would be limited in their ability to perform pre-service review, which leaves post-service or retrospective review, as the primary way MA plans can effectively assess the quality, safety, and appropriateness of a service. We are concerned because if an MA plan is only permitted to review the treatment after it is received, this significantly limits the plan's ability to intervene and avoid potentially dangerous or low-value care before it is provided.

Upon retrospective review, an MA plan may conclude that surgery was not medically appropriate (and therefore not necessary)—and deny coverage—leaving the beneficiary worse off (because they received an inappropriate and invasive level of service) and leaving the provider worse off because the claim was denied. In other words, if, because Medicare covers spinal surgery, an MA plan cannot direct beneficiaries first to less costly and less invasive treatments, beneficiaries lose an important safety net, providers may be facing more claims denials, and the Medicare program loses as well. Services that are covered by Medicare, and may be appropriate for some beneficiaries, may not be the most appropriate service for any particular beneficiary at the time of service.

Similarly, the service may be appropriate, but the provider may be out-of-network. The beneficiary may choose out-of-network services (depending on their plan design), but they should do so with the awareness that the services are out-of-network and may therefore incur higher out-of-pocket costs. Prior authorization avoids out-of-network surprises and the plan can coach and help its beneficiaries to further understand options to consider. It also ensures that out-of-network facilities meet quality and safety standards; beneficiaries may choose their provider, but prior authorization can help ensure that they do not choose ineffective or dangerous services.

We also note that CMS has increased case management requirements for MA plans over the years; CMS believes, and we agree, that case management ensures that beneficiaries receive necessary care and that care is coordinated among disparate providers. Utilization management plays an important role in case management, to ensure that beneficiaries receive the best treatment for them at that time the treatment is necessary. Limiting utilization management may thus limit the value and protection that case management may add for certain beneficiaries. For example, Medicare places benefit period limits on certain services, such as SNF care. After the 100th day of SNF care, the beneficiary must pay all of the costs on their own. An MA case manager can review the treatment plan and ensure that the beneficiary is not placed in SNF care inappropriately and possibly exhausting their benefit period coverage before their benefit need has been met. A beneficiary facing large

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out-of-pocket costs after an unnecessary extended (or serial) SNF visit is not well served by the provider, plan or program if some of the SNF visit could have been avoided.

In addition, MA utilization management also prevents fraud before Medicare beneficiaries and the Medicare program are taken advantage of by unscrupulous providers and vendors. This protects beneficiaries and the integrity of the program. CMS will be forced to pay MA plans more to cover the costs that MA plans could have avoided with appropriate utilization management, including prior authorization, adding costs to the Medicare program.

We also are concerned that CMS has not appropriately considered the costs of its utilization management proposals. Not only will reduce utilization management result in payment for items and services which were not clinically appropriate, but the proposal to extend prior authorization approval and establish a Utilization Management Committee will be expensive. CMS should carefully consider whether the benefits of this proposal will outweigh the costs.

We want to emphasize that our plans do not use utilization management, including prior authorization, to limit access to medically necessary care. As CMS has discovered through its Recovery Audit program, there simply are times when a Medicare beneficiary receives covered benefits in a medically unnecessary setting.[18] Prior authorization is designed to catch these issues before a service is performed so a beneficiary can receive care in the most appropriate setting.

We typically approve 85-90% of all prior authorization requests under our Aetna Medicare plans. Such a high approval rate demonstrates that we do not use prior authorization to limit access. But it also demonstrates that a significant percentage of item and service requests (up to 15%) are not appropriate—the item/service may not be suitable for the beneficiary, or the item/service may not be covered, or the item/service is not medically necessary. Limiting prior authorization and other medical management techniques will lead to more unnecessary or inappropriate care.

Although we appreciate that there has been a great deal of attention paid to utilization management in Medicare, and a great deal of criticism of its use, our plans strive to ensure that the beneficiaries in our plans receive the most appropriate service in the timeliest manner; effective and cost-efficient care ensures our members stay as healthy as possible, and our stewardship of the Medicare program ensures that it stays healthy as well. We succeed when our members live vibrant, healthy lives; erroneously limiting or denying medically necessary care does not serve our mission and we do not do it.

We support a prior authorization program that promotes quality, affordable health care, and reduce unnecessary administrative burdens for both the health insurance issuer and the health care provider. We also agree that the process should be simple, straightforward and clear. We recognize that CMS' intention is to ensure that MA beneficiaries receive benefits

[18] *Fact Sheet: Two-Midnight Rule*. Centers for Medicare & Medicaid Services. https://www.cms.gov/newsroom/fact-sheets/fact-sheet-two-midnight-rule-0.

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that are covered under original Medicare. However, we are concerned that the proposed changes under this section create areas of uncertainty that may lead to excessive limitations on the use of prior authorization, which would increase costs and remove safety and fraud-prevention guardrails.

Recommendations:

- **We recommend that CMS further clarify its intended goals of the proposed changes to §422.101 to avoid excessive limitations on plans' ability to utilize pre-service review and utilization management to ensure that beneficiaries are receiving quality, medically necessary services.**
- **Accelerate the adoption of electronic prior authorization and work with stakeholders to streamline prior authorization processes that ensure safe, affordable care.**

B. Approval Duration

CMS proposes to require that a prior authorization approval must be valid for the duration of the approved course of treatment and that plans provide a minimum 90-day transition period when an enrollee who is currently undergoing a previously approved treatment switches to a new MA plan. While we support the goals of this proposal and continuity of care for beneficiaries, we have several concerns, particularly with regard to the minimum 90-day transition.

First, CMS does not appear to address a scenario where the planned duration of the treatment is unknown at the time when coverage is requested. CMS also does not address a scenario where it is permissible for two MA plans to utilize internal coverage criteria in the absence of a standard under original Medicare. In both of these instances, a new MA plan may be held responsible for the long-term cost of care provided by an out-of-network provider, or for a treatment that may not meet the standards of their internal coverage criteria where such criteria is consistent with CMS policies, but utilization management may vary. These concerns become a greater priority as the number of high-cost and experimental treatments continue to increase.

We also note that a 90-day transition period for medical benefits under MA is quite different from a 90-day transitional fill requirement for Part D covered drugs. Medical treatment plans may be extensive, complicated and, as a result, very expensive. In addition, if a member changes plans, the resources available to the member—including the facilities and providers available—may mean that the care plan should be revised to better utilize the new resources available.

Second, CMS failed to clarify this 90-day transition proposal would not apply to supplemental benefits, as this varies from plan to plan. However, covering only Original Medicare benefits and not others would likely be confusing to beneficiaries, especially if

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CMS puts language in an EOC. CMS would need to address and carve out supplemental benefits that are in the same section of the EOC.

While we generally support continuity of care through the 90-day transition period for basic benefits, we recommend that CMS clarify this policy to allow plans to do the following at the end of the 90-day transition period for basic benefits: (1) for services provided by an out-of-network provider, the new plan can apply out-of-network limits if the beneficiary is informed that the provider is out-of-network, chooses to continue receiving care from that provider and does not switch to an in-network provider; and (2) for treatments extending beyond 90 days where the new plan utilizes its own prior authorization and utilization management criteria, the new plan is permitted to conduct a new review and issue a new decision to go into effect at the end of the 90-day transition period.

These should be communicated to the beneficiary within the 90-day transition period to allow for sufficient notification and planning. Ideally, conversations about a beneficiary's long-term treatments should also take place as part of the enrollment conversation to ensure that the beneficiary selects the best plan to meet their needs.

Recommendations:

- **We support the goals of ensuring continuity of care for beneficiaries. However, we believe that this proposal requires significant operational considerations that make implementation in 2024 difficult. We recommend that CMS finalize this proposal with an effective date of 2026 to align with the effective date of the interoperability standards. In the interim, we request CMS to provide further guidance on this policy, especially as it relates to permissible actions by plans after the 90-day transition period ends.**
- **CMS should clarify that the 90-day transition period applies only to basic benefits and not to supplemental benefits.**
- **CMS should allow plans to conduct their own prior authorization or utilization management review for treatments extending beyond the 90-day transition period. Plans should also be permitted support beneficiary transition to an in-network provider at the end of the transition period.**

C. Establishing a Utilization Management Committee

CMS would also require MA plans to create a new Utilization Management Committee to review all utilization management policies annually and ensure they are consistent with current, traditional Medicare's national and local coverage decisions and guidelines. The Utilization Management Committee would be required to include a majority of members who are practicing physicians, include at least one independent practicing physician, and including members representing various clinical specialties.

MA plans already have numerous multidisciplinary committees and medical advisory boards that review utilization management and other MA policies; these committees include

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practicing health care providers and some committees may even include independent providers. Plans currently use these committees for the review of clinical data and literature, as well as various quality and compliance tasks; CMS' proposal would add an unnecessary layer of complexity on these already functioning groups that is duplicative and unnecessary. While we support the concept of an annual review of all prior authorization and utilization management policies, we believe that plans should also have the flexibility to use current committees and processes to perform these functions. For example, CMS appears to be requiring any prior authorization used by a plan to be reviewed before use, but most of these policies are already currently in use. Supplemental benefits may not have specific prior authorization policies, but plans have internal policies and guidance documents to properly ensure that the correct members receive the benefit; it is unclear if CMS believes those policies are utilization management policies and if so, if they would have to be reviewed before implementation.

In addition, CMS' proposal to include independent providers on the new Utilization Management Committee will create challenges, especially if this is a requirement for 2024. As a requirement that goes into effect for all plans at the same time, we anticipate there will be competition among MA plans to recruit the requisite independent physician. There is a limited number of providers that meet the required criteria and they may have limited time and resources to devote to this task. We support CMS' requirement that these physicians be free of conflict; however, many independent physicians serve as advisors to multiple companies and organizations, including other MA plans and manufacturers of treatments and therapies that may be the focus of certain polices.

CMS would also require the Utilization Management Committee to have a majority of "practicing" physicians serving on the Committee, but CMS does not define "practicing." If CMS considers "practicing" to mean actively seeing patients, there will be even fewer physicians available to sit on these all of these new committees. As a result, we recommend that CMS revise the regulatory text to require that the clinical members be "appropriately licensed and skilled physicians or other qualified health care providers".

We recommend that the composition of the committee reasonably represent multidisciplinary clinical specialties with expertise in the types of claims that the MA plan typically receives. In other words, MA plans should have discretion with respect to the types and numbers of physicians (external and internal); the inclusion of qualified non-physician health care providers such as pharmacists, nurses, and licensed clinical social workers; and qualifications (currently practicing, specialty, education, etc.) of those that serve on the Committee; provided that the plan's Committee reasonably represent the experience, skills and independence needed to competently review the plan's utilization management policies.

CMS also would require all prior authorization policies to be reviewed by the Committee before the policies could be put into place. However, this overlooks the fact that policies are changed throughout the year—new drugs may be introduced, new LCDs are issued, new treatments developed. Of particular note, LCDs are not always released in advance of

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changes. They may be published with retroactive changes and the same LCD can receive multiple updates within the year. If the Committee must review and approve every prior authorization policy, the Committee effectively must be active year-round and in the case of an LCD that is published that is retroactive, there is no ability for the Committee to review it prior to its effective date. In addition, the fact that this Committee must convene for "new" LCD releases and other changes, further limits the personnel that can commit to serving on the Committee and adds further administrative costs.

Recommendations:

- **Permit MA plans to use preexisting committees to complete the required prior authorization policy review. In the alternative, revise the regulation to read as follows:**
  - *(c) Utilization Management Committee Composition. The MA plan must establish a Committee that includes appropriately licensed and skilled physicians or other qualified health care providers. The MA plan has discretion on the types and numbers of external physicians or qualified health care providers that serve on the Committee and discretion in setting reasonably representative qualifications for all individuals that serve on the Committee, provided that the MA plan ensure that various clinical specialties and a wide range of conditions are considered in the development of the MA plan's utilization management policies.*
- **Do not require the Utilization Management Committee to review and approve all prior authorization policies before they are implemented; doing so would require that the Committee meet constantly to review policy updates as Medicare LCDs that are updated on a rolling basis**
- **Provide plans with additional time to recruit, select, and onboard independent providers for the Utilization Management Committee or existing committees serving the function of the Utilization Management Committee.**

D. Specific Concerns for Utilization Management with Part B-covered Drugs

We want to call special attention to CMS' proposal on Medicare Part B drugs. As with physician services, we use utilization management when there is a clinical reason to do so; for example, to ensure the drug is only continued if it is effective, to ensure an IV route of administration is not used excessively when treatment guidelines recommend a switch to subcutaneous, which is covered by Part D and we already follow applicable NCDs and LCDs. We appreciate that CMS clarified that step therapy will continue to be permitted if it does not conflict with step therapy that is either included or specifically disallowed in an applicable NCD or LCD.

We use our pharmacy benefit manager to ensure Part B drugs are covered appropriately. Part B drugs may be effectively managed through a P&T committee structure, but such a structure is not suited for Part C medical reviews. Members of a P&T committee do not have the necessary expertise for Part C medical reviews and adding the necessary expertise

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would make the P&T committee far too big to effectively function. In addition, if Part B drug utilization is reviewed by both the P&T committee and the newly required Utilization Management Committee, there may be conflicting policies and instructions. At a minimum, CMS should allow Part B utilization management to be managed under current P&T processes and removed entirely from this proposal.

If CMS moves forward with its prior authorization proposals and includes Part B, CMS should clarify that pharmacists are qualified health care providers that are sufficiently knowledgeable and skilled to make prior authorization determinations. This clarification should be included in the regulatory text.

Regarding the proposed requirement to publicly post UM criteria, we support increasing transparency. However, we believe the content requirements for Part B drug UM criteria documents should more closely align with those of Part D drugs which are already required to be publicly posted. Although CMS has calculated the level of effort needed for plans to upload criteria documents to their websites, the agency has not accounted for the effort needed for plans to expand the amount of information included in their criteria documents. It is common for these documents to include the coverage criteria for the drug, the approval duration(s), and a reference list. It is less common to include a summary of each citation referenced or the rationale for adopting the policy. Adding this level of detail to existing Part B drug criteria documents and maintaining it over time will require a significant level of effort. Moreover, we do not believe this level of detail for drug criteria documents is needed or desired by providers. In our experience, the average Part D drug criteria document is 1-2 pages long while the average drug criteria document of the type outlined in the Proposed Rule averages 10-15 pages. Many are quite longer. We recommend requiring Part B drug criteria documents to be publicly posted within the proposed timeframe but allowing plans to use their current format so long as a reference list is included. Omitting the detailed information summary and rationale for adopting the policy will balance the need for transparency with a sustainable level of effort and administrative costs for the industry.

Regarding UM approval duration, we have several concerns about this proposal as it relates to Part B drugs. First, managing the approval duration is an important tool used to prevent overutilization. This is done both to reduce fraud, waste, and abuse (e.g., duplicate billing under Part B and Part D, etc.) and to protect patients from continuing medications that are ineffective or no longer effective, especially where the drug poses a safety risk for the patient or prevents changing to a new therapy that may be effective.

Second, we are concerned about how the proposed regulatory language, as stated, would impact approvals of maintenance drugs. Unlike many other Medicare basic benefits, Part B drug therapy is often used for prolonged periods of time. The proposed regulatory language, as stated, could be interpreted as requiring *lifetime* approval durations for maintenance drugs. Although a patient's diagnosis may be unlikely to change, the most clinically appropriate and cost-effective alternatives are likely to change as the pharmaceutical landscape changes over time. A periodic PA requirement prompts the

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provider, patient, and plan to reevaluate the drug therapy, consider alternatives, and make changes if warranted.

Last, as previously stated, the proposed rule does not account for times when the planned duration of therapy is unknown during the PA review. This is a particular concern for Part B drugs given the very short timeframes for reviewing PAs for them (24 hours and 72 hours for expedited and standard requests, respectively) and our experience that PA requests for drugs often do not include the planned duration of therapy. When a PA is approved, the parties to the request must be informed of the terms of the approval, including the approval duration. In addition, the plan must log the approval duration in its software system(s) to effectuate the approval. If a plan is required to approve coverage for the full intended duration of use and the plan cannot obtain this information during the applicable PA review timeframe, the plan would have to deny coverage even though the drug is medically necessary and eligible for coverage.

In addition to our general comments regarding the proposed transition requirement for Medicare basic benefits – which we largely support – we have several concerns that are specific to Part B drugs. For example, Part B drugs differ from other basic benefits in that many of them can be covered under *either* Part B or Part D, depending on the circumstance. One such circumstance depends on whether the drug is dispensed by a pharmacy or furnished in another healthcare setting. Drugs are billed through either medical or pharmacy claims adjudication systems depending on where they are furnished. These adjudication systems use different transaction standards and billing codes and therefore do not communicate with each other. The claims are also billed at different points in time. Pharmacies bill *before* dispensing the drug, while other healthcare settings bill *after* the drug has been administered. The post-administration billing can occur months after the date of service. Another issue is that the interoperability rule does not apply to drugs. Therefore, it is unclear whether the planned improvements that will facilitate transition processes for other Medicare basic benefits will improve data sharing around drug therapy. All of this is to say that it will be very challenging for plans and PBMs to determine when a patient is already taking a Part B drug or has received approval for it by their previous health plan.

Unlike other Medicare basic benefits, there is an existing transition process for drug therapy; it just pertains to Part D drugs. It would be cumbersome and confusing to apply very different transition policies to Part B and Part D drugs, especially when a number of those drugs can be covered under either benefit depending on the circumstance. To the extent practicable, we recommend that CMS align transition rules for Part B drugs with those of Part D. This includes needing the ability to make a Part B vs Part D benefit determination when needed before furnishing a transition supply at a pharmacy. Similarly, plans and PBMs will need to know how to proceed when they are unable to determine at point of service whether the patient is already taking (or had already received prior approval from their previous plan for) the requested drug. In the Part D space, plans are required to assume the patient is already taking the drug when they are unable to determine otherwise at the point of service. This process depends on a lookback period to check for previous claims, which

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due to the lack of interoperability between pharmacy and medical claim adjudication systems noted above, will be very challenging.

In the Part D space, plans are required to apply selected claim edits during the transition period (i.e., safety edits, Part B vs Part D edits, and edits to ensure the drug is being used for medically accepted indication when there is a high likelihood that it is used for a non-Part D eligible purpose). Similarly, we believe UM edits should continue to apply to certain Part B drugs during transition. For example, drugs with significant safety risks (ex. Spravato), those with extremely high cost and limited duration of use (ex. CAR T-cell therapy; gene therapy), those subject to very limited coverage in FFS Medicare (ex. drugs with an NCD covered with evidence development), and those with significant risk of fraud, waste, or abuse. We also ask CMS to consider the implications of providing a transition supply of a Part B drug that is subject to step therapy when the plan is unable to determine whether the patient is currently taking the drug. As CMS explained in the Proposed Rule, step therapy is an important cost management measure for Part B drugs. Under the current rules, plans may only apply step therapy to Part B drugs for new starts or administrations of the drug. Therefore, unless this policy is changed, providing a transition supply of a Part B drug will prevent the application of step therapy.

Recommendations:

- **If CMS retains the Utilization Management Committee requirement, it should allow Part B utilization management to be reviewed by an MA plan's P&T committee, under their current process and without additional requirements or limitations.**
- **CMS should require UM criteria documents to be publicly posted but should not require these documents to contain a detailed summary of each piece of evidence considered or rationale for adopting the policy. Instead, CMS should allow plans to use their current UM criteria format so long as it includes a reference list of the evidence considered in creating the policy. CMS could then wait to see if there is an unmet need on the part of providers, and if so, conduct focus groups with providers to determine the need and work with industry to make the changes. If CMS finalizes the criteria content requirements as proposed, the implementation should be delayed to allow plans time to add the additional content.**
- **CMS should permit P&T committees to determine the appropriate approval durations for Part B drugs. The duration will vary depending on the drug and the circumstance for which it is approved (e.g., the condition being treated, new start vs continuation of therapy, etc.).**
- **CMS should provide additional information, before implementation, of how it expects plans to implement the proposed 90-day transition fill policy. To the extent practicable, CMS should align the transition rules for Part B drugs with those of Part D drugs, including issuing guidance about any UM edits that should still be applied during the transition period.**

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E. Reviewing Medical Necessity Decisions by a Health Care Professional

CMS proposes to modify the requirement with respect to the expertise of the physician or other appropriate health care professional who must review an organization determination (OD) if the MA organization expects to issue an adverse decision based on the initial review of the request. CMS would add to the existing requirement that the physician or other appropriate health care professional who conducts the review must have expertise in the field of medicine that is appropriate for the item or service being requested before the MA organization or AIP issues an adverse OD.

We understand that this additional requirement continues to allow the MA plan discretion in deciding which physician or other appropriate health care professional with sufficient medical and other expertise is appropriate to issue a determination decision and does not require the MA plan to use a physician or health care professional with the same specialty or subspecialty as the treating physician or other health care provider. We strongly support continued plan discretion.

It would be helpful for plans if CMS explained how it envisions medical necessity review processes to work when there are multiple items and services being reviewed and how CMS intends to review whether a plan's adverse decision reviewer had the appropriate expertise. We also ask CMS to explain how it expects plans to comply with this requirement in the event that the item or service involves a more unusual medical specialty or an item or service. For example, many MA plans may offer dental, vision and hearing benefits as a supplemental benefit; does CMS expect each MA plan to have dentists on call 24/7 for medical necessity review? The same would apply to vision and hearing. Most plans do not have dentists on staff, so if so, we note that this requirement will be costly and CMS should both evaluate the aggregate costs of this proposal across the program and determine whether the benefit outweighs the cost.

Recommendations:

- **CMS should finalize this proposal but should use the term "qualified health professional" to avoid ambiguity and to align with National Committee for Quality Assurance (NCQA) utilization management terminology.**
- **Include language in the CFR and/or final rule clarifying that plans have discretion to determine the appropriate expertise of the health care professional who reviews and denies an OD.**
- **Clarify that pharmacists are generally appropriate reviewers of ODs for Part B drugs and other items routinely dispensed by pharmacies.**

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F. Gold Carding

CMS "reiterates" in the preamble to this Proposed Rule that it believes the use of gold-carding programs could help alleviate the burden associated with prior authorization and that such programs could facilitate more efficient and timely delivery of health care services to enrollees. Thus, CMS encourages MA plans to adopt gold-carding programs that would allow providers to be exempt from prior authorization and provide more streamlined medical necessity review processes for providers who have demonstrated compliance with plan requirements.

Gold carding purports to streamline medical management, like prior authorization. Although we appreciate that medical management, including prior authorization, can appear burdensome, the burden is justified. Prior authorization, along with other medical management techniques, are used to protect patients, ensure clinical efficacy, and protect both beneficiaries and the Medicare program from unnecessary charges. Gold carding would circumvent prior authorization, leaving plans unable to review items and services for patient safety, prevent adverse drug interactions, and deter controlled substance abuse. Gold carding would also prevent plans from directing patients to the appropriate setting—including the use of network providers and facilities. Patients may be unaware, for example, that their provider has referred them to a facility that is not in the patient's network. Prior authorization flags that, saving the beneficiary from unintentionally incurring higher out-of-pocket costs.

CMS believes that gold-carding is appropriate for certain providers that are more reliable and more consistently adhere to plan requirements, appropriate utilization of items or services, and other evidence-driven criteria. But this misunderstands prior authorization—the vast majority of items and services (over 85%) subject to prior authorization are eventually approved. Rather, prior authorization ensures that the services received are necessary now (rather than after more conservative options), will be received in the appropriate setting (the most efficient and least invasive), and are covered for that particular beneficiary. A prior authorization request may be approved, but in a different setting, or may be approved after the provider clarifies that other less invasive options are not appropriate.

To bypass this safety, quality and coverage check, the provider should have to meet a materially higher standard than currently required to receive prior authorization. This requires a demonstration of substantial expertise; a provider may be a superlative physician, but no single individual can be an expert at every item or service. Accordingly, we believe that any gold card proposal should require demonstrated expertise and a high enough volume of that particular CPT code to demonstrate such expertise. Because we do not believe that there are a sufficient number of providers that meet these criteria, we do not think that the benefits of establishing and maintaining a gold card program would outweigh the costs in plan resources or the risk to the beneficiaries of the receipt of inappropriate items or services.

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We would also note that prescription drug prior authorizations are materially different than medical items and services; any gold card proposal would have to address those distinctions. Prior authorization for drugs may be even more important to ensure patient safety and prevent adverse drug interactions. Plans and their PBMs are well positioned to prevent adverse interactions via real-time review and there is no justification to remove this key safety checkpoint in the name of gold carding when drug prior authorization is generally more streamlined and administratively simple already. In addition, as with medical prior authorization, drug prior authorization plays a case management roll, including by deterring controlled substance abuse (for example, through opioid prescription tracking).

- **Recommendation: CMS should not require the use of gold carding. Gold carding programs are still relatively new across the few states that have implemented these initiatives. We encourage CMS to wait until sufficient data is available from current state programs to conduct an evaluation of any potential strengths or limitations of gold carding.**

G. Timing and Costs

CVS Health recognizes that utilization management in Medicare has been subject to recent criticism and we appreciate CMS' efforts to address the concerns. We believe that utilization management plays an indispensable role in ensuring beneficiaries receive safe, cost-effective, and efficient items and services. It also serves to protect the Medicare program itself from unnecessary and sometimes fraudulent claims. But we share the frustration of many when prior authorization adds delays to treatment and work for providers. We believe that much of these issues can be addressed with ePA and we stand ready to work with CMS and other stakeholders to further streamline necessary utilization management processes.

We are concerned, however, that CMS has not properly considered the costs of its proposals. Each proposal adds administrative and claims costs to plans. In addition, each proposal diverts current resources away from where they are deployed. In short, if CMS chooses to finalize any of its proposals, plans need sufficient time to properly comply. Such compliance may include contracting with additional qualified health professionals, additional actuarial analyses of transition costs, and revising current utilization management roles.

At the same time, as CMS is aware, the currently proposed interoperability rule would impose additional prior authorization requirements, both substantive and procedural. These proposals do not appear to have been harmonized with the utilization management proposals in this Proposed Rule. The interoperability proposal will also create a great deal of work and absorb a great deal of plan resources. However, the interoperability proposal also sets the infrastructure to support the goals of many proposals in this rule. For example, ensuring the 90-day transition in treatment will rely on the payer-to-payer API framework to ensure that a new plan has all the necessary information on a new enrollee's treatment.

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Recommendations:

- **Harmonize the prior authorization requirements with interoperability prior authorization requirements, specifically that any changes CMS proposes should be effective no earlier than the date the interoperability prior authorization requirements are effective (which is currently proposed to be effective for plan year 2026).**
- **CMS should delay enforcement of the utilization management proposals it finalizes in this Proposed Rule until additional guidance is provided by CMS and plans are able to update policies, procedures, organizational structure, and data systems to meet the new requirements.**
- **Evaluate the costs of these proposals to determine whether the benefits are justified by the costs.**

IV. Marketing and Beneficiary Communication (§§422.2262, 422.2263, 422.2264, 422.2267, 422.2272, and 422.2274)

CMS proposes significant marketing and communication changes. We support CMS in targeting deceptive marketing practices and we are committed to partnering with CMS to ensure that beneficiaries receive clear, correct and helpful information about their benefit plan options. CVS Health would urge CMS to balance beneficiary protections with maintaining a convenient and efficient beneficiary experience. We believe that some of CMS' proposals without further clarification or guidance, may have unintended consequences to many stakeholders, including plans, brokers, agents, and, most importantly to the beneficiary.

A. Beneficiary Contact

While CVS Health is supportive of standards to prevent misleading and unwanted beneficiary contact, we note that codifying several of the proposed changes have the potential to drive up wait times for the beneficiary, impacting their experience. We support CMS' proposal to prohibit unsolicited door-to-door contact; however, we seek clarification on the opt-out proposal and have concerns with CMS' proposals requiring time between marketing interactions and beneficiary enrollment.

To eliminate unsolicited contact, CMS proposes that if the MA organization or Part D sponsor reaches out to beneficiaries regarding plan business, the MAO must provide notice to all beneficiaries whom the plan contacts at least once annually, in writing, of the individual's ability to opt out of future calls regarding plan business. We support this requirement to provide beneficiaries with the opportunity to opt-out of communication annually. Aetna currently operates program outreach to existing plan members via outbound call campaigns to explore other Medicare products that may be of interest or serve the beneficiary's needs. We recommend that CMS continue to allow MAOs and Part D sponsors to contact current members with an existing relationship to the plan. These should not be considered "cold calls."

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We also recommend that CMS not finalize the proposal limiting the time a sales agent can call a potential enrollee to six months following the date that the enrollee first requested information. This timeframe may negatively impact beneficiaries who provides an agent with their contact information and permission to contact, especially at the end of the calendar year. Instead, we recommend that CMS provide a 13-month limitation on this interaction. This would allow a beneficiary to maintain a consistent contact through the start of the following Annual Enrollment Period in the event that they want to switch to a new plan and do not want to initiate a new search. As with any contact, the potential beneficiary would be permitted to opt-out of communication at any time.

CMS' proposal to ban follow up with a beneficiary within 48 hours of the beneficiary initiating interest through the completion of a Scope of Appointment (SOA) form merely forces a beneficiary—who may have been ready to enroll—to find another time to actually complete enrollment. Beneficiaries' time is valuable. This may be particularly important toward the end of the month (or the end of their enrollment period) – a two-day delay in enrollment may lead to a more significant delay in coverage. Many times, a beneficiary may also initiate contact by approaching an agent directly as part of a "walk-in assistance" interaction. In this instance, the beneficiary may not want to complete a SOA and wait an additional 48 hours. In addition, we have consumers that contact us via our website and request a callback at a specified time; that time may be within the next 48 hours and we need to be able to contact them at their preferred time.

If finalized, we recommend that CMS provide beneficiaries with the opportunity to opt out of the 48-hour window if they are ready to engage with a particular agent or plan. This can be communicated to the beneficiary through required language on the SOA, such as "CMS generally requires that a plan broker or agent must wait 48 hours between completing this Scope of Appointment and the actual sales or enrollment meeting. You have the right toto waive this 48-hour waiting period if you are ready to proceed with a sales or enrollment meeting."

Similarly, the prohibition on marketing events within 12 hours of an educational event at the same location may simply discourage brokers and plans from hosting educational events. Educational events are strong sources of information that provide the necessary knowledge to beneficiaries that help them learn about Medicare and their options, this rule is likely to lead to less education. We believe that CMS intends to have all beneficiaries have access to the full range of options available to them; however, limitations on sales following an education event may have a negative impact on access. Rather than setting the time standard, CMS could consider requiring that agents can be in the same building as an educational event but not in the same room, with a clear signage and announcements delineating the educational event from the optional opportunity to interact with agents.

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Recommendations:

- **Finalize the prohibition on unsolicited door-to-door contact without prior appointment**
- **Finalize the requirement for an MAO or Part D sponsor to provide an annual notice to opt-out of communication. CMS should maintain flexibility with the way this notice can be provided through electronic and mailed written communication.**
- **Do not finalize limitations on the ability for a sales agent to call a potential enrollee more than six months following the date that an enrollee first requested information. Instead, we propose a limitation of 13 months following the initial request. This would allow continuity of communication with a beneficiary who contacted a plan at the end of the calendar year, through the start of the following Annual Enrollment Period.**
- **Do not finalize the 12-hour prohibition on marketing and educational events taking place in the same location and the 48-hour ban on enrollment follow-up following the completion of an SOA form. We encourage CMS to instead maintain these as guidelines rather than codifying them as standards, consider reasonable exceptions to these timelines, and/or consider alternative approaches to ensuring the separation between education and marketing interactions.**

B. General Communications Materials and Activity Requirements and General Marketing Requirements

CVS Health appreciates CMS' concern that marketing materials may be misleading, overwhelming, or confusing to beneficiaries. We believe that CMS may be underestimating the value of third-party agent and broker communications in generally educating beneficiaries about their benefit options, without ever mentioning a specific issuer or plan or attempting to "sell" any coverage. Moreover, these agents and brokers may assist beneficiaries with benefits outside of Medicare, such as life or travel insurance, and beneficiaries may seek out reputable third-party agents and brokers based on their brand, customer service and other services. It is preferable for the beneficiary and plans if it is clear that these products and services are not associated with or offered by the MA or Part D plan. We recommend that CMS carefully consider the varied products and services these agents and brokers may offer and not unduly limit or inadvertently prevent agents and brokers from providing these services.

If CMS intends to move forward with these proposals, we will ask CMS to provide more specific guidance through the final rule, the Medicare Communications and Marketing Guidelines (MCMG), and additional subregulatory guidance and examples. For example, plans and brokers need clarification on difference between "marketing," "general communication," and "education." We are concerned with limitations that may be

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interpreted overly broadly (e.g., use of a Medicaid card as a visual example in educating an enrollee being reported as misuse/misleading).

In addition, CMS should clarify the definition of "plan name," and precisely how an image of a Medicare card may be used. For example, plans may show beneficiaries an image of a Medicare card to determine if the beneficiary may be dually eligible or already have coverage. There are other areas that need clarification; for example, differentiating between what rules apply to Third Party Marketing Organizations (TPMOs), First Tier, Downstream, and Related Entities, and plans themselves. Similarly, CMS would prohibit the use of the Medicare name, CMS logo, or official products, including the Medicare card, in a misleading manner, but the rule does not provide sufficient guidance on what, precisely, CMS means by "misleading." The examples provided by CMS in the preamble are subjective (e.g., "tiny" and "difficult to read"). An alternative to the proposed subjective rule might be to provide a more objective approach such as specifying where the disclaimer must appear on the marketing piece along with font size and type so that it is more prominent and conspicuous. The defined objective rule would provide a safe harbor for plans by rule instead of it being based on personal subjectivity. In short, CVS Health is concerned that while we generally understand CMS' purpose, without clarification, the proposal may be overly restrictive and contribute to more beneficiary confusion rather than targeting and eliminating deceptive practices.

In implementing these new proposals, CMS must also update the MCMG with sample marketing materials and language, including examples that are not compliant. Updated guidance and examples in the MCMG would provide all plans with a clear standard that we can refer to as we exercise oversight over our own marketing material, as well as material created by TPMOs and brokers. It would also be helpful to see how CMS envisions the discloser/disclaimer that must list every sponsor name in marketing materials. Given the number of sponsors and plan names, it would be helpful to see how CMS believes that this disclosure can be made without confusing the beneficiary or swallowing the substantive content. For example, while we can envision how this may work in print according to the proposed font standards, television, online, and social media advertisements may be more difficult to create. An alternative approach could be to require that TPMOs and brokers include an updated page on their website listing the names of all carriers they contract with, organized by the states in which those particular carriers are sold.

Similarly, while CVS Health supports the prohibition on plans advertising benefits that are not available in a service area in a misleading manner, we need clarification on the use of references to benefits in general advertising. Current ads may say "dental, vision" with the clear disclaimer that benefits may vary and the expectation that an agent must walk through the specific benefits available in a given area if the potential enrollee contacts the plan or agent. General ads will be especially tricky in multi-region/state areas where local advertising spans across areas, such as D.C., Maryland and Virginia and requiring specificity in these types of advertisements will be very costly to provide little added value. We urge CMS to ensure that this new proposal would not limit the ability to produce general marketing material.

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One way to enforce this proposal in a balanced manner is to set thresholds for the use of permissible general references to benefits in a given area. For example, if 85 to 100 percent of Aetna's plan offerings in a given area offer a particular benefit such as dental coverage, we state that "most plans offer dental coverage." If 65 to 84 percent of our plans carry the benefit, we state that "many plans offer dental coverage," and if 40 to 64 percent of plans carry the benefit, we say "some plans offer dental coverage" with the additional disclaimer that "not all benefits available in all plans." CMS can utilize similar thresholds to strike a balance on oversight without unintentionally penalizing plans already in compliance.

Recommendations:

- **CMS must update the Medicare Communications and Marketing Guidelines with guidance clarifying the requirements proposed in this section. Updated guidance, along with examples of compliant and non-compliant material would provide all plans with a clear standard that we can refer to as we exercise oversight over our own marketing material, as well as material created by TPMOs and brokers.**
- **CMS should ensure that these proposed requirements do not limit the ability to create general advertisements, especially in multi-state regions where it may be difficult to regulate the range of broadcast advertising. We suggest ways that CMS can enforce thresholds and standards without restricting general marketing.**

C. Required Materials and Content

We support the proposal to require the use of the Pre-Enrollment Checklist (PECL) and standardized checklists to ensure that agents screen for the information necessary to identify the plan that best meets the beneficiary's health care needs. We continue to recommend that these be recognized as guides for scripts/discussions and that each agent must still be able to tailor their conversation to the beneficiary as long as the material in the PECL is discussed.

- **Recommendation: We support the required use of the PECL as a guide to ensure agent scripts and conversations cover essential information with beneficiaries.**

D. Licensing of Marketing Representatives and Confirmation of Marketing Resources

Aetna allocates significant resources to monitoring the TPMOs, agents, and brokers with whom we work. We hold our contracted partners to the same code of conduct that Aetna employees are held to. We strongly support CMS' proposal that MA plans have an oversight plan in place and that plans report agents engaged in non-compliant activity to CMS. We recommend that CMS continue to work with plans to identify the most efficient ways to

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engage in real-time oversight and reporting. As CMS notes, Aetna, along with many other plans already utilize call recordings, secret shoppers, and other mechanisms to monitor agent and broker compliance.

While Aetna agrees that plans must be responsible for reporting instances of non-compliance to CMS, we are concerned that the expectation to do this in real time may result in overreporting and an increased need for both CMS and the plans to spend time and resources investigating a large number of cases instead of homing in on those agents and brokers that are clearly non-compliant. We thoroughly review every Aetna-related complaint received directly to us or through CMS (e.g., 1-800-MEDICARE or Medicare.gov). In many instances, after reviewing call recordings between an agent and beneficiary, we find that the agent was not deceptive or non-compliant, but instead may benefit from additional training and coaching to improve their communication. While we support the requirement to report non-compliant agent and broker interactions to CMS, we also recommend that CMS still allow plans to perform their own review and performance improvement activity.

Furthermore, to better target plans, brokers, and agents who may be engaged in non-compliant activity, we encourage CMS to work with the industry to set standards on key indicators, such as inappropriate rates of rapid disenrollments. MAOs and CMS should focus greater oversight on those plans who exceed these standards.

Recommendations:

- **Finalize the requirement that MAOs have an oversight plan in place and report non-compliant agent activity to CMS. However, CMS should work with plans to identify ways to monitor compliance in real-time.**
- **CMS should work with the industry to develop key indicators for non-compliance, such as rapid disenrollments linked to a particular agent or broker.**

E. Prohibition on Distributing Personal Beneficiary Data Collected by a TPMO

CMS proposes to address issues with TPMOs distributing beneficiary contact information to multiple entities. CMS believes that when a beneficiary calls a company based on an advertisement, the beneficiary is only expecting to connect with that particular company, not to have return calls made to their personal home or cell number from other companies.

CVS Health appreciates CMS' concern and we agree that beneficiaries should not receive an unreasonable number of marketing inquiries. However, we believe that CMS' proposal is too broad and should not prohibit any distribution of beneficiary data collected by a TPMO. This would limit information provided to a beneficiary to a point where a beneficiary could receive too little information about available plans; a single TPMO, contacted directly by a beneficiary, may not work with all available issuers or have experience with all available

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plans. Limiting TPMOs from sharing beneficiary leads means that beneficiaries may not receive all the information necessary to make the best coverage decision for them.

To address the issue that CMS has identified, we believe that CMS could propose a limit on how long a TPMO would be permitted to distribute/sell leads to other TPMOs. This would prevent "old" or "stale" information from being shared, helping to ensure that only beneficiaries that are interested in being contacted are contacted. For example, CMS could propose something along these lines: "permission to contact shall expire once the contact is made or nine months after the original date of receipt for MA plan and PDP leads, whichever comes first. If a permission to contact is provided by another TPMO source, the original date of the TPMO shall be used."

Alternatively, or in addition, we believe that it would be reasonable for CMS to limit the number of TPMOs with which the initial, lead-generating TPMO could share the beneficiary information. In other words, CMS could limit the number of times that a lead could be sold.

- **Recommendation: CMS should not prohibit all distribution of beneficiary information collected by a TPMO. Instead, CMS should consider other reasonable limits to protect beneficiaries, including prohibitions on the sharing of "stale" information or limiting the number of times the same beneficiary's information may be shared.**

V. Strengthening Translation and Accessible Format Requirements for Medicare Advantage, Part D, and D-SNP Enrollee Marketing and Communication Materials (§§ 422.2267 and 423.2267)

Current section 422.2267 provides that "all required materials and content" must meet standards specified by CMS. Under the proposal, CMS would now require MA organizations, cost plans, and Part D sponsors to provide all required materials to enrollees in any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package service area or accessible format using auxiliary aids and services upon receiving a request for the materials or otherwise learning of the enrollee's preferred language and/or need for an accessible format using auxiliary aids and services.

CMS also proposes that for D-SNPs, the individualized plans of care for special needs plans must also be provided in the preferred language/method upon receiving a request. Finally, fully integrated dual eligible special needs plans (FIDE SNPs), highly integrated dual eligible special needs plans (HIDE SNPs), and applicable integrated plans (AIPs), translate required materials into any languages required by the Medicare translation standard plus any additional languages required by the Medicaid translation standard as specified through their Medicaid capitated contracts.

CVS Health fully supports CMS' efforts to ensure that Medicare and Medicaid beneficiaries receive accessible information on their benefits. CVS Health offers a number of accommodations to customers, patients, and colleagues in order to make our services

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accessible to everyone, including individuals with disabilities. We've built strong partnerships with community organizations to ensure we're a proper reflection of the customers and members we serve. Enterprise-wide, we strive to meet and exceed best practices and standards for accessibility and we continue our efforts, every day.

We strongly support the concept of making required member materials accessible to all members but as proposed, we are concerned with both the length of time translation of care plans could take as well as the potentially high costs of translating all required materials on a *standing basis*. While plans currently provide these materials translated on request, plans may not have all of the required materials translated into every possible required language at the ready. These materials are often prepared well in advance of open enrollment for the following plan year and requiring all plans to have all materials translated on a standing basis, whether or not there is a need for such translation by the beneficiary, diverts resources away from other necessary services and may be quite costly for plans.

CMS guidance provides that required communications must be delivered to beneficiaries within a certain timeframe. As a result, plans may still have to send the English version to meet deadlines and then send requested translation or accessibility format. Operationalizing a method for removing this duplication is complex, time-consuming, and costly. For example, the initial setup for Braille accommodation is 20 working days with an additional 10 days for production after plan approval. Beneficiaries who opt-in for audio versions of documents will receive a paper copy first, then an audio version more than five days later. After initial setup, Braille and audio-created beneficiary communications take at least five days (for audio) and seven days (for Braille), and documents cannot be created and maintained to send Braille or audio within three days of the trigger. Not only are these processes time and resource intensive, but they are also costly.

When variable text documents must be translated, the time and resources required, and the resulting costs, increase. For additional context about the complexities involved in complying with this proposal we highlight the following examples:

- **Part D Transition Letters:** These letters must be created and sent within three days of adjudication of a temporary transition fill. The member document is personalized, including name, address, medication, and timing. Although all communications are sent to print within 24 hours of the notice trigger, because of the time required for alternate formats and translations, an initial English copy would still need to be sent first in order to meet the required communication deadline.
- **Coverage Determinations:** These must be sent within 72 hours for standard determinations and 24 hours for expedited requests. These compressed turnaround times include weekends and holidays—times when a translation service may not be available. There is not enough time to complete a translation or alternate format in the timeframe allotted, so an initial English copy would still need to be provided to be compliant.
- **Part D Member Pharmacy Directories:** These must be sent within 3 days of a member request. These are also personalized to include geo-coded pharmacies

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based on the beneficiaries' exact address. The complexity of collecting this data combined with a need for translation or alternate format is not feasible in 3 days and an initial English copy will need to be provided to meet the delivery timeframe requirements.

- **Medication Therapy Management (MTM) Comprehensive Medication Review (CMR):** Standardized communications must be sent out within 14 calendar days. These documents, averaging around 10 pages each, are highly customized to each beneficiary and therefore take time to properly format and/or translate.

We also appreciate CMS' proposal to have care plans accessible to beneficiaries. However, we think this too will require additional time and resources to implement. As CMS is aware, the care plan may start with a relatively standard framework, but it is quickly customized for the beneficiary. Because of the various parties involved in the care plan design process, it may be difficult for plans to ensure that every part is accessible. For example, if a treatment provider makes notes, it may not be possible for the plan to ensure that those notes are translated or provided in accessible formats such as Braille. Even for items that the plan can translate, we note that care plans often involve complex and technical terms—terms that may not be easily translated immediately.

Additional resources are required when a beneficiary needs both an alternative accessible format and translated materials. CVS Health currently does not have templates in place for all proposed translations in alternate formats and would not be able to provide them on a standing basis without a delay in delivery. This is another example of an occasion that would require us to provide the materials first in English, to meet CMS' deadlines, and then again in the appropriate format/translation. Finally, we note that CMS may not appreciate that these new requirements may require revisions to vendor contracts or contracting with entirely new vendors to ensure that we are able to translate documents on a standing basis. Contracting also adds to the time needed in order to comply with the proposal.

In CMS' estimated impact grid, it states it would cost $10.4 million for plans to provide materials to enrollees on a standing basis. CVS Health's estimation shows that this is grossly underestimated when taking operational updates and maintenance, CVS staffing increases, and IT programming into account.

- For translation alone, to meet current mandated turn-around times per letter without sending an initial English version, CVS Health would need to increase the number of templates exponentially. For example, currently the English language EOB letter type has 135 templates. Increasing the number of templates to accommodate more 30 languages would increase vendor programming by over $23 million each year and translating those templates would cost an additional $4 million annually. We would also need to update current source systems to pull in additional language codes which would cost approximately $2.8 million annually.
- For the accessibility portion of the proposed rule, costs to produce the EOB alone would increase by approximately $3 million annually for Braille versions and $1 million annually for audio versions. Accessibility cost increases are significantly less

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than translations due to the lower demand for these services, which is why CVS Health is also in favor of expending these resources on more advanced technologies to meet the needs of today's beneficiaries.

- Finally, these work product increases would need be accompanied by approximately 5x the current operational workforce to meet these demands.

CVS Health supports alternate formats to meet beneficiary needs; however, we believe that utilizing currently available technology can result in more beneficial and efficient ways to meet beneficiary needs. For example, we have found that many blind and visually impaired beneficiaries use screen readers as an accessibility aid. In a 2017 study conducted by WebAIM, a nonprofit organization based at the Center for Persons with Disabilities at Utah State University, 75.6% of respondents noted they exclusively rely on screen reader audio and only 4.9% responded they exclusively rely on printed Braille materials.[19]

In short, CVS Health strongly supports accessibility and we already strive to ensure access, every day. We recommend that CMS consider delaying the effective date of these requirements, to ensure that all plans can comply.

Recommendations:

- **Finalize the proposal to provide all required materials in translated and alternative formats but delay the effective date to apply to materials for the 2025 plan year as many materials for the 2024 plan year have already been prepared.**
- **Align translation thresholds at the federal-level rather than setting state-specific standards.**
- **Clarify that plans may provide certain translated materials and accessible formats within a reasonable timeframe after standard materials have been provided; particularly for documents such as care plans that may contain information tailored to the beneficiary.**
- **Permit the use of new technology and other auxiliary aids, such as e-readers/screen readers for the blind and visually impaired rather than Braille. With the availability, expediency, and increased adoption of screen readers, the requirement for Braille printing of documents is duplicative, expensive, and obsolete.**
- **Permit plans to meet this requirement through immediate resources to support beneficiaries, such as translative services, which already exist and work well.**
- **Consider finalizing this requirement for those communications that are most critical for a beneficiary (ANOC, EOC, Formulary, Summary of Benefits) versus requiring all Medicare communications listed in eCFR 422.2267 and 423.2267.**

[19] WebAIM Screen Reader User Survey #7 Results. Institute for Disability Research, Policy, and Practice. https//webaim.org/projects/screenreadersurvey7/.

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VI. Other Medicare Advantage Proposals (§§ 422.111, 422.112, 422.113, 422.116, 422.152, and 422.267)

A. Appointment Wait Time Standards

CMS proposes to codify certain wait time standards from current guidance and to extend those standards to behavioral health services. CMS clarifies that the new minimum appointment wait time standards would be added to the existing requirement that MA organizations establish written policies for the timeliness of access to care and member services so that MA organizations must have appointment wait times that meet or exceed the standards proposed. CMS also solicits comments on alternative specific appointment wait times standards to apply to MA organizations.

CVS Health's goal is to ensure that our members are as healthy as they can be; access to services in a timely manner is critical to that goal. But we must remind CMS that health plans alone cannot solve systemic access issues. Plan standards have to consider the availability of providers in an area. CMS also must be mindful of geographical differences. Different areas have different numbers of providers in any particular specialty and this is true whether the area is categorized as rural or urban. Providers also determine whether they have capacity, and plans must rely upon providers to continue to update their availability. Provider shortages may create wait time challenges that are simply not within the control of plans or even healthcare systems. CMS should consider way of identifying and addressing systemic capacity issues; plans cannot solve this issue.

We are particularly concerned that the proposed wait time standards do not seem typical or particularly realistic, particularly for a Medicare or Medicaid population. There seems to be a disconnect between the actual systemic capacity of health care providers in the United States and the standards CMS has included in the proposed rules. In sum, plans that make good faith efforts to create robust networks and keep their information updated should not be penalized for systemic access problems or other external factors that may impact wait times such as enrollee geography, weather, and provider preference. We urge CMS to revise its expectations to be more realistic and to recognize the limited ability plans have to control wait times.

Recommendations:

- **Maintain wait times as standards in guidance, but do not codify them.**
- **Align wait time standards for behavioral health services with the NCQA standards which are already standardized across provider types.**
- **Consider options to increase the availability of providers and clarify that good faith efforts to create robust networks and keep relevant information updated will not be penalized for systemic access problems.**

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With respect to particular proposals, we recommend that CMS:

- **Consider an initial period of monitoring to better understand the current state of wait times across primary care, behavioral health, and specialty care. Intentional assessment and evaluation may better inform standardization requirements.**
- **Consider implementing only the primary care time proposal as a pilot. Lessons learned from the primary care pilot may then inform appropriate standards for behavioral health services. By tiering implementation, we believe there will be increased efficiency and quality.**
- **The primary care pilot can also help CMS determine what, if any, compliance thresholds should apply to 90 and 95 percent of appointments.**

In addition, CVS Health asks CMS for clarification on the following items:

- **Is telehealth included in wait time standards? We believe that allowing plans to include telehealth appointments in the numerator and denominator of the measure more accurately reflects actual patient access.**
- **How does CMS propose to account for the variation in availability of certain specialties? We do not believe it is appropriate, or even possible, to measure actual accessibility if CMS does not account for systemic accessibility, national shortages, etc.**
- **How does CMS propose to accommodate member preference in the measurement? For instance, a member may intentionally schedule an appointment over a month in advance to accommodate travel or other schedules. Or they may prefer that particular provider and are willing wait longer to see them than another provider that may be available to them within the prescribed time frame.**
- **How does CMS propose to consider no-shows? Medicaid providers, in particular, may double-book in anticipation of high no-show rates; this may make their availability materially different from a provider that sees a high percentage of established patients and has a very low rate of no-shows.**

B. Behavioral Health Network Adequacy

CMS would add three new behavioral health provider specialty types to the network adequacy evaluation, specify that access to service standards include access to providers that specialize in behavioral health services, and add all the new behavioral health specialty types to the list of the specialty types that that will receive the credit if the MA organization's contracted network of providers includes one or more telehealth providers of that specialty type that provide additional telehealth benefits for covered services.

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CMS also proposes to add behavioral health services to the types of services for which MA organizations must have programs in place to ensure continuity of care and integration of services, including for community-based and emergency services.

As explained above, CVS Health recommends that CMS consider a pilot program for wait times, using primary care. Based on that pilot, CMS could then develop wait time standards for behavioral health. In the alternative, we suggest that CMS clarify that behavioral health wait time standards are just standards and are not requirements. As CMS is aware, the United States does not have a sufficient number of behavioral health providers to meet its need. We encourage CMS to explore other means to increase the number of behavioral health providers available. While CVS Health strongly supports expanded access to behavioral health services, the limited number of providers is exacerbated by the limited number of providers willing to contract with plans that reimburse based on Medicare payment rates. Plans have a limited ability to address these workforce challenges and any CMS proposal related to behavioral health should consider these limits.

CVS Health supports adding the three new behavioral health provider specialty types to the network adequacy evaluation, but we recommend that this provision not be effective before plan year 2025. We also recommend that as additional provider types are added to network adequacy standards, CMS should improve the exceptions process as the density of available providers will always vary by region and there may be limitations as a result. We also support the 10-percentage point credit for behavioral health telehealth providers for network adequacy.

Recommendations:

- **Consider a pilot wait time program (described above) and inform a future behavioral health wait time proposal based on the results of the pilot.**
- **Clarify that any of the standards finalized from this Proposed Rule are standards, not requirements.**
- **Add the three new behavioral health provider specialty types to the network adequacy evaluation, but this addition should be effective no sooner than plan year 2025, especially for prescribers of medications for Opioid Use Disorder (MOUD). Removal of the X-waiver requirement under the Consolidation Appropriations Act of 2023 and other pending regulations will lead to fluctuations in the MOUD provider population between now and 2024.**
- **Improve the exceptions process to address the workforce issues in behavioral health.**
- **Finalize the telehealth behavioral health provider credit for network adequacy.**

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C. Enrollee Notification Requirements for Medicare Advantage (MA) Provider Contract Terminations

CMS proposes to add additional enrollee notification requirements for provider contract terminations focused on primary care and behavioral health providers. We are concerned that as proposed, CMS' requirements would disrupt current industry standards on beneficiary notification and potentially create more beneficiary confusion.

CMS proposes to require that a termination notice be sent to all enrollees who have ever been patients of these terminating primary care or behavioral health providers (not just current patients). We are concerned that proposal, without a definitive time limit, is overly broad and would require significant staff time and resources. Beneficiaries may be confused perceive their plans as "out of touch" if they are being contacted about a provider they have not seen in years.

CMS also proposes that MAOs notify enrollees at least 45 calendar days before the contract termination for primary care or behavioral health providers. The industry standard for this notification is currently 30 days as there may be providers who terminate their contract with short notice. We recommend that CMS maintain the existing requirement to provide enrollees with notice no less than 30 days after the receipt of a provider's notice of contract termination.

Recommendations:

- **Do not finalize the proposal that a termination notice be sent to all enrollees who have ever been patients of a terminating provider. CMS should work with plans to create a defined cut-off period for those enrollees who should be notified. For example, "notice should be sent to enrollees whose last visit/encounter occurred within X number of years from the date of termination."**
- **CMS should maintain existing standards for plans to notify enrollees of contract termination within 30 days of the plan's receipt of the provider notice. Written notice should be considered sufficient for meeting this requirement.**

D. Health Equity

CMS notes that current regulations require MA organizations to ensure that services are provided in a culturally competent manner and in this proposal, CMS says it is further clarifying the broad application of this requirement to include limited English proficiency, race, culture and ethnicity, disability, LGBTQIA+, individuals in rural areas and individuals adversely affected by persistent poverty or inequality.

CMS proposes to codify two provider directory best practices as regulatorily-required, so that an MA organization would be required to include each provider's cultural and linguistic capabilities, including languages (including American Sign Language) offered by the provider or a skilled medical interpreter at the provider's office in their provider directories.

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In addition, MA organizations would be required to identify which providers offer medications for opioid use disorder. While we support the intent of ensuring that provider directories serve as a resource to help beneficiaries find culturally competent care, we continue to emphasize the challenge of maintaining accurate, up-to-date provider directory information as this is a shared responsibility between providers and health plans.

Recommendations:

- **CVS Health strongly supports broadening the requirement that MAOs provide culturally competent care to all beneficiaries.**
- **We support CMS' proposal to require the inclusion of each provider's cultural and linguistic capabilities in the provider directory. However, we note that MA organizations are limited in the information that they can collect through provider-reported responses.**

E. Digital Health Education for MA Enrollees Using Telehealth

CMS proposes to require MA organizations to have procedures to identify enrollees with low digital health literacy and offer them digital health education to assist with accessing any medically necessary covered benefits that are furnished when the enrollee and the provider are not in the same location using electronic exchange. We agree with CMS that supporting digital health literacy will help improve enrollee access to services through telehealth. We also agree with CMS' assessment that equity in digital health literacy is difficult to attain due to a variety of factors such as but not limited to age, education level, language barriers, and the lack of private space or technology to support a virtual visit. To that end, we would welcome working with CMS to design standard communications that CMS could provide to all beneficiaries; this would ensure that all beneficiaries receive the same, accurate digital literacy support and education.

MA organizations would also be required to provide information about digital health education available on request. While we support the collection of this information, we ask that CMS delay any requirement to collect and provide information to CMS until 2025. This will allow plans to focus first on the development and testing of screening methods that best fit the populations they serve. This will also provide us with additional time to develop an infrastructure for data collection. For example, information about an enrollee's digital health literacy may come up across a variety of interactions, such as a provider visit, a case manager conversation, or even as part of a customer service call.

Additionally, we remind CMS that measuring ongoing engagement with digital health education may be difficult to track. While CVS Health and Aetna already provides several educational resources on our website[20], there may be cases where a referral to a

[20] Joseph, C. *Telemedicine: How to take advantage of this health care perk*. Aetna. https://www.aetna.com/health-guide/what-is-telemedicine.html.

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community organization or partner may be more appropriate to provide the enrollee with targeted education on their specific need. Aetna is currently partnering with local communities on pilots to improve digital health literacy.[21] We encourage CMS to utilize the lessons learned from this activity to build the framework for data collection and measurement efforts.

Recommendations:

- **We support the identification of enrollees with low digital health literacy and offering those enrollees digital health education. CVS Health encourages CMS to develop standard beneficiary materials that can be provided on websites or in written material.**
- **We encourage CMS to maintain flexibility with the requirement to screen beneficiaries for digital health literacy this as there are currently no standardized methods for screening and there may be wide variation in the levels of reported digital health literacy among enrollees.**
- **We recommend that CMS require data collection on enrollee digital health literacy and engagement in educational resources no earlier than 2025. This will allow plans to focus first on the development and testing of screening methods that best fit the needs of the populations they serve.**

F. Quality Improvement Program

CMS proposes to require MA organizations to incorporate one or more activities into their overall quality improvement program that reduce disparities in health and health care among their enrollees.

CVS Health supports CMS' efforts to increase quality and reduce health inequities. CVS Health and Aetna have already implemented several programs to reduce disparities, including staff training to ensure that underserved populations have access to customer service. grievance, and appeals services that are culturally and linguistically appropriate, including required training in conscious inclusion and unconscious bias for all our employees. We further appreciate and strongly support CMS' proposal to allow plans to define appropriate quality improvement activities.

- **Recommendation: We support this proposal. We strongly support plan's ability to define appropriate quality improvement activities that address their member's unique circumstances.**

[21] Community News: *Aetna Medicaid gave $450,000 to support Texas communities.* CVS Health. Sep. 13, 2022. https://www.cvshealth.com/news/community/a-commitment-to-community-aetna-empowers-local-organizations-to.html.

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VII. Shortages of Formulary Drug Products During a Plan Year (§ 423.120)

CMS proposed to codify and expand existing sub-regulatory guidance regarding shortages of formulary drug products during a plan year. Specifically, it proposes to require Part D plans to permit enrollees affected by a shortage to obtain coverage for a therapeutically equivalent drug or an interchangeable biological product, if any, for at least the duration of the shortage without having to obtain an exception or meet any prior authorization or step therapy requirements. CMS states that Part D sponsors would be required to cover a therapeutically equivalent drug or interchangeable biological product as an alternative to the formulary product subject to shortage if there is claim submitted for the alternative.

If this is the case, CVS Health requests CMS to specify any requirements for implementation, including expected timing after the FDA lists a new drug shortage on its website. We also ask for guidance on acceptable approaches that would meet the intent of the requirement. For example, can the coverage for a therapeutically equivalent drug be provided through a process such as call center entry of an override for individual members who are unable to fill the drug in shortage, or is there an expectation or requirement that coverage must be provided at the point-of-sale?

Recommendation:

- **CMS should provide guidance on the implementation of the requirement to cover an alternative formulary product during a drug shortage if a claim is submitted for the alternative. This guidance should include (i) giving plans and their PBMs sufficient time after the FDA lists a new drug shortage on its website to implement this requirement, and (ii) allowing alternative approaches to coverage at point-of-sale, such as allowing a call center to enter an override for individual members who are unable to fill the drug during the shortage.**

VIII. Changes to an Approved Formulary (§§ 423.4, 423.100, 423.104, 423.120, and 423.128)

Currently Part D sponsors may, subject to certain requirements, immediately remove from the formulary a brand name drug and substitute its newly released generic equivalent. CMS proposes to permit Part D sponsors, subject to the same conditions, to immediately substitute: (i) a new interchangeable biological product for its corresponding reference product; (ii) a new unbranded biological product for its corresponding brand name biological product; and (iii) a new authorized generic for its corresponding brand name equivalent.

CVS Health applauds the proposals to expand flexibility to include interchangeable biologics, unbranded biological products and authorized generics. However, CVS Health believes the current requirement to implement a formulary enhancement (i.e., addition of a new product) 'at the same time' as a negative formulary change could potentially

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undermine the intended benefit. A better member experience, increased industry adoption, and opportunity to reduce costs may result if plans had additional implementation flexibility.

Specifically, plans can expedite implementation of a formulary enhancement (e.g., a new generic or authorized generic) to provide beneficiaries with access to a new lower cost alternative as soon as possible. However, additional time is often required to complete other activities prior to making and implementing decisions regarding the current formulary product. This may include activities such as evaluation of the new product's attributes (e.g., formulation, interchangeability, pricing), confirmation of sufficient availability in the marketplace, communication of changes, and updating of systems. Providing a window of time after addition of the new product to implement a corresponding negative change (instead of requiring that both changes be implemented simultaneously) would support these activities, with the goal of providing a seamless member transition, avoiding potential delays in access to care and a better member and provider experience.

This may be particularly impactful in scenarios where there are multiple interchangeable biologics and it may not be readily apparent to the member, pharmacist, or physician as to the preferred interchangeable product, which may lead to a poor member experience and potentially delayed access to care. This added time would still allow plans to follow their existing best practices for providing retrospective member notifications, including through use of the Explanation of Benefits (EOB). CVS Health requests that adding language to Section 4 of the Calendar Year (CY) 2024 Explanation of Benefits (EOB) model to support these immediate substitution changes, to align with planned edits for the CY24 Notice of Formulary Change letter, as the EOB is used to notify beneficiaries.

Recommendations:

- **For situations where plans are permitted to make immediately formulary substitutions, CMS should allow plans a window of time to remove the current formulary product rather than requiring that the removal occur at the same time as the addition. This flexibility will allow plans to ensure a seamless transition for beneficiaries.**
- **CMS should revise Section 4 of the Calendar Year (CY) 2024 Explanation of Benefits (EOB) model to provide language supporting these immediate substitutions changes**

IX. Standards for Electronic Prescribing (§ 423.160)

CMS proposes to adopt the NCPDP SCRIPT Standard, Version 2022011 as the standard for electronic prescribing transactions, and the NCPDP Real-Time Prescription Benefit Standard, Version 12 as the standard for real-time benefit tools ("RTBTs") to be supported by Part D sponsors. Compliance with both of these standards would be required by January 1, 2025. However, since the new electronic prescribing standard would be effective from the

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effective date of the final rule and CMS proposes to allow use of the current standard, NCPDP SCRIPT standard version 2017071, until January 1, 2025, this means there would be a transition period from the effective date of a final rule until January 1, 2025, during which both standards would be available for use.

CVS Health supports updating the e-prescribing standard and the adoption of a standard for RTBTs, which will ensure consistency across the industry. In this regard, we recommend that CMS considers requiring that patient- facing RTBTs also use the same NCPDP standard to assure consistent information is received by both beneficiaries and the prescribers, regardless of the channel. To take advantage of the most recent enhancements to the RTBT standard, we also support NCPDP's recommendations to adopt the Real-Time Prescription standard version 13, instead of version 12.

CVS Health also recommends adoption of NCPDP SCRIPT version 2023011, rather than 2022011 as outlined in the proposed rule to allow for the most current version of SCRIPT to be implemented.

While CVS Health appreciates the transition period and January 1, 2025, compliance date, we ask CMS to extend the compliance period by at least 12 months to January 1, 2026 and allow for an 18-month transition period for both standards. This longer implementation period is necessary because many of the same resources will be utilized to implement and test both the new e-prescribing SCRIPT standard and the RTBT standard. In addition, the proposed timeline overlaps with the upcoming changes proposed to the NCPDP Telecommunication Standard upgrade to Version F6 and NCPDP Batch Subrogation updates (CMS-0056-P). There are also several other significant Medicare Part D changes occurring in 2025 due to the Inflation Reduction Act, such as a maximum monthly cost-sharing program, Medicare Part D redesign, and significant updates to the Prescription Drug Event (PDE) file layouts. Many of these changes will impact the RTBT, and the longer time frame will allow sufficient time to validate the new requirements, such as the Maximum Out-of-Pocket (MOOP), reductions in beneficiary cost-sharing due to the new manufacturer discount program, and the ability for the beneficiary to opt into the maximum monthly cost-sharing program, prior to using the new standard to communicate these benefits to the prescriber. Finally, requiring implementation of the new e-prescribing and RTBT standards at the same time as these major changes will stretch available resources to the limit, require multiple processes and system changes at the same time, and increase the risk of errors, which in turn, may cause beneficiary disruption.

Recommendations:

- **Adopt NCPDP Real-Time Prescription Benefit Standard, Version 13, instead of Version 12, and require the same standard for patient facing RTBTs.**
- **Delay the compliance date until at least January 1, 2026, for implementation of both NCPDP SCRIPT Standard and the NCPDP Real-Time Benefit Standard to allow 24 months for implementation and allow an 18-month transition period.**

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X. Gross Covered Prescription Drug Costs (§ 423.308)

CMS proposes to revise its regulatory definition of ''gross covered prescription drug costs'' ("GCPDC") to mirror the statute's language and to remove the phrase ''actually paid.'' CMS states that this change is to remove any ambiguity that might arise from the current regulatory definition as it may now also be applicable outside of the reinsurance context as a result of the use of the term GCPDC in the Inflation Reduction Act of 2022 ("IRA") for other purposes. CMS states that since he revised definition would not change the fact that Part D reinsurance is ultimately based on net drug costs or change the final reinsurance payment amount a Part D sponsor receives, the proposed revision would not constitute a change in policy or require a change in operations under Part D and would not result in government savings or costs.

CVS Health has concerns with the proposed revision and, contrary to CMS' conclusion, believes it will have a major negative impact on the Part D program and government costs. While the current regulatory definition is relevant only to the calculation of reinsurance costs, as CMS indicates, under the IRA the definition will be used to determine "negotiation-eligible" drugs under the Medicare Drug Price Negotiation Program ("Program"). By revising the definition of GCPDC to exclude all direct and indirect remuneration ("DIR"), including manufacturer rebates received after point-of-sale ("POS"), the proposed definition will disincentivize manufacturers from providing such rebates. Instead, single-source drug manufacturers will focus solely on the negotiated price of their drugs, with the result that Part D sponsors and their PBMS will have dramatically reduced leverage to negotiate rebates with those manufacturers and Part D drug costs will increase, in some cases dramatically. We do not believe that this is consistent with Congressional intent, nor do we believe that CMS is compelled to this conclusion by the definition of GCPDC in the statute.

Section 1860D-15(b)(3) of the Social Security Act ("Act") defines GCPDC as "the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year and costs relating to the deductible. Such costs shall be determined whether they are paid by the individual or under the plan, regardless of whether the coverage under the plan exceeds basic prescription drug coverage." There is no reference to manufacturer discounts or rebates in this definition or to the term "actually paid."

While the term "actually paid" is used in the definition of "allowable reinsurance costs" in Section 1860D-15(b)(2) to make clear that such costs must be calculated after considering all "discounts, chargebacks and average percentage rebates," it does not necessarily follow that GCPDC must be calculated before manufacturer discounts are taken into account. On the contrary, the reason allowable reinsurance costs are a subset of GCPDC has nothing to do with manufacturer rebates, but simply because allowable reinsurance costs are limited to costs (1) incurred by the plan alone, not the enrollee, and (2) for basic prescription drug coverage only. This is precisely how CMS described the distinction in the preamble to the 2005 rule, stating (emphasis added):

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Since allowable reinsurance costs (the subset of gross covered drug costs that are attributable to basic coverage only and are actually paid by the sponsor or plan) can only be fully known after all costs have been incurred for the payment year, we proposed to make payments on an incurred basis to assist PDP sponsors and MA organizations with cash flow.[22]

Any other interpretation would have the anomalous result of determining negotiation-eligible drugs not on the basis of the actual cost to the Part D program of such drugs, but rather, on whether manufacturer discounts, if any, are passed through at POS or after POS. This would give manufacturers considerable control over GDPDC based not on their actual charges, but simply on when they provide their discounts, thus opening up the Program to manipulation and gaming. It is not conceivable that Congress could have intended that if single-source Drugs A and B cost $1200 and $1000 respectively before rebates, but $700 and $1000 respectively after rebates, that Drug A would be considered a higher-cost drug than Drug B and so more likely to be negotiation-eligible.

- **Recommendation: Consistent with the statutory language and Congressional intent, CMS should not change its definition of "gross covered prescription drug costs."**

XII. Part D Proposed Automatic Shipment Requirements (§ 423.505)

CMS proposes to codify its automatic shipment policies consistent with longstanding sub-regulatory guidance. Specifically, among other requirements, CMS states that it proposes to require Part D sponsors to require their network pharmacies to provide a minimum of two shipping reminders to the Part D enrollee prior to shipment, and that sponsors "may specify an approximate shipping date range (for example, 2–3 calendar days) in lieu of an exact date in shipping reminders." However, the proposal then goes on to state that the reminders must include "the scheduled shipping date."

Consistent with CMS's description of its proposal in one section of the preamble, current CMS guidance requires only that the shipping reminder include only a shipping date range in lieu of an exact shipping date. It is not clear whether CMS intends to change this requirement, since it provides no discussion or explanation for the new regulatory text that would require the "scheduled shipping date," and, as mentioned above, there is inconsistent language in the preamble discussion.

Whatever the intent, we ask CMS to consider retaining its policy from the 2020 Final Call Letter that allows a shipping date range, rather than an exact date. This is particularly important because CMS notes it has not received complaints about the current policy. Pharmacies do not have control over the shipment process, and there are many variables that could cause a shipment to arrive a day before or after the anticipated delivery date. Requiring pharmacies to specify an exact date would likely lead to greater beneficiary

[22] 70 Fed. Reg. at 4312.

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anxiety and dissatisfaction, since beneficiaries would have relied on the date specified in the shipping reminder, and there are likely to be occasions when, through no fault of the pharmacy, the actual delivery date is different from that specified in the reminder. A narrow date range is much less likely to lead to such frustration and anxiety and still provides sufficient information for beneficiary planning purposes.

Within the shipment reminder CMS proposes to include, "any applicable cost sharing." CVS Health believes including the applicable cost-sharing in the reminder could lead to confusion if a beneficiary has other medication activity within their plan that causes the benefit level to change between the two reminders. For example, at the time of generating the first or second shipping reminder, it may appear the next mail-order pharmacy claim for a maintenance medication will be covered under the initial coverage limit (ICL). However, a beneficiary might then fill an antibiotic or other acute medication at a retail pharmacy prior to the final processing and shipment of the maintenance medication. This scenario could cause the maintenance medication to be covered partially or fully within the coverage gap, which could impact a beneficiary's cost sharing.

As stated earlier, CVS Health recommends codifying the language finalized within the 2020 Call Letter published on April 1, 2019 in which CMS finalized shipment reminders for cost share to be flexible and plans were permitted to provide information on how to determine cost-sharing of an upcoming shipment, in lieu of the exact cost sharing amount.

- **Recommendation: CMS should codify its current automatic shipment policy, which is working well and for which there have been no complaints and continue to allow shipment reminders to include a date range rather than an exact shipment date and allow information on how to determine cost-sharing in lieu of the exact cost sharing amount.**

XI. Civil Money Penalty Methodology (§§ 422.760 and 423.760)

CMS proposes to revise its "minimum penalty increase policy" with respect to the calculation of civil monetary penalty (CMP) amounts. Among other changes, CMS proposes to eliminate the policy finalized in the Contract Year (CY) 2022 rule to update the minimum CMP penalty amounts no more often than every three years. CMS also proposes to remove the annual cost-of-living multiplier. CMS states that in hindsight "other parts of the regulations" unnecessarily complicated CMS's approach to calculating CMPs, which has the effect of limiting CMS's ability to protect beneficiaries when CMS determines that a higher CMP amount than would normally be applied under the CMP methodology is warranted.

The proposals, if finalized, would allow CMS to set the minimum penalty and aggravating factor amounts each year rather than every three years. While CVS Health appreciates the need for CMS to be able to impose higher penalties in some cases to protect beneficiaries, nothing in the current policy prevents that and, as CMS states, it promotes transparency and consistency. It is for this reason that CVS Health welcomed the language providing that CMS would update minimum penalty amounts no more often than every three years,

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commenting that it would help to ensure that plans in a given audit cycle would be subject to the same penalty amounts. If this language is now removed as proposed, the potential now exists that plans going through a program audit could be subject to different penalty amounts during the same audit cycle, resulting in inconsistencies and disparate treatment. CVS Health recommends that CMS reconsider removing the "minimum penalty increase policy" because this policy helps to ensure parity.

- **Recommendation: In order to ensure transparency, consistency and parity between plans, CMS should retain the regulatory language that provides that minimum penalty amounts will be adjusted no more often than every three years.**

XII. Part D Sponsor Website Requirements (§§ 423.2265(b)(12) and 423.2265(c)(1)(vi))

CMS proposes, consistent with existing policy, to require a Part D sponsor to post its utilization management (UM) criteria, as approved by CMS, be posted on the plan's website by October 15 prior to the plan year. CMS states that plans may continue either to post plan-specific UM criteria within a custom form or to post these separately from the model form.

CVS Health supports this requirement, but since CMS does not always approve all UM criteria before October 15 of the prior plan year, we recommend that CMS require that the UM criteria be posted by October 15 or after CMS provides approval, if later.

- **Recommendation: CMS should specify that UM criteria must be posted on a Part D sponsor's website by the later of October 15 of the preceding year or after CMS approves the criteria.**

XIII. Part D FDR Subcontractors May Terminate Only at the End of a Month (§§423.505)

CMS proposes a provision will require that contract termination between a Part D sponsor and an FDR initiated by the FDR, providing certain functions as denoted, could only occur after a 60-day notice period and have an effective date that coincides with the end of a calendar month. CVS Health understands that the proposal relates to contract termination for said functions as initiated by the FDR and not the plan or PBM's contracts with downstream entities. As an example, CVS Health understands that the proposed rule is not related to situations where a plan or PBM terminates a pharmacy (due to beneficiary risks or contract violations), but only situations when a pharmacy initiates the termination.

- **Recommendation: CVS Health seeks clarification from CMS that the proposed rule is applicable to terminations initiated by the FDRs and not by the plan or PBM's contracts with downstream entities.**

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XIV. Request for Comment on the Rewards and Incentives Program Regulations for Part C Enrollees (§ 422.134 and Subpart V)

Reward and incentives programs have become an effective way to increase beneficiary engagement in their own care. We appreciate that CMS recognizes that current regulations on the parameters for what is considered a "cash equivalent" may be unclear, especially as gift cards increasingly become a preferred beneficiary reward due to their ability to control the use of the gift card funds.

- **Recommendation: We support CMS providing more specific guidance, especially on the definition of a "cash equivalent," through the Rewards & Incentives regulation so that we can more easily determine which types of rewards are acceptable to CMS.**

PUBLIC SUBMISSION

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Comment On: CMS-2022-0191-0001
Medicare Program: Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, etc.

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Comment on CMS-2022-0191-0001

Submitter Information

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General Comment

Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, CMS-4201-P

Attachments

ALHC Comment Letter_MA Part D Rule 2023.0213_FINAL

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VIA ELECTRONIC SUBMISSION: http://regulations.gov/

February 13, 2023

Chiquita Brooks-LaSure
Administrator, Centers for Medicare and Medicaid Services

Meena Seshamani, MD, Ph.D.
Principal Deputy Administrator and Director
Center of Medicare

Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS–4201-P
P.O. Box 8013
Baltimore, MD 21244

Re: Alignment Health Plan Comments on CY 2024 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Program CMS–4201–P

Dear Administrator Brooks-LaSure and Deputy Administrator Seshamani:

On behalf of Alignment Health, we appreciate the opportunity to comment on the proposed rule: 87 FR 79452 released December 27, 2022 by the Centers for Medicare & Medicaid Services (CMS) titled: *"Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications."*

BACKGROUND

Alignment Health is championing a new path in senior care that empowers members to age well and live their most vibrant lives. Alignment Health is a tech-enabled Medicare Advantage company that serves approximately 108,000 members in 52 counties across six states. The company partners with nationally recognized and trusted local providers to deliver coordinated care. Every member also benefits from Alignment Health's customized care model, powered by its 24/7 concierge care team and purpose-built technology, AVA®. Alignment's mission-focused team makes high-quality, low-cost care a reality for members every day. As we scale our high-quality plans nationwide, Alignment Health upholds its core values of leading with a serving heart and putting the senior first and honoring the voice of the patient.

Alignment Health has dealt with unique challenges with having ten H-contracts ranging in membership from 47 to 77,589 in multiple markets, with the delegated provider healthcare model in California, and with the lingering impacts of the COVID Public Health Emergency, we are proud of our strong Medicare Advantage Star Ratings. Alignment achieved 5 out of 5 stars for its North Carolina HMO plan and an overall 4 stars for its HMO in California in 2023, marking the sixth consecutive year the plan has earned 4 stars or more in California. Alignment Health is also rated 5-star for Part D, as well as rated 5-star in CAHPS "Rating of Health Plan" 2018-2022 which demonstrates our commitment to providing consistent well-coordinated care to our members, to the Centers for Medicare and Medicaid Services (CMS) and the Stars Program evolving goals.

ALIGNMENT HEALTH COMMENTS ON SELECTED PROVISIONS

III. Enhancements to the Medicare Advantage and Medicare Prescription Drug Benefit Programs

P. Medicare Advantage (MA) and Part D Marketing (Subpart V of Parts 422 and 423)

CMS proposes changes related to MA and Part D marketing and advertising rules. We support CMS' proposals to help better educate Medicare beneficiaries about the choices in coverage and protect them from misleading advertising and marketing practices. **We are concerned, however, that more time for implementation is necessary due to the need for more guidance from CMS and potential expanded training for downstream entities well in advance of the fall 2023 Annual Enrollment Period (AEP).** We would like to seek clarification and offer comments on the following provisions:

- CMS proposes to prohibit plans from advertising benefits not available in a service area, unless doing so is unavoidable in a local market.
  We seek clarification from CMS on the definition of "unavoidable." We believe "unavoidable" may be open to interpretation by each organization.

- CMS proposes to require plans to provide an opportunity for a beneficiary to opt-out from contact regarding plan business at least annually in writing. CMS solicits comment on

whether CMS should expand notice requirements to ensure that Medicare beneficiaries are not marketed by MA and Part D plans in a way that is similar enough to cold calling that it should be prohibited.
We recommend this be one-time, upon enrollment and beneficiaries could opt-out by calling in at any time. By requiring plans to send out an annual letter asking for beneficiary preference creates added burden and confusion for beneficiaries.

R. Part D Medication Therapy Management (MTM) Program (§ 423.153(d))

We support the MTM program goals to reduce medication errors and optimize therapeutic outcomes for beneficiaries with multiple chronic conditions who are taking multiple Part D drugs. Alignment Health believes that the most effective approach is to target MTM program eligibility based on the value of the MTM services to the member, favoring quality of health outcomes over quantity of eligible members. We remain committed to making MTM services available to enrollees with complex drug regimens who would benefit most from MTM services. **Accordingly, Alignment Health has serious concerns with the expanded eligibility criteria for the MTM program as constructed and recommends CMS withdraw the proposed targeting criteria requirements for the reasons outlined below:**

- It will be duplicative of numerous clinical programs and drug management programs in place that target comprehensive disease state, medication drug reviews, and medication adherence management. There are several CMS Part C and Part D Star and HEDIS measures in place today to monitor and measure outcomes for many of the same chronic conditions, including but not limited to:
    - D08: Medication Adherence for Diabetes Medication
    - D09: Medication Adherence for Hypertension (RAS antagonists)
    - D10: Medication Adherence for Cholesterol
    - D12: Statin Use in Patients with Diabetes (SUPD)
    - C06: Care for Older Adults – Medication Review
    - C09: Diabetes Care – Eye Exam
    - C10: Diabetes Care – Kidney Disease Monitoring
    - C11: Diabetes Care – Blood Sugar Controlled
    - C12: Controlling Blood Pressure
    - C13: Reducing the Risk of Falling
    - C08: Osteoporosis Management in Women who had a Fracture
    - C15: Medication Reconciliation Post-Discharge
    - C16: Statin Therapy for Patients with Cardiovascular Disease

- As such, there will be significant overlap between the populations in these programs/measures and those that meet the expanded MTM program eligibility criteria, resulting in substantial additional costs to the MTM program without necessarily supporting value-based outcomes. Additionally, the expanded eligibility criteria will make it difficult to continue to prioritize members with complex disease states, such as respiratory

disease and mental health, that do not currently receive as much focus but can significantly benefit from interventions to address gaps in care.

- In addition, it will create extensive administrative strain and operational challenges for health plans and providers alike. We expect that most health plans will not have the staffing to support the aggressive increase in MTM volume and are concerned that there is not enough supply of qualified pharmacists and MTM vendors/contractors to meet the high demand that will be created. The focus of the MTM program will shift from quality to quantity, reducing the amount of time pharmacists are able to dedicate to member interviews, as well as the comprehensiveness of medication reviews, in order to keep up with the volume demand to maintain the Part D Star rating for the MTM Program Completion Rate for CMR. We recommend CMS retire this Star rating measure and make it into a display measure or modify it to shift the focus from the quantity to the quality of calls made.

- The high touch requirements under the expanded MTM program may result in increased member abrasion and drive members to request to be put on a Do Not Contact list, preventing other types of program participation and meaningful outreach conducted by the plan. Similarly, there will be an increase in provider abrasion as provider offices will receive an exponential increase in recommendations related to Targeted Medication Reviews that may detract from their ability to effectively address gaps for patients most in need of therapeutic interventions identified through the MTM program. Increased member and provider abrasion and engagement will detract from the larger overall goals of these MTM programs, to the detriment of health outcomes.

We urge CMS to withdraw the proposed targeting criteria requirements under the MTM program. Instead, we recommend CMS continue to offer Part D sponsors the flexibility to manage the MTM program criteria to bring MTM services to the proportion of members that would most benefit from the program, allowing the focus to remain on the quality of health outcomes rather than the quantity of eligible members enrolled in the program.

V. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System

D. Adding, Updating, and Removing Measures (§§ 422.164 and 423.184)

CMS proposes the following Part C and Part D measure specific changes:

- Adds the Part D Concurrent Use of Opioids and Benzodiazepines measure to 2026 Star Ratings.
- Adds the Part D Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults measure to 2026 Star Ratings.
- Adds the Part D Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults measure to 2026 Star Ratings.

We urge CMS to withdraw adding these measures to the 2026 Star Rating system or, at a minimum, to delay their implementation. These measures pose similar challenges as the High-Risk Medication (HRM) measure and the Drug-Drug Interactions (DDI) measure that CMS previously retired. Moving these three measures to a Star Rating will cause delays in beneficiaries getting access to needed prescriptions, and result in unnecessary disruptions in therapy as the majority of members meeting the measure criteria will be on an established therapy that was deemed clinically appropriate by prescribers. It will lead to implementation of tighter utilization management and safety edits, placing additional burden on prescribers, pharmacists, and beneficiaries without necessarily changing overall drug utilization rates. Though plan coverage limitations may superficially lower PDEs, ultimately, they are not able to prevent beneficiaries from proceeding to fill prescriptions by paying out of pocket.

Moving these three measures to Star Ratings will also place increased administrative burden on the healthcare system. It will result in additional work for pharmacists, prescribers, and Part D sponsors related to prior authorization reviews, increase requests to prescribers, and increase case management volume. This will also negatively impact member satisfaction with the prescription drug benefit and result in increased grievances and lower CAHPS scores. We are concerned that behaviors related to these measures will be difficult to influence beyond what is currently done without causing member/prescriber abrasion.

Specific comments on the Concurrent Use of Opioids and Benzodiazepines Measure:

- Duplicative of Medicare Part D required Drug Management Programs (DMPs) and Overutilization Monitoring System (OMS) reporting for beneficiaries who are at risk for misuse or abuse of frequently abused drugs. Part D sponsors are regularly engaged in the case management of Potential At-Risk Beneficiaries (PARBs) reported through OMS. In addition, sponsors also proactively identifying PARBs through DMPs and report any sponsor-identified PARBs through OMS.

- Duplicative of concurrent drug utilization review (cDUR) systems and point-of-sale safety edits, outlined below, that help prevent and address prescription opioid overuse.
    i. Care coordination edit at 90 morphine milligram equivalents (MME) per day
    ii. Hard edit at 200 MME per day or more
    iii. Hard edit for 7-day supply limit for initial opioid fills (opioid naïve),
    iv. Soft edit for concurrent opioid and benzodiazepine use
    v. Soft edit for duplicative long-acting (LA) opioid therapy
    vi. Morphine milligram equivalent (MME) hard edit

  These safety edits help fulfill cDUR requirements outlined in 42 CFR § 423.153(c)(2) and prompt prescribers and pharmacists to conduct additional safety reviews to determine if the enrollee's drug use is appropriate and medically necessary. As part of industry standard, there is also widespread adoption of additional safety alerts at the time of dispensing to proactively engage both patients and prescribers about opioid overdose risk and prevention.

- Duplicative of MTM Programs. The MTM program is designed to assure that covered Part D drugs are appropriately used to optimize therapeutic outcomes and to reduce the risk of adverse events, including adverse drug interactions. Overlap between 1) the populations that meet the MTM program eligibility criteria and 2) an at-risk beneficiary (ARB) that must be targeted for enrollment in MTM, ensures that beneficiaries on frequently abused drugs, such as opioids/benzos, receive a comprehensive medication review along with targeted medication recommendations. Therefore, we believe the MTM program currently addresses the appropriate use of opioids and benzos.

For the reasons outlined above, we urge CMS to withdraw or delay adding these measures to the 2026 Star Rating system.

K. Calculation of Star Ratings (§§ 422.166(a)(2)(i) and 423.186(a)(2)(i))

CMS proposes to make a "technical amendment" to fix a "codification error" in 42 C.F.R. §§422.166(a)(2)(i) and 423.186(a)(2)(i) through the notice and comment rulemaking process under Section 553 of the Administrative Procedure Act ("APA") (5 U.S.C. §553). By doing so in the MA-PD Proposed Rule, CMS is acknowledging that the "technical amendment", i.e., the addition of regulatory language that was inadvertently removed from a regulation that had previously gone through the notice and comment rulemaking process, is in fact an ***amendment to the regulation*** that ***must go through the notice and comment rulemaking process***.

Pursuant to 5 U.S.C. §551(5), an agency must use the same procedures when they amend or repeal a rule as they used to issue the rule. *See e.g.*, *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 101 (2015). Although CMS has stated that the language at issue was inadvertently removed from the regulation, and that its intent to implement the Tukey outer fence outlier policy for the 2024 Star Ratings (i.e., the Star Ratings issued in October 2023) has not changed between the time the policy was initially codified in the regulation (June 2020) and when the language was removed from the regulation (May 2022), the practical effect of adding this language back into the regulation at this time is to impose a ***substantive change*** to the agency's policy ***as it is currently stated in the regulation***. *See e.g.*, *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87 (1995). Specifically, anyone looking at the regulatory language in 42 C.F.R. §§422.166(a)(2)(i) and 423.186(a)(2)(i) published in the current online version of the Code of Federal Regulations, the e-CFR (Electronic Code of Federal Regulations) that was last amended on February 1, 2023,[1] would find no mention of the implementation of the Tukey outer fence outlier policy under the regulations related to the "Calculation of Star Ratings" for the MA and Part D programs.

Further, while preamble language can be useful in interpreting the regulation, it does not itself qualify for judicial deference. *See e.g.*, *United States v. Mead Corp.*, 533 U.S. 218 (2001).

[1] The last update to Title 42 of the Code of Federal Regulations in the Annual Edition of the Code of Federal Regulations was made in October 2021. On the Code of Federal Regulations website (available at www.govinfo.gov), there is a link directing the public to "Click here to access the e-CFR (Electronic Code of Federal Regulations), the regularly updated online version of the CFR."

Currently, the preamble language from the June 2020 and May 2022 MA-PD Final Rules does not reflect what is actually stated in the current version of the regulation and therefore cannot be relied upon to justify merely making a "technical amendment" to the regulations in order to implement the Tukey outer fence outlier policy as originally proposed in 2020.

Accordingly, by CMS' own admission, CMS cannot simply re-instate language that was removed from the regulation without going through the notice and comment rulemaking process. And by doing so, the APA requires CMS to provide the public with notice and an opportunity to comment on the implementation of the policy itself (i.e., the application of the Tukey outer fence outlier policy for the 2024 Star Ratings). Furthermore, CMS must give real consideration to the comments submitted with respect to the re-addition of the Tukey outer fence outlier policy to the regulation at this time, and not just to comments that speak solely to CMS' act of re-instating language that was removed from the regulation. Specifically, there is actual performance data available now, which was not available at the time the policy was initially codified in the regulation, that CMS needs to consider before implementing the Tukey outer fence outlier policy for the 2024 Star Ratings. This data, as described below, shows a substantially significant shift away from what CMS stated the impact of the policy would be back in 2020, and therefore requires adequate consideration by the agency now before merely re-instating the language that was removed from the regulation. Such data, which is fundamental to assessing the impact of the policy, was not, and could not have been, known at the time the policy was initially adopted in 2020 because it was not available at that time.

Now that the data is available, as part of the rulemaking process, CMS must prepare a new Regulatory Impact Analysis (as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking (August 13, 2002), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)) that adequately assesses the costs and benefits of the proposal to implement the Tukey outer fence outlier policy. CMS cannot rely on the Regulatory Impact Analysis used in 2020, given that other policies related to the mechanism for calculating the Star Ratings continue to evolve, and the availability of actual performance data to assess the impact of the Tukey outer fence outlier policy on the calculation of the Star Ratings has changed. **CMS must delay the implementation of the regulatory amendment and re-assess the policy before merely finalizing it as originally proposed in 2020.**

Figure 1: Tukey Methodology Timeline



We appreciate CMS' continuous efforts to increase the predictability and stability of Star Rating cut points while making them meaningfully distinguish the true performance. However, there are serious reliability issues along with unintended, unexpected, and uncontrollable consequences of implementing the Tukey methodology for the 2024 Star Ratings. **We strongly urge CMS to delay implementation of the Tukey outer fence outlier policy at least until the 2026 Star Ratings in order to allow for time to mitigate these serious issues prior to implementation.** Implementing the Tukey methodology for the 2024 Star Ratings will cause unexpected, unintended, and uncontrollable impact to MA plans, provider partners and millions of beneficiaries. We outline the main issues below:

Issue 1: ***Based on current data simulations, there will be a significant impact on 3, 4 and 5 Star cut points, which is contrary to the impact previously stated by CMS.***

CMS stated in the April 2019 MA-PD Final Rule and reiterated in both the February 2020 MA-PD Proposed Rule and the June 2020 MA-PD Final Rule, that CMS had conducted simulations of the impact of applying the Tukey methodology. The results of CMS' simulation of the impact of the application of the Tukey methodology are as quoted below:

> *"In general, there tend to be more outliers on the lower end of measure scores. As a result, the **one to two star threshold** often increased in the simulations when outliers were removed compared to the thresholds when outliers were not removed, **while other thresholds were not as impacted**."*

This was repeated multiple times within these rules. Between June 2, 2020, and December 27, 2022, CMS did not provide additional or differing guidance on the simulated impact of the Tukey outer fence outlier policy. Alignment (and anecdotally many other MA plans) trusted and relied on CMS' earlier statements that application of the Tukey methodology would not have much impact beyond the 1 to 2 star cut point thresholds. We only had the opportunity to

measure the real impact of application of the Tukey methodology and other cut-point methodological changes in October 2022 after the 2023 Star Ratings were made publicly available. CMS also released the Tukey simulation cut points for the first time on December 19, 2022 that enabled health plans to validate their calculations and identify any issues with implementing this methodology. Based on these, we observed for at least seven measures (two HEDIS and five Administrative measures), that cut points will be **substantially** impacted beyond just the 1 to 2 star threshold [*Table 1*]. Most of these measures have a weight of 4 and therefore have a very large impact on the overall Star Ratings.

Table 1: Measure Impact

Measure			Actual RY 2023 Released Cut points				Simulated RY 2023 Tukey Cut points (Guardrails applied)				Difference between Actual and Simulation Cut points			
Name	Type	Weight	1 to 2 Stars	2 to 3 Stars	3 to 4 Stars	4 to 5 Stars	1 to 2 Stars	2 to 3 Stars	3 to 4 Stars	4 to 5 Stars	1 to 2 Stars	2 to 3 Stars	3 to 4 Stars	4 to 5 Stars
Call Center – Foreign Language Interpreter and TTY Availability (C28)	Admin	4	36	59	83	94	76	82	89	95	+40	+23	+6	+1
Call Center – Foreign Language Interpreter and TTY Availability (D01)	Admin	4	30	64	80	91	68	81	91	97	+38	+17	+11	+6
Complaints about the Health/Drug Plan (C23/D02)	Admin	4	1.53	0.89	0.5	0.19	0.68	0.43	0.25	0.12	-56%	-52%	-50%	-37%
Plan Makes Timely Decisions about Appeals (C26)	Admin	4	59	75	85	97	89	93	97	100	+30	+18	+12	+3
Reviewing Appeals Decisions (C27)	Admin	4	68	83	91	97	84	90	95	98	+16	+7	+4	+1
Diabetes Care – Blood Sugar Controlled (C11)	HEDIS	3	39	62	75	83	63	72	80	86	+24	+10	+5	+3
Care for Older Adults – Medication Review (C06)	HEDIS	1	43	70	82	93	73	82	91	96	+30	+12	+9	+3

Based on CMS' multiple statements starting in April 2019 that application of the Tukey methodology will impact primarily 1 to 2 star cut point values, and the fact that the simulation cut points were only just recently released on December 19, 2022, Alignment and other MA plans did not anticipate such substantial cut point increases for the 3 to 4 star and 4 to 5 star cut point values in these measures. The higher performance targets were not known in advance of the Measurement Year, which is why the Tukey methodology should not be implemented until the 2026 Star Ratings, so that MA plans have time to implement necessary changes to get prepared for the higher performance targets, before the 2024 Measurement Year begins. There needs to be enough time for collaboration, education, and planning with provider network and vendor partners to address these unexpectedly higher performance targets.

We respectfully request CMS further consider how the inaccurate guidance on the true impact of application of the Tukey methodology, coupled with the lack of available data to assess that impact, have created an undue burden for MA plans to work with their vendors and providers in time for the 2024 Star Ratings. This will have negative implications on members, providers, and the community. Delaying implementation of the Tukey outlier deletion model until the 2026 Star Ratings will allow Alignment and other MA plans sufficient time to modify current provider and vendor contracts and collaboratively develop implementation tactics and strategies.

Issue 2: ***There will be a significant decline in predictability and stability of the cut points even though the intention was to increase the predictability and stability year to year***.

CMS emphasized repeatedly in **both the February 2020 MA-PD Proposed Rule and the June 2020 MA-PD Final Rule**, that CMS was making cut point methodology changes and applying the Tukey methodology to increase the stability and predictability of the non-CAHPS measure cut points:

> *"We propose the use of Tukey outlier deletion, which is a standard statistical methodology for removing outliers,* ***to increase the stability and predictability of the non-CAHPS measure cut points****."*

CMS also implemented the 5% guardrail policy to reduce the fluctuation and instability of the cut points and to improve their year-to-year predictability:

> *"…a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from 1 year to the next. Prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap)…"*

CMS also said they will apply the 5% guardrail on prior year's simulated data in the first year that the Tukey methodology will be implemented:

> *"In the first year that this would be implemented, the prior year's thresholds would be rerun, including mean resampling and Tukey outer fence deletion so that the guardrails would be applied such that there is consistency between the years."*

When CMS made these statements in the previous rule, it asserted that "***thresholds other than 1 to 2 Star thresholds were not as impacted***" and that its intention was to increase stability and consistency of cut points between the years. However, now that the impact of Covid-19 has largely been mitigated and we have the benefit of actual simulated cut points for the 2023 Star Ratings using the Tukey methodology, it is clear that CMS' proposed reliance on the Tukey methodology will significantly impact cut points across the board for many measures. Based on the recently published simulations, implementation of the Tukey methodology will create major instability in the first year of its implementation as it significantly impacts the 3 to 4 and 4 to 5 Stars thresholds, which does not align with CMS' earlier comments and simulations.

For example, as shown below in Table 2, a contract that achieved an 85 on the *Plan Makes Timely Decisions about Appeals (C26)* measure earned 4 Stars for this measure under the 2023 Star Ratings. If the Tukey methodology is implemented for the 2024 Star Ratings, the 4 Star threshold for this measure is expected to jump to 97 or even higher (potentially 12+ percentage points increase). The same plan that earned 4 Stars on this measure for its 2023 Star Ratings would only get 2 Stars when the Tukey methodology is applied, even if the plan improves its performance on this measure from 85 to 90 (which is the same as the max amount set in the guardrails). Accordingly, even where contracts show significant improvement in performance,

they would see a substantial decline in their Star Ratings on such a highly weighted measure. This would negatively impact the contracts that have committed resources and effort to try to improve, create an unnecessary financial burden on plans and their provider partners, and create confusion with beneficiaries when they evaluate a plan's Star Ratings.

Table 2: 2023 Star Rating Simulation with Tukey for Plan Makes Timely Decisions about Appeals (C26)

Measure Name	Measure Type	Measure Weight	Actual RY2023 Released Cut points				Simulated Tukey Cut Points (Guardrails applied)			
			1 to 2 Stars	2 to 3 Stars	3 to 4 Stars	4 to 5 Stars	1 to 2 Stars	2 to 3 Stars	3 to 4 Stars	4 to 5 Stars
Plan Makes Timely Decisions about Appeals (C26)	Admin	4	59	75	85	97	89	93	97	100

In summary, even though CMS' stated intention for applying guardrails and the Tukey methodology was to increase the predictability of cut points, it would instead create instability and confusion for beneficiaries. **Alignment Health respectfully asks CMS to delay implementation of the Tukey methodology until the 2026 Star Ratings so that plans have enough time to implement necessary processes to achieve these new targets.**

Issue 3: *These changes will have a substantial impact on the 2024 Star Ratings, but due to the timing of CMS' release of simulated results for the 2024 Star Ratings, MA plans had no opportunity to address performance through arrangements with delegated entities.*

MA plans rely on the performance of certain delegated entities and provider partners to serve their enrolled beneficiaries. The plans set contractual obligations, such as Service Level Agreements (SLAs) and yearly goals based on various criteria including Star Rating cut points.

For example, as discussed above, if the Tukey methodology were applied to the 2023 Star Ratings, the measure *Plan Makes Timely Decisions about Appeals (C26)* would show a dramatic increase for the 2 to 3 Star cut point value (18 percentage points), the 3 to 4 Star cut point value (12 percentage points), and the 4 to 5 Star cut point value (3 percentage points increase and perfect "100") between the actual 2023 Star Ratings cut points and the simulated 2023 Tukey cut points.

The simulation for applying the Tukey methodology to the 2023 results for the companion measure *Reviewing Appeals Decisions (C27)* would also show substantial increases for the 2 to 3 Star cut point value (7 percentage points) and the 3 to 4 Star cut point value (4 percentage points). Both of the referenced measures currently are 4x weighted administrative measures (and will continue to have a weight of 4 at least until the 2026 Star Ratings), which has a considerable impact on the overall Star Ratings results.

Many of the areas reflected in the Star Ratings measures depend on delegated entities even when delegated entities are not responsible for a specific function. For example, for *Plan Makes Timely Decisions about Appeals (C26)* measure, time begins on the date the plan, any unit in the

plan, or any delegated entity for the plan (including delegated entities that are not responsible for processing appeals) receives the reconsideration request. Similarly, for *Reviewing Appeals Decisions (C27) measure,* any delegated entity's decision on an appeal request (even if they are not delegated to make the decision) is binding upon the plan. Accordingly, contractual obligations and SLAs are critical parts of delegation oversight and management. This is especially so in heavily delegated markets like California. However, due to CMS' very late release of the Tukey simulation cut points (on December 19, 2022 – which is the end of the measurement period) and the unexpected impact on higher Star cut-points (contradicting CMS' earlier simulations and statements), MA Plans are unable to make any adjustments to their contracts and SLAs on a retrospective basis. From the simulated cut-points, even one appeal could have a huge impact on the overall Star Rating of a contract. Plans had no opportunity to prepare for these higher cut-points prior to the start of the measurement period.

Delaying implementation of the Tukey outer fence outlier policy until the 2026 Star Ratings Cycle would allow Alignment and other MA plans sufficient time to work with delegated entities and develop implementation tactics and strategies to achieve these unexpectedly higher thresholds.

Issue 4: *The Tukey methodology will increase all cut point thresholds significantly and move the thresholds much closer to each other for many highly weighted measures. This would impact the measures' reliability and statistical significance and require adjustment of each measures' minimum denominator criteria.*

CMS currently applies minimum denominator thresholds for each measure to ensure that contracts have ***enough data to reliably and accurately report on their true performance***. The implementation of the Tukey methodology would have a substantial impact on the cut points for many highly weighted measures. That is ***why it is critical to re-evaluate and re-calculate minimum denominator requirements for the continued reliability of these measures*.** This is crucial to prevent an unintended and major negative impact on growing and/or high performing contracts.

Figure 2: 2023 Star Rating Simulation with Tukey

a)

2023 Star Rating Cutpoints	
1 Star	
2 Star	59
3 Star	75
4 Star	85
5 Star	97

# of untimely appeals	Denominator								
	3	5	7	9	11	15	20	25	30
0	100	100	100	100	100	100	100	100	100
1	66.7	80.0	85.7	88.9	90.9	93.3	95.0	96.0	96.7
2	33.3	60.0	71.4	77.8	81.8	86.7	90.0	92.0	93.3
3	0.0	40.0	57.1	66.7	72.7	80.0	85.0	88.0	90.0

b)

2023 Star Rating Cutpoints (\w Tukey)	
1 Star	
2 Star	89
3 Star	93
4 Star	97
5 Star	100

# of untimely appeals	Denominator								
	3	5	7	9	11	15	20	25	30
0	100	100	100	100	100	100	100	100	100
1	66.7	80.0	85.7	88.9	90.9	93.3	95.0	96.0	96.7
2	33.3	60.0	71.4	77.8	81.8	86.7	90.0	92.0	93.3
3	0.0	40.0	57.1	66.7	72.7	80.0	85.0	88.0	90.0

For example, the "*Plan Makes Timely Decisions about Appeals*" measure has a minimum denominator threshold of 11. Any contract that has fewer than 11 appeals is not rated on this measure due to "not having enough data." Figure 2 illustrates the impact of implementing the Tukey methodology on the reliability of this measure. Figure 2a represents the 2023 Star Rating cut points for this measure and Star Ratings under different denominator vs. untimely appeal scenarios. Figure 2b represents the same scenarios using the simulated 2023 Star Rating cut points using the Tukey methodology. As seen in Figure 2a, with the minimum denominator threshold scenario (11), there was a meaningful decrease in Star Ratings with each additional untimely appeal for the 2023 Star Ratings. If a contract had 0 untimely appeals, it achieved 5 Stars. If a contract had 1 untimely appeal, it achieved 4 Stars. If a contract had 2 untimely appeals, it achieved 3 Stars. If a contract had 3 untimely appeals, it achieved 2 Stars.

However, with the new Tukey methodology (Figure 2b), if the minimum denominator stays the same, **a contract having only one untimely appeal would earn only 2 Stars.** This would be **a drastic decrease in performance rating based on the plan missing a deadline on a single appeal that might have been caused by a minor clerical error, typo in entering dates, delegated entity oversight or another minor issue.** This one untimely appeal would **reduce the rating for this 4x-weighted measure from 5 Stars down to 2 Stars and would substantially impact the plan's overall mean and variance scores, including the reward factor.**

Figure 3: 2023 Star Rating Simulation with Tukey

a)

2023 Star Rating Cutpoints	
1 Star	
2 Star	59
3 Star	75
4 Star	85
5 Star	97

Avg Membership	#CTMs																			
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
400	0.21	0.41	0.62	0.82	1.03	1.23	1.44	1.64	1.85	2.05	2.26	2.47	2.67	2.88	3.08	3.29	3.49	3.70	3.90	4.11
800	0.10	0.21	0.31	0.41	0.51	0.62	0.72	0.82	0.92	1.03	1.13	1.23	1.34	1.44	1.54	1.64	1.75	1.85	1.95	2.05
1200	0.07	0.14	0.21	0.27	0.34	0.41	0.48	0.55	0.62	0.68	0.75	0.82	0.89	0.96	1.03	1.10	1.16	1.23	1.30	1.37
1600	0.05	0.10	0.15	0.21	0.26	0.31	0.36	0.41	0.46	0.51	0.57	0.62	0.67	0.72	0.77	0.82	0.87	0.92	0.98	1.03
2000	0.04	0.08	0.12	0.16	0.21	0.25	0.29	0.33	0.37	0.41	0.45	0.49	0.53	0.58	0.62	0.66	0.70	0.74	0.78	0.82

b)

2023 Star Rating Cutpoints (\w Tukey)	
1 Star	
2 Star	89
3 Star	93
4 Star	97
5 Star	100

Avg Membership	#CTMs																			
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
400	0.21	0.41	0.62	0.82	1.03	1.23	1.44	1.64	1.85	2.05	2.26	2.47	2.67	2.88	3.08	3.29	3.49	3.70	3.90	4.11
800	0.10	0.21	0.31	0.41	0.51	0.62	0.72	0.82	0.92	1.03	1.13	1.23	1.34	1.44	1.54	1.64	1.75	1.85	1.95	2.05
1200	0.07	0.14	0.21	0.27	0.34	0.41	0.48	0.55	0.62	0.68	0.75	0.82	0.89	0.96	1.03	1.10	1.16	1.23	1.30	1.37
1600	0.05	0.10	0.15	0.21	0.26	0.31	0.36	0.41	0.46	0.51	0.57	0.62	0.67	0.72	0.77	0.82	0.87	0.92	0.98	1.03
2000	0.04	0.08	0.12	0.16	0.21	0.25	0.29	0.33	0.37	0.41	0.45	0.49	0.53	0.58	0.62	0.66	0.70	0.74	0.78	0.82

As another example highlights, CMS requires a minimum denominator threshold of 800 for the "*Complaints about Health/Drug Plan"* measure. Any contract that has less than an average of 800 enrollees is not rated on this measure due to "not having enough data." Figure 3 illustrates the impact on the reliability of this measure that would occur from implementing the Tukey methodology. Figure 3a represents the 2023 Star Rating cut points for this measure and Star Ratings under different denominator vs. number of CTM scenarios. Figure 3b represents the same scenarios using the simulated 2023 Star Rating cut points using the Tukey methodology.

As seen in Figure 3a, with the minimum denominator threshold scenario (average of 800 enrollees), there was meaningful cut point ranges for the 2023 Star Ratings. If a contract with an average of 800 enrollees had 0 or 1 CTMs, it achieved 5 Stars. If the contract had 2 to 4 CTMs, it achieved 4 Stars. If the contract had 5 to 8 CTMs, it achieved 3 Stars. If the contract had 9 to 14 CTMs, it achieved 2 Stars. However, if the Tukey methodology were applied and the minimum denominator stays the same, a contract having 6 CTMs would earn 1 Star (Figure 3b), as opposed to 3 Stars without applying the Tukey methodology. Similar to the "*Plan Makes Timely Decisions about Appeals"* measure, there would be a drastic decrease in where the plan falls on the cut points from having just one additional CTM making cut point ranges less meaningful, and thus, have a substantial negative impact on the contract's overall Star Rating due to decreased reliability of this measure to distinguish true performance for certain denominators.

As illustrated in the above examples, CMS' implementation of the Tukey methodology without a thorough statistical analysis and adjustment of the required minimum thresholds would have significant unintended impact on the overall Star Ratings. Further, as stated in April 2019 MA-PD Final Rule, CMS evaluates measures for retirement when scores are compressed and topped out such that the measure has low reliability. Given that we now have the simulated results for all measures and there are substantial increases in all cut points for many highly-weighted measures, overall reliability of each measure also needs to be thoroughly examined before Tukey implementation.

We appreciate CMS' efforts to ensure the reliability of the measures to accurately reflect the true performance of the contracts. **However, for the reasons outlined above we strongly urge CMS to delay adoption of the Tukey outer fence outlier policy model until the 2026 Star**

Ratings and mitigate the stated issues before implementation.

Thank you for the opportunity to submit comments on the CY 2024 Medicare Advantage and Medicare Prescription Drug Programs proposed rule. Alignment Health appreciates your commitment to these programs and the beneficiaries we serve together in partnership. Please do not hesitate to contact me at DMaroney@ahcusa.com should you have any questions.

Sincerely,



Dawn Maroney
President, Markets & CEO Alignment Health Plan

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PUBLIC SUBMISSION

Docket: CMS-2022-0191
Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024

Comment On: CMS-2022-0191-0001
Medicare Program: Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, etc.

Document: CMS-2022-0191-0730
Comment on CMS-2022-0191-0001

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General Comment

The Pharmaceutical Care Management Association appreciates the opportunity to comment on the U.S. Centers for Medicare & Medicaid Services' proposed rule titled "Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications" as published in the Federal Register on December 27, 2022.

Attachments

PCMA comments on CMS-4201 2024 Part C D rule - February 13 2023

Enclosure - Groom Gross Covered Prescription Drug Cost (PCMA comments - February 13 2023)

PCMA

February 13, 2023

Submitted electronically via http://www.regulations.gov

The Honorable Xavier Becerra
HHS Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Ms. Chiquita Brooks-LaSure
CMS Administrator
U.S. Centers for Medicare & Medicaid Services
Attention: CMS–4190–P
P.O. Box 8013
Baltimore, MD 21244–8013

RE: Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications (CMS-4201-P)

Dear Secretary Becerra and Administrator Brooks-LaSure:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to comment on the U.S. Centers for Medicare & Medicaid Services' (CMS) proposed rule titled "Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications" (hereafter referred to as proposed rule), as published in the *Federal Register* on December 27, 2022.[1]

PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans (PDPs) and operate specialty pharmacies for more than 275 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and the Exchanges established by the Affordable Care Act (ACA).

In this letter, PCMA provides discussion and recommendations on the following topics:

I. **Proposed Changes to the Regulatory Definition of "Gross Covered Prescription Drug Costs":** CMS should decline to finalize any changes to the definition of "gross covered prescription drug costs" at 42 CFR 423.308.

[1] 87 Fed. Reg. 79452, December 27, 2022.

II. **Implementation of Other Provisions of the IRA Related to Medicare Part D:** CMS should indicate in the final rule that it will administer the pricing of drugs subject to direct negotiation in a manner similar to, and in conjunction with, the new Manufacturer Discount Program set to begin in 2025.

III. **Updating and Incorporating Long-standing Program Guidance into the Code of Federal Regulations:** We offer several recommendations related to proposals offered by CMS. In general, we support the principle of codifying guidance, which is often stored in several places, to improve the efficiency of plan and beneficiary interactions.

IV. **Request for Comment on the Rewards and Incentives Program Regulations for Part C Enrollees:** CMS should identify a path forward to maintain or improve the ability of MA and Part D plan sponsors to offer enrollees cash equivalent rewards and incentives.

V. **Revisions to the Medication Therapy Management (MTM) Program:** CMS should not finalize this proposal. It should instead undertake a stakeholder engagement exercise to determine which aspects of the MTM program are worth going forward. In addition, CMS should provide more flexibility to help plan sponsors reach the thousands of beneficiaries who are already MTM eligible but not yet engaged.

VI. **Revisions to the Medicare Overpayment Provisions of the Affordable Care Act:** CMS should clarify the continued need for an investigation period and further clarify how plans that receive overpayments on capitated rates would calculate and return these amounts.

VII. **Proposals intended to streamline the adoption of electronic health information interchange:** CMS should update the e-PA standard to NCPDP SCRIPT version 2022011, align the standards and requirements for electronic prescribing and related activities across the Part D program and ONC Health IT Certification program, and finalize an F6 compliance date 44 months after the effective date of the final rule, ensuring that stakeholders have sufficient time to develop and test changes before rolling them out.

VIII. **Changes to the Medicare Part C & D Star Ratings program:** We offer several measure-specific and methodology recommendations to improve the accuracy of plan-level calculations.

PCMA

IX. **Transitioning away from Public Health Emergency (PHE)-related policies for Coronavirus-19 covered items and services:** CMS should align COVID PHE unwinding with plan year 2024 and formally acknowledge the appropriateness of UM for commercial units of the oral antivirals and monoclonal antibodies for the Medicare program.

Thank you for the opportunity to provide these comments. We look forward to working with you on your ongoing efforts to improve the Part D program and implement the Inflation Reduction Act.

Sincerely,

Tim Dube

Tim Dube
Vice President, Regulatory Affairs

Enclosure: Groom Law Group memo

cc: Jonathan Blum
Meena Seshameni, MD
Amy Larrick Chavez-Valdez
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PCMA

I. Proposed Changes to the Regulatory Definition of "Gross Covered Prescription Drug Costs"

CMS is proposing to amend its regulatory definition of "gross covered prescription drug costs" (GCPDC) under 42 C.F.R. § 423.308 to remove all references to the term "actually paid" within the definition to "clarify that GCPDC are not net of all [direct and indirect remuneration]."[2] CMS states that the current definition "may have led to ambiguity as to when the [direct and indirect remuneration] would be netted out."[3] CMS further states that "the use of the phrase ['actually paid'] could create ambiguity when GCPDC is referenced outside of the reinsurance context (as it is now by the [Inflation Reduction Act, or IRA])."[4] Importantly, CMS asserts that the proposed change would "have no impact on Part D payment calculations or reporting requirements" and that "no other rules or policies would be affected by this proposed change, including the rules regarding how to account for coverage not provided by the Part D sponsor…."[5] CMS concludes by stating that "[r]emoving the phrase 'actually paid' from the regulatory definition of GCPDC as proposed would eliminate any ambiguity in the regulation text and help to ensure there is a consistent understanding of the meaning of this term for purposes of both the Part D program and the relevant provisions of the IRA."[6]

PCMA disagrees with CMS's assertions that its proposed re-definition of GCPDC will have no impact on the Part D program. Importantly, the proposed re-definition of GCPDC threatens to undermine Part D plan sponsor and manufacturer negotiations for a wide range of Part D drugs —beyond those selected for Maximum Fair Price (MFP) negotiations. We argue below that CMS's proposal to re-define GCPDC so it is not net of all rebates is precluded by the plain statutory text. We recognize that CMS has suggested that this clarification is necessary based on the existing statutory definition. We believe this legal interpretation is unnecessary, and jeopardizes savings to the program. We have attached an independent legal analysis which outlines how the proposed clarification would actually functions in direct opposition to numerous existing canons of statutory interpretation.

***PCMA recommendation*: CMS should decline to finalize any changes to the definition of "gross covered prescription drug costs" at 42 CFR 423.308.**

A. The Proposed Rule Threatens the Market-Based Structure of the Part D Program

In the proposed rule, CMS mis-states the impact of its proposed GCPDC definition on the Part D program overall, and the agency omits any discussion of how its proposed definition

[2] 87 Fed. Reg. at 79612.
[3] *Id.* at 79611.
[4] *Id.*
[5] *Id.* at 79612.
[6] *Id.* at 79613.



would affect negotiations between Part D plans and manufacturers, including omitting any regulatory impact analysis (RIA) of the agency's proposal.

As CMS is aware, the Part D program is a private sector solution to providing prescription drug coverage in an affordable way to seniors and the disabled. Congress chose this approach because other means of providing seniors with affordable access to prescription drugs would have negatively affected employers providing prescription drug coverage. Congress intended for drug plan sponsors to use their “bargaining power” and their existing business relationships to “negotiate discounts” from drug manufacturers and pharmacies and “drive down the cost of prescription drugs” through “competition,” and then pass those savings on to enrollees and the government in the form of lower premiums and thus reduced government subsidies.[7]

Predictably—and as intended by Congress—Part D plan sponsors have long emulated the private market, in which rebates are central. Since the mid-1990s and through the earliest days of Part D, PBMs and manufacturers in both the commercial and Part D contexts have converged around a business model in which manufacturers pay retrospective rebates to PBMs after the product is dispensed to the enrollee, and PBMs pass rebates on to plan sponsors. Plan sponsors under Part D are then required to report the full amount of the rebates (including any portion that may be retained by the PBM pursuant to the contract between the PBM and plan sponsor) to CMS as drug price reductions and pass the savings on to the government and plan enrollees in the form of reduced premiums and increased benefits. Thus, rebates are a key tool that Part D plans use to offer more competitive and affordable plan options to enrollees. Without the price concessions secured by PBMs as rebates pursuant to market competition that are then reported as direct-indirect remuneration (DIR) after the point-of-sale (POS), Part D plans' ability to offer affordable prescription drug coverage is stymied.

CMS's proposed GCPDC re-definition, however, undermines Part D plan sponsors' negotiating leverage by incentivizing manufacturers to target strategies to reduce total plan expenditures on their drugs to receive a lower ranking, without reducing their own revenues. For example, if manufacturers understand that gross, rather than net prices, will determine whether a drug is selected for negotiation under the Inflation Reduction Act (IRA), manufacturers are less likely to agree to rebates with Part D plans as those price concessions will not be accounted for when the federal government selects drugs for negotiation under the IRA. Under the incentives created by the proposed rule, manufacturers may consider negotiating rebates with plan sponsors only if the concessions are passed through at the POS, so that they are reflected in the revised construct of GCPDC. Furthermore, price concessions at the POS may also signal to other market participants

[7] Conference Report, Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 108 Cong. Rec. S15670, S15761-72 (Nov. 24, 2003) (Statement of 21 Sen. Bill Frist), https://www.congress.gov/congressional-record/2003/11/24/senate-section/article/S15670-2.



regarding an acceptable level of discounting, thereby promoting tacit collusion among competing drug manufacturers and undermining market competition.[8] Either way, CMS's proposed GCPDC definition has downstream implications of crippling Part D plans' ability to engage in genuine market negotiations that secure rebates and reduce Part D costs for enrollees. The effect is clearly not limited to drugs selected for negotiation under Section 1193, contrary to CMS's language in the proposed rule.

***PCMA recommendation*: CMS should decline to finalize this rule so as not to upset the market-based mechanisms by which Part D currently works.**

B. CMS Did Not Fulfill Its Obligations Under the Administrative Procedures Act (APA) and Other Laws and Regulations

In part, CMS avoided discussing the policy implications described above because it did not conduct an RIA for its proposed reinterpretation of the GCPDC definition. Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits.[9] Circular A-4 states that:

> A good regulatory analysis should include the following three basic elements: (1) a statement of the need for the proposed action, (2) an examination of alternative approaches, and (3) an evaluation of the benefits and costs—quantitative and qualitative—of the proposed action and the main alternatives identified by the analysis.[10]

Here, CMS did not conduct an RIA for this proposal. It is unclear whether CMS's omission of the policy implications of its proposed policy was a product of failing to conduct an RIA, or *vice versa*, but CMS has not fully assessed this change sufficiently to determine the "benefits and costs" of its proposed action.

Further violating the public trust, the data upon which the public could conduct its own analyses – namely the Medicare Parts B and D drug spending dashboards – have not been updated with program year 2021 expenditures. It is a version of these data that will be used for the initial drug selection process. They are typically released about 12 months after the

[8] Testimonies of Drs. Fiona Scott-Morton and Craig Garthwaite to the House Judiciary Committee, Subcommittee on Regulatory Reform, Commercial and Antitrust Law (Mar. 7, 2019), https://judiciary.house.gov/calendar/eventsingle.aspx?EventID=1976.
[9] *See generally* Executive Order 12866 – Regulatory Planning and Review (September 30, 1993), https://www.archives.gov/files/federal-register/executive-orders/pdf/12866.pdf; Executive Order 13563 – Improving Regulation and Regulatory Review (January 18, 2011), https://obamawhitehouse.archives.gov/the-press-office/2011/01/18/executive-order-13563-improving-regulation-and-regulatory-review.
[10] *See* Circular A-4 (September 17, 2003), https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/.

close of the program year, but at the time of this filing are not yet available.[11] So, not only has CMS failed to show the effect of its proposed change on the Medicare program, but the public also has not had an adequate opportunity to make fully informed comments about the effects of this change.

***PCMA recommendation*: Before considering any changes to the regulatory definition of GCPDC, CMS should undertake a regulatory impact analysis in consultation with the stakeholder community.**

C. The Proposed GCPDC Re-definition Violates The Non-Interference Clause

The Part D noninterference clause states that "in order to promote competition under [Part D], the Secretary may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors."[12] Yet this is precisely what CMS's proposed re-definition of GCPDC does: it significantly alters the incentive structure for manufacturers to provide rebates to Part D plans by making rebates less attractive to manufacturers concerned about Medicare negotiation under the IRA. In such circumstances, rebates paid by manufacturers will simultaneously represent concessions to the Part D plan on price and increase the likelihood that the drug will be selected for negotiation by Medicare since such price concessions would not be reflected in the drug's "total expenditures" calculation.

While Congress did provide an exception to the noninterference clause to implement the Medicare negotiation program, such amendments do not apply to drugs that are **not** subject to Medicare negotiation.[13] Yet CMS's proposed GCPDC re-definition will have repercussions on drugs regardless of whether they are negotiated by Medicare. In particular, Congress amended section 1860D-11(i)(3) of the Social Security Act (SSA) to clarify that the Secretary "may not institute a price structure for the reimbursement of covered part D drugs, *except as provided under the [Medicare negotiation program]."*[14] In order to require reimbursement at the MFP for a Part D drug, the exception to the noninterference clause for implementation of the Medicare negotiation program was specifically added to paragraph (3), which describes the prohibition against the institution of a price structure for the reimbursement of a covered Part D drug. However, paragraph (1), which prohibits the interference with Part D negotiations between plans and drug manufacturers, was conspicuously not amended. As such, Congress did not intend to undermine the private market model of the Part D program that relies on negotiations between manufacturers and Part D plans, yet this is precisely what CMS's proposed GCPDC re-definition will do. Therefore, CMS's proposed definition violates

[11] The 2020 data were released on January 21, 2022. Had CMS met that timeline for 2021 program data, the public would have had at least a limited opportunity to review these data and be better informed about the drugs most likely to be selected under the proposed rule, and under any alternative definitions.
[12] Social Security Act, § 1860D-11(i)(1).
[13] Section 1198(b)(1)(C) of the Inflation Reduction Act, amending section 1860D-11(i) of the Social Security Act.
[14] *Id*. (Emphasis added).



the noninterference clause, even after considering the amendments made by Congress to section 1860D-11(i)(3) as part of the IRA.

***PCMA recommendation*: CMS should withdraw this proposal since it exceeds its statutory authority. Changes to this definition interfere with the arm's length contract bargaining between manufacturers and PBMs.**

D. Proposed GCPDC Re-Definition Is Precluded by the Statutory Definition of GCPDC

CMS's proposed GCPDC definition is inconsistent with the statutory definition of GCPDC at section 1860D-15(b)(3) because it distorts the meaning of the phrase "*costs incurred by the plan*, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs…." Specifically, in only considering rebates that are passed at the POS, CMS's proposes re-definition of GCPDC ignores other rebates collected by—and therefore costs avoided by—Part D plans.

For example, if a drug has a wholesale acquisition cost (WAC) price of $1,000 but a price net of rebates of $750, the costs "incurred by the plan" are $750, not $1,000. Under CMS's proposed re-definition, however, CMS would treat the $1,000 as the costs "incurred by the plan." This artificially inflates CMS's calculation of the drug costs borne by the Part D plan and fails to acknowledge the private-market structure of the Part D program that relies on Part D plans negotiating rebates on drugs to reduce costs and offer more comprehensive prescription drug benefits to Part D enrollees.

In the proposed rule, CMS points out language in section 1860D-15(b)(2) of the SSA that defines "allowable reinsurance costs" as a "subset" of GCPDC, and the agency notes that section 1860D-15(b)(2), unlike the statutory definition of GCPDC, uses the phrase "actually paid" (net of discounts, chargebacks, and average percentage rebates). As a result, CMS suggests that because section 1860D-15(b)(2) uses the term "actually paid" and is a "subset" of GCPDC, it follows that GCPDC cannot also be costs "actually paid" by the Part D plan.

Although we acknowledge this distinction in the statutory language between the definitions for "allowable reinsurance costs" and GCPDC, CMS's characterization of the distinction ignores the rest of the language in both statutory provisions. Specifically, the "allowable reinsurance costs" *involves a more limited data set that would* ***not*** be in excess of "such costs that would have been paid under the plan were basic prescription drug coverage, or, in the case of a plan providing supplemental prescription drug coverage, if such coverage were standard prescription drug coverage."[15] By contrast, GCPDC are "costs incurred" by the Part D plan "**regardless** of whether the coverage under the plan exceeds basic prescription drug coverage."[16] In other words, contrary to CMS's characterization, GCPDC involves a more

[15] Social Security Act, § 1860D-15(b)(2)(A).
[16] *Id.* at § 1860D-15(b)(3).



expansive data set than "allowable reinsurance costs" not because of how rebates themselves are treated (i.e., whether they are "actually paid" or not), but because "allowable reinsurance costs" are limited *to a specific type of drug coverage* (basic prescription drug coverage or standard prescription drug coverage).

***PCMA recommendation*: CMS's proposed change should not be adopted and contradicts the statutory intent of defining GCPDC.**

E. Proposed GCPDC Definition is Arbitrary and Capricious and Fails to Provide Notice to Stakeholders

CMS's lack of *any* discussion in the proposed rule of how its proposed reinterpretation of GCPDC will affect either (i) negotiations between Part D plans and manufacturers or (ii) Medicare Negotiations under the IRA is arbitrary and capricious and deprives stakeholders of the ability to meaningfully consider the proposal and submit informed comments to the agency.

Under the APA, an agency undergoing notice-and-comment rulemaking cannot fail to consider an important aspect of a selected regulatory approach.[17] The agency's articulation of the basis and ramifications of its proposed policies is critical to ensuring that the notice adequately "apprises interested parties of the issues to be addressed in the rule-making proceeding with sufficient clarity and specificity to allow them to participate in the rulemaking in a meaningful and informed manner."[18] By contrast, notice is not adequate if it is dedicated entirely to describing *only one* of the impacts of the proposed policy.[19] Failing to conduct an RIA means this policy is *prima facie* arbitrary.

As discussed above, CMS not only fails to discuss the full impact of its proposed reinterpretation of the regulatory definition for GCPDC, the agency characterizes its proposed reinterpretation as essentially a harmless technical change without any substantive impact on the status quo: "[t]he proposed change would have no impact on Part D payment calculations or reporting requirements…[m]oreover, no other rules or policies would be affected by this change…."[20] CMS fails to even mention, much less discuss, the consequences of its policy on the selection of drugs for negotiation under the IRA and the impact on Part D program negotiations. While CMS expressly solicits comments on more than 50 different policies in its 298-page rule, any solicitation of comments on the re-definition of GCPDC is notably absent. Based on the proposed rule, many stakeholders may fail to submit comments based on CMS's representation that the proposal is inconsequential.

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[17] *See Motor Vehicle Mfrs Ass'n v. State Farm Auto Ins. Co*., 463 U.S. 29, 43 (1983) ("an agency rule would be arbitrary and capricious if the agency… entirely failed to consider an important aspect of the problem").
[18] *Am. Md. Ass'n v. United States*, 887 F.2d 760, 767 (7th Cir. 1989).
[19] *MCI Telecomm. Corp. v. FCC*, 57 F.3d 1136 (D.C. Cir. 1995).
[20] 87 Fed. Reg. at 79612.

The APA protects stakeholders from an agency's failure to *publicly* consider an issue prior to enacting binding rules. CMS is assuming that stakeholders are able to identify *unstated* policy implications and to simultaneously define the agency's position on those *unstated* policy implications. This is an inappropriate assumption for an agency to make and violates the APA.[21]

***PCMA recommendation*: CMS should abandon this proposed change because it violates the agency's obligations under the APA.**

F. The Proposed Rule Conflicts with Congress' Intent in Passing the IRA

CMS also fails to discuss how its proposed GCPDC re-definition would impact Medicare Negotiation itself. Under CMS's proposed GCPDC re-definition, for purposes of identifying and ranking Part D negotiation-eligible drugs, the Secretary would disregard rebates and other price concessions not passed through at the POS irrespective of how successful Part D plans are in negotiating pricing for those same drugs. Incongruously, this increases the likelihood that Medicare will negotiate pricing on drugs that are already successfully negotiated by Part D plans. This will lead to higher Part D program spending, including for beneficiaries.

The proposed rule would ignore existing PBM-negotiated savings. CMS does not explain why it believes that Congress would want to disregard rebates that Part D plans are successfully negotiating when identifying negotiation-eligible drugs. Given the limited number of drugs that the Secretary may negotiate each year, it is redundant that the Secretary would negotiate pricing on drugs for which Part D plans are already successfully negotiating rebates by relying on an approximation of gross pricing that does not reflect the true cost to the plans or to Part D program spending. If CMS believes that this proposed rule change "clarifies" the intent of the law, it should also have described what alternative it is clarifying against, such as basing the ranking on net program expenditures, instead.

The proposed rule will lead to an inefficient drug selection process. The proposed GCPDC re-definition will result in different drugs being eligible for negotiation, to the detriment of CMS's goals in saving money for taxpayers and beneficiaries, than under the alternative (based upon net price instead). Accounting for other exclusions in the IRA, PBMs negotiated price concessions exceed 50% for the top-ten drugs likely to be selected under

[21] *Chamber of Commerce of the United States v. SEC*, 370 U.S. App. D.C. 249, 259, 443 F.3d 890, 900 (2006) ("By requiring the 'most critical factual material' used by the agency be subjected to informed comment, the APA provides a procedural device to ensure that agency regulations are tested through exposure to public comment, to afford affected parties an opportunity to present comment and evidence to support their positions, and thereby to enhance the quality of judicial review.")

the proposed rule.[22] Independent estimates validate the savings plans and PBMs are able to generate: the Medicare Trustees and CMS Office of the Actuary (OACT) estimate that manufacturer DIR was $30 billion in 2020, or 20% of total Part D spending.[23] Rather, CMS should aim its crosshairs at negotiation-eligible single source drugs without significant price concessions already on the books.

CMS will not meet its savings goals. When CMS moves on to negotiating prices with manufacturers, it will be bound to pay not more than a "ceiling price" based on the length of time the drug has had a "monopoly" or the average enrollment-weighted net price paid by Part D plans. CMS will find more success where the time-based ceiling price provides them leverage over the PBM-negotiated price, since the time-based price is more independent of market forces. Namely, if CMS negotiates for drugs with significant PBM price concessions, they are relying on manufacturers to offer additional discounts to generate any savings at all. By our analysis, PBMs generated nearly $17 billion in savings for the likely top-ten drugs subject to direct negotiation. To meet the Congressional Budget Office's goals,[24] CMS will need to save an additional $4.8 billion, which is a tall order. Instead, if CMS selected drugs based on the highest net program spending, it would more accurately identify drugs where the time-based ceiling price yields savings over the PBM negotiated price.

CMS will pass these higher costs on to beneficiaries. CMS is also risking the significant savings that PBMs negotiate for beneficiaries by proposing to re-define GCPDC. Manufacturers currently negotiate with Part D plans for formulary coverage and preferred formulary placement, including whether cost sharing takes the form of copayments (typical for preferred drugs) or coinsurance.[25] These negotiations enable plans to meet and exceed the adequate formulary requirements under the law.[26] Many high-spend drugs face direct brand drug competition for preferred formulary placement, which incentivizes manufacturers to offer substantial discounts on these products. Under the rule, CMS would supplant PBM discounts that yield copayments for preferred drugs rather than coinsurance. Even if the discounts are similar, manufacturers may lack an incentive to further negotiate with PBMs for preferred status. Enrollees taking preferred brands today, with copays under $50 for cost

[22] PCMA analysis of the Medicare Part D drug dashboard for program year 2020, using SSR Health price concessions data, and accounting for exclusions from the negotiation-eligible drug list pursuant to Sec. 1193 of the SSA. As noted previously, drugs selected for 2026 will be identified using 2021 program data, and accordingly we made several adjustments to the 2020 data to estimate 2021 program experience.
[23] PCMA analysis of the 2022 Medicare Trustees Report and the 2023 Part C & D proposed rule provision on pharmacy DIR, in order to remove pharmacy price concessions from OACT's total DIR estimate.
[24] See CBO, Estimated Budgetary Effects of H.R.5736, the Inflation Reduction Act of 2022,", at page 7, https://www.cbo.gov/system/files/2022-08/hr5376_IR_Act_8-3-22.pdf. CBO estimates that this provision will generate $4.8 billion in savings for 2026, beyond what PBMs already generate.
[25] In 2022, nearly 100% of MAPD enrollees and 65% of PDP enrollees had copayments for preferred drugs, rather than coinsurance. See Kaiser Family Foundation, https://www.kff.org/medicare/issue-brief/key-facts-about-medicare-part-d-enrollment-and-costs-in-2022/.
[26] 42 C.F.R. § 423.120(b)(2).

sharing, will be facing 25 to 33% coinsurance payments for these same drugs, because CMS has limited the ability of PBMs to negotiate on their behalf.

CMS should strive to create a system that is transparent and lacking loopholes. One reason CMS may think that defining GCPDC to exclude price concessions is correct is to reduce the risk of "gaming" the ranking. However, if CMS is concerned that selecting drugs based on actual net prices paid creates incentives to increase price concessions, then it should remember that the data for selected drugs eligible for MFPs in 2026 is based on 2021 total spending, and for 2027, on 2022 total spending. For 2028, Parts B and D drugs will be selected based upon 2023 data, and for Part D, that means contracts and bids closed before the IRA was enacted. These historical data cannot be "gamed" in any fashion. At worst, CMS is trying to solve a problem for 2029. As we described above, changing the rules now creates a slew of unintended consequences across all negotiations – not just those drugs subject to MFP in 2026 and beyond.

Current federal program experience confirms our concerns. Our concerns regarding reduced leverage in the face of significant government mandated discounts are not just mere speculation. We see in other heavily discounted federal prescription drug programs that additional manufacturer price concessions are miniscule, especially relative to the size of the mandated discount. For instance, in Medicaid, manufacturers lack incentive to offer meaningful supplemental rebates to Medicaid managed care plans beyond those offered to the state to secure coverage under the Medicaid Drug Rebate Program (MDRP). Similarly, there is very limited evidence of any real savings available at "subceiling" prices under the 340B program since manufacturers lack significant incentives to offer steeper discounts.

Indeed, the Medicare Part D program itself illustrates that manufacturers will not offer additional discounts or rebates when plans are required to cover a particular drug. The first threshold of coverage—placement on the formulary—is most critical for manufacturers and can significantly affect a manufacturer's willingness to negotiate on pricing. We see this with the "protected class" coverage mandate. Under this policy, Part D plans must cover on their formulary all or substantially all drugs in six protected classes. While manufacturers can offer additional rebates on drugs in protected classes to improve tiering, all analyses of Part D data have consistently shown manufacturers offer only marginal rebates, at best, for these drugs.[27] CMS needs to consider that the private market forces that work in beneficiaries' favor today are neutered when it comes to selected drugs.

[27] "Report to the Congress: Medicare and the Health Care Delivery System," Medicare Payment and Advisory Committee (June 2020), at 143-44. MedPAC remarks on a study finding that "manufacturers provided rebates on fewer brand-name drugs in the protected classes (13 percent vs. 36 percent of all brand name drugs) and that the rebates they did provide were smaller (14 percent of gross costs vs. 30 percent for all brand-name drugs) (*c.f.* Johnson et al. 2018).

***PCMA recommendation*: CMS should decline to finalize the proposed change because it would undercut the agency's ability to generate savings for the program and beneficiaries.**

G. Congress Ratified the Regulatory Definition of GCPDC When It Enacted The IRA

Congress enacted the IRA fully expecting that it would be implemented using the current GCPDC regulatory definition upon which Part D negotiations have been predicated for nearly two decades. In other words, Congress did not expect that, after enacting the IRA without any substantive amendments to the GCPDC statutory definition at section 1860D-15(b)(3), CMS would invert its longstanding interpretation of GCPDC under the pretext that the agency is adopting a nonconsequential clarification.

CMS's revised interpretation of GCPDC contravenes a longstanding principle of statutory interpretation—the ratification doctrine—that "Congress is presumed to be aware of any administrative or judicial interpretation of a statute and [Congress] adopt[s] that interpretation when it re-enacts a statute without change."[28] The IRA represents one of the most comprehensive statutory schemes in modern history—yet Congress adopted only conforming amendments to section 1860D-15(b)(3) of the SSA.[29] As such, Congress is presumed to have incorporated the existing GCPDC regulatory definition when it enacted the IRA, and it understood that the established regulatory regime would dictate implementation of the IRA absent specific statutory amendments.[30] This is particularly true given that the current GCPDC regulatory definition has persisted since the inception of the Part D program—nearly two decades ago—without change.[31]

***PCMA recommendation*: CMS should reject the proposed rule because the existing definition was assumed by Congress in enacting this new policy.**

[28] *Lorillard v. Pons*, 434 U.S. 575, 580 (1978) (alterations made).
[29] Section 11201(b)(3) of the IRA amended section 1860D-15(b)(3) of the Social Security Act solely to ensure that manufacturer discounts under the new manufacturer discount program of section 1860D-14(g) are factored into GCDPC).
[30] *Lorillard*, 434 U.S. at 580 ("Congress adopts a new law incorporating sections of a prior law, Congress normally can be presumed to have had knowledge of the interpretation given to the incorporated law, at least insofar as it affects the new statute."); *see also Bragdon v. Abbott*, 524 U.S. 624, 645 (1998) ("When administrative and judicial interpretations have settled the meaning of an existing statutory provision, repetition of the same language in a new statute indicates, as a general matter, the intent to incorporate its administrative and judicial interpretations as well.").
[31] *United States v. Blavatnik*, 168 F. Supp. 3d 36 (D.D.C. 2016) (holding that the ratification doctrine applied in the case before it particularly since the "consensus [as to the interpretation is] so broad and unquestioned that [the Court] must presume Congress knew of and endorsed it.") (alterations made).

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H. CMS Has Discretion in Selecting Drugs and Does Not Need to Finalize this Change

In the proposed rule, CMS argues that it is making this change to the definition of GCPDC to conform the regulatory text to the statutory text, considering the IRA provision that describes how CMS will select drugs for negotiation. CMS implies that it must select drugs based on its new conceptualization of "gross." However, had Congress explicitly wanted CMS to select drugs by total payments made to pharmacies by plans and beneficiaries (as the new GCPDC maps to), rather than incurred program costs, Congress had access to a much plainer language way to describe it. Congress had other alternatives to more clearly define an amount approximating gross costs.

For example, Congress could have simply defined "total expenditures," in the case of expenditures with respect to Part D drug selection, to mean "total payments made by plans to participating pharmacies on the basis of negotiated price including dispensing fees." They could have defined "total expenditures" as "based upon the spending amounts published by CMS in their annual Part B and Part D drug spending dashboards," or even as "those costs incurred under a Part D plan before excluding any direct or indirect remuneration from any source." Unlike the term Congress instead chose to reference – GCPDC – there is no ambiguity in these alternatives. By referring CMS to GCPDC instead, as we argue elsewhere, Congress is directing CMS to focus on drugs that represent the highest costs to the program and beneficiaries, since those are the drugs where reinsurance reconciliations occur, and thus accounting for the work that PBMs and Part D plan sponsors already do on CMS's behalf. Even if the agency finds the term GCPDC less than clear (or ambiguous), it is certainly a reasonable interpretation of the statute to look at the existing regulatory definition of the term at the time of enactment as a basis for that meaning.[32]

***PCMA recommendation*: CMS should reject the proposed rule because making this change is premature. It should engage manufacturers and PBMs and beneficiaries to ensure that the "right" criteria are used to define negotiation-eligible drugs.**

I. The Proposed GCPDC Re-Definition Could Introduce Similar Incentives to the Delayed Part D Rebate Rule

CMS's proposed reinterpretation of the definition of GCPDC could inadvertently produce the same outcome as the Health and Human Services (HHS), Office of the Inspector General's

[32] *See Sebelius v. Auburn Reg'l Med. Ctr.*, 568 U.S. 145, 158, 133 S. Ct. 817, 826 (2013) ("A court must uphold the Secretary's judgment as long as it is a permissible construction of the statute, even if it differs from how the court would have interpreted the statute in the absence of an agency regulation."). *See also Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512, 114 S. Ct. 2381, 2387 (1994) (observing in a Medicare case that Chevron deference "is all the more warranted when, as here, the regulation concerns 'a complex and highly technical regulatory program,' in which the identification and classification of relevant 'criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns.'" (citations omitted).

(OIG's) rebate rule, which Congress delayed implementation of until 2032, nearly a decade from the IRA's enactment. In that delay, HHS alleged that since "beneficiary out-of-pocket costs are often calculated based on the list price of the drug (i.e. before rebates are paid), beneficiaries pay higher cost sharing than they would if discounts were reflected at the point of sale."[33] HHS's proposed solution at that time was to remove protection for rebates under the discount safe harbor and to "create new safe harbor protection for point-of-sale reductions in price, which will directly reduce beneficiary out-of-pocket spending at the pharmacy counter."[34] HHS added that the intent of the Part D Rebate Rule was "to create incentives for manufacturers to lower their list prices…."[35] The rule, however, would have increased costs to the federal government by $196 billion over ten years.[36] This proposed rule will inject similar incentives to the ones that Congress rejected outright when delaying the HHS OIG rebate rule in two of its most recent legislative enactments.[37] Without this regulatory change, the incentives in place today would remain. If CMS makes this change, they've introduced a new incentive for manufacturers to reduce their likelihood of selection by reducing their products' GCPDC through up-front discounts (rebates at POS or otherwise). That shift in strategy, as it would have under the rebate rule, will increase costs on all parties, and benefit only drug manufacturers by reducing the probability of selection.

***PCMA recommendation*: CMS should not adopt a rule change that contradicts Congressional intent and is known to cause economic harm comparable to the delayed rebate rule.**

J. The Proposed Rule Ignores Evolving Trends Among Part B and Part D Drugs and Unnecessarily Treats Part B and D Drug Spend Differently

CMS's proposed re-definition of GCPDC creates an unlevel playing field between Part D drugs – subject to negotiation for 2026 and 2027 – and Part B drugs – which can be negotiated beginning in 2028. The proposed change yields a methodology for measuring Part D spend that stands in stark contrast to how Part B drug spend will be measured for purposes of selecting negotiation eligible drugs. In sum, CMS's proposed re-definition of GCPDC will unnecessarily advantage manufacturers of Part B drugs by mitigating the risk that they will be selected for negotiation, for two reasons.

At the outset, it bears noting that Part B drugs have a structural advantage in mitigating their selection for Medicare negotiation, because Medicare Advantage (MA) utilization is not

[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] *Id.* at 76721; *see also* "Proposed Safe Harbor Regulation," CMS Office of the Actuary (Aug. 30, 2018), https://aspe.hhs.gov/sites/default/files/private/pdf/260591/OACTProposedSafeHarborRegulationImpacts.pdf.
[37] See Sec. 9006 of the Infrastructure Investment and Jobs Act of 2020 (Public Law 117-59, November 15, 2021) and Section 11301 of the IRA.



accounted for when determining negotiation-eligible Part B drugs.[38] Because MA payments for drugs are made under Part C of title XVIII, MA utilization—and the rebates that MA plans negotiate with manufacturers—are not factored into a Part B drug's Medicare spend. By contrast, section 1192(d)(1)(A) of the IRA provides that "total expenditures" for Part D drugs are determined "under Part D of title XVIII." Medicare Advantage Prescription Drug (MA-PD) plans that offer prescription drug coverage offer such coverage under Part D, and therefore MA-PD plan Part D utilization is included when determining a Part D drug's total expenditures.

As CMS is aware, most new Medicare enrollees with Part B coverage are electing MA-PD plans rather than original Medicare. By 2025, half of Medicare beneficiaries will be enrolled in such plans as opposed to original Medicare.[39] As a result, "total expenditures" under Part B for purposes of Medicare negotiation will be calculated on a dwindling population year-over-year, compared to Part D drug spending. Naturally, this tilts drug selection toward Part D drugs because regardless of a Part B drug's cost, the utilization multiplier will progressively decline over the years based on current projections. Ideally, CMS would base drug selection on per-beneficiary spend, or account for Part C spending on Part B drugs, though we recognize these options would require a legislative change.

Moreover, CMS's proposed GCPDC re-definition undermines the current similarity in methodologies for calculating Parts B and D drug spending. Part B "total expenditures" will be based on Average Sales Price (ASP) payments to providers "under Part B".[40] ASP represents the sum of all sales, minus most non-government discounts, across a wide class of purchasers lagged over a 12-month period to account for annual contracts.[41] These discounts include volume-based rebates to physician and hospital purchasers, and price concessions to plans in exchange for favorable treatment on commercial formularies—the latter being virtually identical to DIR under the current definition of GCPDC. Importantly, the ASP methodology focuses on what the *government* pays for a Part B drug, and it aligns with the current GCPDC definition that similarly focuses on what the *government* ultimately pays for a Part D drug. The proposed GCPDC definition would invert this relationship by continuing to count Part B drug spend based on government spending via ASP payments, but only counting Part D *plan* spending rather than what the *government* actually pays for a Part D drug, net of price concessions.

***PCMA recommendation*: CMS should decline to finalize this proposal because it disadvantages Part D drugs compared to Part B drugs in terms of likelihood of selection for negotiation.**

[38] Per section 1192(d)(2)(B) of the Act, Part B "total expenditures" are determined under "Part B of title XVIII".
[39] "Medicare Advantage: A Policy Primer", The Commonwealth Fund (May 3, 2022), https://www.commonwealthfund.org/publications/explainer/2022/may/medicare-advantage-policy-primer.
[40] *See generally* Social Security Act § 1847A and 42 CFR 414.
[41] *Id.* at §§ 1847A(c)(3), 1847A(c)(5)(A).

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II. Implementation of Other Provisions of the IRA Related to Medicare Part D

In the previous section, we discussed our concerns with one of just two provisions in the proposed rule related to implementation of the IRA. CMS makes one further proposal, related to new eligibility criteria for the Low-Income Subsidy (LIS) program. We also wish to highlight areas where CMS should consider future rulemaking or guidance to shore up the financial guardrails that protect Part D plans and beneficiaries from high and rising prices for prescription drugs. We close this section by reminding CMS that PBMs can play a critical role in the actual administration of the direct negotiation program, for Part D covered drugs, and should be involved early on as CMS thinks through the operational considerations.

A. CMS Will Increase LIS Eligibility to 150% of the Federal Poverty Limit (FPL)

In line with the requirements of the IRA, CMS proposes to increase eligibility for the full LIS subsidy to individuals with incomes at or below 150% of the FPL. PCMA believes that streamlining the LIS eligibility and enrollment process will improve access for the few hundred thousand beneficiaries currently eligible only for partial LIS subsidies. It will also simplify the administration of the Part D program for plans and pharmacies, with a more unified benefit–either LIS or not LIS–rather than the several "middle grounds" plans must accommodate under current applicable law.

Based on initial analyses by our member companies, we anticipate that plans with higher proportions of LIS beneficiaries will see an oversized premium impact in the shift to the new benefit structure. This could create churn and a disproportionate impact to LIS beneficiaries if there are not steps taken to moderate it. CMS should take steps to make the transition for current LIS enrollees, and future ones, as seamless as possible. With all the changes coming to the Part D program beginning in 2023, there's a high likelihood that the national average monthly bid amount (NAMBA) that the LIS benchmark is based upon could rise substantially, or fluctuate significantly, for 2024, 2025, and 2026. Beneficiaries prefer to remain in their existing plans, but LIS enrollees who do not initially select their plans are at risk of being automatically reassigned if their current plan experiences significant variations over the next few plan years. We believe CMS has the authority to make two changes outlined below in plan offering guidance that it should signal in the final rule.

1. **CMS should increase the *de minimis* premium amount from $2 per member per month to $5.** Alternatively, CMS could consider basing the *de minimis* on a percentage of the NAMBA, as a longer-term transition, in case the NAMBA increases substantially due to all of the compounded changes of the IRA. The *de minimis* level is defined in guidance only at this point, not regulation,[42] and CMS could increase the level to minimize enrollee disruption in the Final Notice and Call Letter, for example.

[42] 42 CFR 423.780 states simply that a Part D plan may waive "a *de minimis* amount" but does not define the amount itself.

2. **CMS should permit Part D plan sponsors to offer a fourth PDP in a region that is LIS-only for plan year 2024 and 2025.** To further reduce enrollment churn, CMS should also allow a fourth PDP that is designated for the LIS population. Their needs often differ significantly from the non-LIS population, and one way CMS could reduce overall costs is to allow plans to create benefit designs that specifically engage this population's needs. Having a fourth plan in place will also reduce enrollment churn year to year during assignment and reassignment periods. We recognize that the current limit of three plans per region was codified in 2021, for plan year 2022.[43] We recommend CMS consider engaging CMMI or other existing waiver authority[44] to protect LIS beneficiaries for a time-limited period under this other authority.

***PCMA recommendation*: In implementing the eligibility expansion for full LIS, CMS should reduce plan reassignments by increasing the de minimis and use its demonstration authority to allow plan sponsors to offer a fourth, LIS-only plan for 2024 and 2025.**

B. Financial Guardrails to Protect Part D Plans and Beneficiaries

Through the IRA, Part D enrollees will see cost sharing relief beginning in plan year 2023, by limiting cost sharing for covered insulins and Advisory Committee on Immunizations Practices (ACIP) recommended vaccines. In 2024, eligibility increases for the LIS program, and non-LIS enrollees will no longer face coinsurance during the catastrophic benefit phase. The Coverage Gap Discount Program (CGDP) is replaced by a new Manufacturer Discount Program (MDP) starting in 2025, and beneficiaries can opt to "smooth" large pharmacy cost sharing by paying over several months.

These benefit design changes are financed in part by shifting the liability of these costs onto pharmaceutical manufacturers, Part D plan sponsors, and taxpayers. To mitigate some of the cost increase on plans, Congress included a temporary retroactive subsidy payable to Part D plan sponsors since these changes for insulins and vaccines were not included in the Final Rate Notice and bids for plan year 2023. Beginning in 2024, CMS will adjust direct subsidy amounts paid to Part D plans to limit any increases in beneficiary base premiums to no more than six percent (the "premium stabilization program" or PSP). Importantly, PSP is designed to minimize premium impact on the aggregate. CMS does not propose any regulatory definitions for PSP in this rule, leaving many questions unanswered.[45] Therefore, beyond

[43] 86 Fed. Reg. at 5864, January 19, 2021.
[44] We wish to remind CMS had the HHS OIG Part D Rebate Rule been finalized, CMS had committed to use its Section 402 authority to operate a narrowed risk corridor demo program to minimize premium effects of the policy.
[45] For example, we remain unclear on the funding source for any premium overage beyond 6% of the baseline benchmark premium.

PCMA

PSP, CMS should consider updating risk corridor and risk adjustment programs as well, under its existing authority.[46]

Risk corridors in Part D are designed to protect plans if their enrollees' prescription drug costs are much higher than expected and provide savings to CMS if plans instead overbid for providing these benefits. By narrowing the risk corridors–currently set at 5% above or below the expected cost–to something more like 2.5% above or below, plans will be able to bid with more certainty, having less to "lose" if they underbid.

In contrast to risk corridors, which protect plans from significant losses at the end of the year, risk adjustment is a prospective CMS program that helps reduce risk based on the plan's actual enrollment, over the course of the year, paid through the Direct Subsidy. Plans are protected against having an unusually unhealthy population and CMS is protected against plans ending up with unexpectedly healthy enrollees. However, CMS indicates in the CY2024 Advance Notice that there has not been sufficient time for the agency to update the risk adjustment model for 2024 given the timing of the passage of the IRA. This makes the need for narrowed risk corridors even more pressing to account for the changes related to the maximum out-of-pocket costs (MOOP), $35 copay cap for covered insulin products, vaccines at $0, and LIS expansion.

Both risk corridors and risk adjustment are important programs that keep plans participating in the Part D program. We recognize that Congress intended for PSP to be the mechanism by which additional plan and program risk would primarily be mitigated. However, having narrower risk corridors and more finely-tuned risk adjustment is an important "belt and suspenders" approach CMS should consider, for CY2025 and beyond. Given that there are significant questions about funding for PSP, any additional methods CMS can use under current law to reduce risk should be explored, including its existing demonstration authority.

***PCMA recommendation*: CMS should declare in the final rule and eventual Final Notice that it is exercising its existing authority on risk corridors and risk adjustment to help manage premium increases on beneficiaries.**

C. PBMs Can Administer the Direct Negotiation Pricing for Part D Covered Drugs

PBMs can help CMS solve a major operational challenge created by Part D covered drugs subject to direct negotiation: how will pharmacies be held harmless? Pharmacies will continue to purchase drugs through wholesale channels at wholesale prices, not at the MFP determined by CMS. We recommend that CMS leverage the new MDP, which replaces the

[46] We acknowledge that in the Advance Notice, CMS has declined to update the risk adjustment and risk corridor programs for CY2024 to address the IRA's changes. See We acknowledge that in the Advance Notice, CMS has declined to update the risk adjustment and risk corridor programs for CY2024 to address the IRA's changes.

current CGDP. In theory, the mechanisms under which MDP operates are identical to the CGDP, just at different discount levels and in two benefit phases, not one. Layering the MFP assessment into the same system minimizes the number of touchpoints needed on any one claim. We lay out a proposed process below.[47]

Part D plans currently reimburse pharmacies the lower of ingredient cost or the contracted negotiated price, minus beneficiary cost sharing. Comparing multiple prices is built into the PBM-pharmacy claims adjudication process already, for example, to ensure beneficiary copays do not exceed the covered ingredient cost amount. Plans will need to have loaded the MFP prices as "negotiated price" in order to calculate beneficiary cost sharing under the law. This means the PBM has all the data it and CMS needs to be the main intermediary.

The pharmacy then holds the risk on the difference between ingredient cost and MFP. Therefore, for MFP-priced drugs, to keep pharmacies whole, PBMs would need to pay the higher of invoice or negotiated price for these drugs, in a flip to current procedures, minus beneficiary cost sharing. Again, PBMs can do this because they already have built the logic to protect beneficiaries from extremes.

Upon paying the pharmacy the full ingredient cost rather than negotiated price minus cost sharing, the PBM would send the necessary data on this claim to a third-party administrator (TPA), as it does under the CGDP today. (We imagine this can happen monthly, just like with CGDP and presumably the future MDP.) The TPA would then bill manufacturers of the MFP-priced drugs for the difference between pharmacy acquisition cost and plan-covered amount. Manufacturers would dispute or pay. The TPA would then distribute funds back to the covering plans.[48]

We expect the replacement for CGDP – the new 10% and 20% MDP – would operate substantially identically to the existing CGDP. A process to hold pharmacies harmless should fit neatly into that same framework, without creating any new procedures for Part D plans, the TPA, or manufacturers. Further, operating MDP and MFP in the same system is the best solution because MFP-priced drugs are excluded from MDP. This has the added benefit of reducing unnecessary manufacturer disputes, if the same TPA is processing both kinds of discounts in the same way, and in the same time frame.

[47] We note that CMS has opened an Information Collection Request on the initial draft manufacturer agreement for the MDP. PCMA will be filing separate and additional timely comments on this draft. See 88 Fed Reg 7976, February 7, 2023.

[48] This is identical to how the Coverage Gap Discount Program works today. Plans send data on claims in the Coverage Gap to Palmetto GBA, the CGDP TPA, each month. Palmetto invoices manufacturers based on these data, resolves disputes, receives the payments from the manufacturers, and distributes payments back to Part D plans quarterly.

***PCMA recommendation*: CMS should indicate in the final rule that it will administer the pricing of drugs subject to direct negotiation in a manner similar to, and in conjunction with, the new Manufacturer Discount Program set to begin in 2025.**

III. Updating and Incorporating Long-standing Program Guidance into the Code of Federal Regulations

In 2019, the U.S. Supreme Court ruled in favor of plaintiff Allina Health Services, finding that CMS must undertake notice-and-comment rulemaking prior to changing any "rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard governing the scope of [Medicare] benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits."[49] In the intervening years, we have discussed the implications of this case with CMS and are wholly aware that much of the current Part D program operates through subregulatory guidance, built to clarify terms codified in federal regulations at the program's outset in 2005. We fully understand the monumental undertaking it is for CMS to revise its regulations to account for up to 17 years of program guidance. We appreciate that in one rule CMS cannot completely update the regulatory framework for the program. We have offered—and hereby continue to offer—our support in identifying and prioritizing guidance that is either incomplete, outdated, or where multiple versions may be contradictory.

While Herculean in size, this effort is also critical to get right. Each MA and Part D plan sponsor relies on up-to-date guidance to design its benefits and comply with all of the important beneficiary protections. CMS's network of regulations and guidance is vast, and spans contract terms with first tier downstream contractors like PBMs, which administer many of the Part D plan functions. CMS also limits how plans can be marketed to potential enrollees, and determines rights and obligations for contracted network providers, pharmacies, and enrollees. There are limited arenas designated by the federal statute in which state governments can also influence the operation of MA and Part D within their boundaries. Nine of the 34 PDP regions include more than one state; having to follow multiple state rules beyond the federal standards adds significant administrative expense to plan operations. Having a single, clear, national standard published in the Code of Federal Regulations (CFR) for these and other topics will reduce confusion among all regulators (state or federal), plan sponsors and their contractors, and beneficiaries and their advocates, helping to provide a uniform benefit to all Part D enrollees.

In the sections below, we provide comment on a handful of CMS's content, where we have substantive input to what CMS is proposing. We are not commenting on each provision in the rule that CMS seeks to codify. Our lack of comment does not mean a full endorsement of any given policy, just merely that there is no substantive change to the guidance that we recommend at this time.

[49] *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019)



A. Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools (§§ 422.101, 422.112, 422.137, and 422.138)

CMS makes several proposals for MA plans to ensure their coverage determinations and utilization management (UM) protocols mirror coverage decisions made within traditional Medicare and holding the plans to these decisions for specified durations and transitions. We wish to raise five considerations for CMS, regarding (1) related rulemaking, (2) recognition of existing PBM procedures, (3) caution regarding tying private market coverage criteria to traditional Medicare, (4) being careful about transitions in Part B drug therapy, and (5) too broadly defining the applicability period of a prior authorization (PA).

First, while PCMA generally does not comment upon pure MA proposals, there is related rulemaking open that would touch upon the electronic health information exchange aspects of this topical area.[50] We ask that CMS ensure that both rules, once final, are coordinated in both approach and implementation time frames.

Second, many of the processes described by CMS regarding MA coverage determinations and UM mirror existing requirements in the Part D program. Acknowledging that the rule would only modify MA regulations, we respectfully ask that CMS explicitly differentiate Part B drugs from other covered items and services. Under an MA-PD, the contracted PBM may play a role in coordinating all prescription drug decisions, based on previous CMS regulations allowing for step therapy and prior authorizations to “cross” the two benefits. For this reason, CMS should clarify that the existing Part D portion of the plan’s Pharmacy and Therapeutics (P&T) committee is sufficient for meeting the requirements under the proposed rule. CMS should also clarify that P&T committees are designed for the exclusive review of determining coverage for pharmaceuticals, not non-drug covered items and services.

Third, CMS proposes to bring MA coverage more in line with traditional Medicare, when a better shift would instead be to open traditional Medicare to the kinds of competition that MA is able to generate to reduce costs and improve outcomes. This proposal counteracts its own stated goals. It reduces consumer choice, if all MA plans cover what traditional Medicare covers, how the traditional program covers it. It complicates medical decision-making, traditional coverage policies are often vague and reliant on the contractor’s final decision rather than clearly stated in summary benefit documents, and it raises costs for all. Today MA plans have flexibility to perform medical management (e.g., having a patient try conservative

[50] 87 Fed. Reg. 76238, December 13, 2022. Comments for this regulation are not due until March 13, 2023. It would require that MA plans improve the electronic exchange of healthcare data and streamline processes related to prior authorization, while continuing CMS’ drive toward interoperability if finalized in current form.



therapies before surgery, redirecting a patient to a safer or more cost-effective site of care, etc.). CMS is saying that this is 'plan developed' criteria that will not be allowed to be used in addition to an applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), or other Medicare rule that applies to MA plans. Traditional Medicare is not set up to do medical management or very much in the way of prior authorization. As managed care plans, MA organizations are structured to perform case management services. It's part of how MA plans achieve the results that they do. The proposed rule would limit MA plans from performing the "managed" part of "managed care."

Fourth, there are complexities with Part B drugs that could make it very challenging to tell if a patient is already taking one when they join a plan (either switching to a new MA-PD or a new PDP). Under MA-PDs, PBMs often process Part B drug claims, or play a role in the organizational determination aspect of coverage, but not in all cases. The new plan may cover a given drug under a different benefit than the prior plan. Under PDPs, Parts A and B claims data access is prohibited to be used for coverage determinations. CMS needs to recognize in both cases that the full transitional coverage period might be needed to verify the appropriateness of continued care with the drug.

Finally, CMS proposes to require PAs be valid for the entire "course of treatment." The current standard is that the PA is valid for the rest of the plan year. However, it introduces serious concerns regarding cost-containment that should not be overlooked. One extreme interpretation could be requiring a lifetime approval duration for maintenance medications. The proposal restricts a tool that plans use to prevent overutilization of drugs. Overutilization can increase costs, harm patients, and prevent or delay a switch to a more appropriate treatment. It also restricts an important tool that plans use to limit fraud, waste, and abuse, as recognized by CMS's precluded prescriber program. Instead, we recommend CMS offer plans the flexibility to define both a minimum and a maximum time period for PAs. P&T committees are best positioned to ensure approval durations are not overly restrictive. Otherwise, this rule may create a situation where there is no clear time limitation and potentially no limitation on a provider continuing to furnish services.

***PCMA recommendation*: We appreciate CMS's intent in clarifying the coverage requirements applicable to MA but are concerned that the proposed rule would implicate unrelated areas, and otherwise raise costs.**

B. Review of Medical Necessity Decisions (§§ 422.566, 422.590, and 422.629)

We appreciate that CMS is carrying over to the MA regulations much of the language that has been applied to Part D plan sponsors since plan year 2012.[51] CMS's goal here should be to completely align the two programs, rather than have distinguishing differences. In many organizations, the same teams operate the coverage determination (CD) and organization

[51] 76 Fed. Reg. at 21576, April 15, 2011.



determination (OD) processes. Having them apply the same criteria regarding which clinician can render a denial of an initial coverage request will best reduce burdens. With this in mind, we offer the following recommendations for the final rule:

1. **CMS should add complementary language to 42 CFR 423.566.** We agree with CMS's sentiment that the reviewer of an OD need not be of the same profession or specialty as the item or service being reviewed. We believe this should carry over to Part D CDs as well. CMS should add the sentence "The physician or health care professional with expertise in the field reviewing the request need not, in all cases, be of the same specialty or subspecialty as the treating physician or other health care provider," in the corresponding Part D regulatory text. We have added "with expertise in the field" to CMS's proposed sentence, to bring the Part D text in line with the Part C text in spirit. Pharmacists may be the most appropriate final reviewer for a CD or an OD. CMS in the rule writes that plans should be able to decide the appropriate reviewer for each OD (and thus CD). We encourage CMS to memorialize this in the regulatory text, as well.

2. **CMS should identify other ways to reduce burdens on MA and Part D plan sponsors.** PCMA remains convinced that CMS should lighten burdens on plans further by allowing pharmacists to play additional roles on redetermination requests.[52] The initial check on a redetermination is that everything required is submitted. Under current guidance, only a medical director can make that determination. This adds undue cost to plan sponsors and diminishes the role of pharmacists in community and managed care settings. We note that most of the guidance appearing in the current appeals and grievances chapter is not yet being codified by CMS.[53] This guidance is critical to plans and advocates alike and should be high on CMS's list, going forward.

3. **CMS should take care to quantify these changes and all guidance-to-regulation changes.** Because preceding guidance to this rule change was never captured in formal administrative budgets, the time and money burden of this proposal does not reflect the actual costs incurred by PBMs and plans to perform ODs and CDs.

***PCMA recommendation*: We support codifying this longstanding process under MA with the caveat that CMS should not require that there be an exact match between the service requested and the qualifications of the medical director reviewing the request. We request CMS consider aligning the Part D rules to match the new language. We also request CMS consider allowing Part D coverage redeterminations to be initially reviewed by pharmacists.**

[52] Letter from Tom Barker, of counsel to PCMA, to HHS OGC. April 30, 2019. Attached to this letter as supplemental material.
[53] The updated Appeals and Grievances chapter was last published in August 2022, 3 years after *Allina*. Available at: https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.



C. Part C and Part D Midyear Benefit Changes and Part D Incorrect Collections of Premiums and Cost Sharing (§§ 422.254, 423.265, 423.293, 423.294)

CMS proposes to codify its existing guidance prohibiting midyear benefit enhancements (MYBE), outside of CMS-approved or maintenance formulary changes, that would reduce premiums or "bid-level" cost sharing after the beginning of the marketing period. We will focus on CMS's proposals regarding the Part D regulations, rather than those under MA.

CMS's proposal would establish a *de minimis* threshold for refunds and recoveries associated with incorrect collections of premiums and cost sharing. We support this proposal in principle as we have found that very small refunds generate an abrasion with beneficiaries and complaints asserting the plan sponsor is being wasteful. As proposed, this approach limits administrative costs, which in turn creates savings that can be passed along to beneficiaries. There are a few considerations CMS should reconcile, however, in a final rule:

1. The proposed rule reads as if the *de minimis* would be optional. We recommend CMS make the threshold mandatory, otherwise enrollees who switch plans may be confused.

2. CMS does not need to fully align Parts C and D regulations in this instance, because prescription claim processing differs significantly from medical claim processing. Prescription claims adjustments affect the enrollee's True out-of-pocket (TrOOP), including pushing someone into or out of the coverage gap. There is no similar cliff in MA – the out-of-pocket (OOP) maximum is much more transparent. At the claims level, pharmacies aren't sending monthly bills for unpaid cost sharing, and increasing or reducing cost sharing at the POS instead would require significant programming time, and likely new National Council for Prescription Drug Program (NCPDP) standards.

We also want to raise several concerns to CMS on a few areas that need further specification prior to finalization. This proposal does not align with the six-year overpayment lookback period CMS proposes to also codify, elsewhere, at §§ 422.326(c), 423.360(c), and (§ 401.305(a)(2). Further, numerous situations can cause overpayments and underpayments, but almost always require adjusting one or more claims (and related Prescription Drug Events (PDES)) or deleting PDEs (which typically results in claim adjustment activity). These activities most often result in changes to a beneficiary's financial accumulators, not only on the claim that was initially affected, but on multiple claims that had financials predicated on the original state of the affected claim. In other words, when one claim changes, it often affects other claims for that beneficiary for that plan year.

If CMS intends the adjustment activity should not be performed at all for affected claims that are older than the specified three-year lookback, the overpayment requirements would need to be changed to three years to align with the adjustment time frames, as there would be no



other way to correctly identify and calculate all the financial impacts resulting from an identified issue for plan years prior to the three-year time frame. Alternatively, does CMS intend claims outside the three-year lookback period (but within the six-year overpayment lookback period) be adjusted to correct the payment with CMS, but that a plan would not be allowed to initiate reimbursements or recoveries with the beneficiary, the pharmacy, or any other payers or other involved entities (e.g., long-term care (LTC) facilities), based on the resulting financial changes caused by these adjustment activities? If so, a plan would have no way to recoup their losses when an overpayment is identified and corrected. If this is the case, how does CMS want these losses reported?

Finally, we appreciate the in-place waiver under the COVID-19 public health emergency (PHE) declaration, intended to ensure adequate pharmacy access (cost-sharing waivers) that would otherwise violate the uniform benefit provisions. We request that CMS offer a transition period on this waiver, including into plan year 2024, should some or all of the covered items and services affected by the waiver not yet be either fully U.S. Food and Drug Administration (FDA) approved[54] or be available as commercial stock.[55]

***PCMA recommendation*: CMS should finalize this proposal, with modifications to not fully align Part D and MA rules, further consideration given to the overpayments provision of the rule, and regarding the post-PHE expectations.**

D. Call Center Interpreter Standards (§§ 422.111(h)(1)(iii)(A) and 423.128(d)(1)(iii)(A)) and Call Center Teletypewriter (TTY) Services (§§ 422.111(h)(1)(iv)(B) and 423.128(d)(1)(v)(B)) and Updating Translation Standards for Required Materials and Content (§§ 422.2267 and 423.2267)

CMS proposes several changes framed as codifying existing guidance with regard to language access plans (LAP) for individuals with limited English proficiency (LEP). First, it proposes to codify and clarify standards for interpreters available to enrollees by phone. Second, it would require that teletypewriters assistance be available to callers within seven minutes of the call. Third, CMS proposes to update its marketing and communications standards, such that plans would be required to have materials available in an enrollee's stated preferred language and in auxiliary form, if requested. CMS justifies this latter rule change by describing its work with Medicare-Medicaid Plans (MMPs), noting the prevalence

[54] As CMS is aware, Congress's FY2023 Omnibus Appropriations bill requires Part D plans to cover as "covered Part D drugs" any oral antiviral available under an Emergency Use Authorization (EUA) to treat COVID-19 through plan year 2024. The waiver need not include this additional language, but the existing waiver on collecting cost-sharing and ability to pay (and how to report) pharmacy dispensing fees should persist through plan year 2024 for continuity.

[55] It remains unclear how many doses of US government purchased doses (USG) of the two oral antivirals remain circulating. Even if or when these drugs receive full FDA approval, USG stock may still be circulating. CMS's waiver extension should apply to USG doses only, not commercially acquired product.



of non-English speaking beneficiaries, and those with difficulty hearing or reading, and linking these vulnerabilities to a higher likelihood of decreased health outcomes. Under the rule, once a plan becomes aware of an individual's needs it must honor all requests in the individual's preferred format. PCMA and its members are sympathetic to CMS's concerns and support this specific proposal. We offer several recommendations and considerations below on how to achieve the remainder of CMS's aims in a less burdensome manner.

First, as CMS acknowledged in last year's 2023 proposed rule, changes to other HHS regulations regarding LAP are underway. While we appreciate that for plan year 2023, CMS simply reverted to preceding rules, in this rulemaking CMS is instead aiming to codify an expected behavior. We ask that CMS ensure any requirements imposed on Part D plans are consistent and implemented in coordination with changes issued by the HHS Office of Civil Rights (OCR). As of this writing, OCR's final rule is expected this spring. For this reason, CMS should delay the requirements of this rule, since any change in OCR regulations that CMS wishes to impose on Part D plans will not have been available for public comment. At worst, CMS should "gate" any new requirements on them being compatible with the new OCR rule and defer any enforcement until plan year 2025. This will afford the industry sufficient time to sort out the new OCR requirements across all affected lines of business. A one-year delay will also provide plans sufficient time to set up the IT resources necessary to support fulfilling multiple language/fulfillment requests on a standing basis.

Second, in response to CMS's proposals on interpreter standards, TTY toll time and standing requests for non-English language materials, we recommend CMS consider several process efficiencies, and a number of open questions we have, before finalizing the language as proposed:

1. **Alternative delivery mechanisms.** Non-English physical materials production is typically outsourced, and three days is not enough time for Braille documents produced on demand, especially if it is non-English Braille. CMS should provide flexibility for plans to meet the time requirement in other ways. If the individual has a named Representative, could delivery of the materials to the appointment of representative (AOR) meet CMS's needs while the plan works to provide the document to the individual? Or would the delivery of a document via an e-reader be sufficient rather than Braille printed materials? Or could a plan offer telephonic translation services to the member, by bringing a translator or TTY on the line to help answer any questions in lieu of fulfilling the document in the alternate format?

2. **Single, national standards can simplify processes.** CMS cites its learnings from MMPs to justify the need for standing requests for these materials. As CMS is aware, one of the reasons it took so long to launch, the Medicare-Medicaid Plans (MMPs) was trying to navigate the differences in state law compared to CMS marketing guidance. Will CMS issue a single national standard to simplify all Part D communications – including among



MMPs – despite the Medicaid tie-in to that program? If CMS is so inclined, working across its silos to create a single Medicare **and Medicaid** standard would also be beneficial to participants.

3. **Alternative format requests.** How do enrollees request alternative formats? Can a Representative make the request? Can CMS provide model scripting to plans to discuss alternate format/translation requests with members? Enrollees may not understand what they are asking for, and then have more questions about the document they received instead. For example, many request large print but then are unhappy with the amount/type of paper received which results in grievances.

4. **Has CMS considered development model documents in large print and the 15 nationally most-common languages and Braille and Spanish Braille?** Having plans create these themselves based on the CMS model document, rather than CMS undertaking the work as a one-time expense, when they are likely contracting for similar work for the traditional Medicare program, seems unnecessarily burdensome on plans. If plans had a library of CMS-endorsed translations available, delivery would be more streamlined as well. Large print documents are difficult to convert from regular size print; it requires essentially an entire new typeset and layout, at additional expense for each plan sponsor.

5. **Can CMS and plans incorporate English language literacy into addressing social determinants of health?** As CMS noted in the rule convincingly, non-English speakers achieve worse health outcomes. What are CMS's expectations, and has it considered the role that its model documents can play in leveling the field in regard to English proficiency?

6. **Non-standard notices and time frames.** Beyond the model documents provided by CMS in English and Spanish, there are also many communications that are unique to an individual's specific situation that would need to be separately translated. Many of these communications, such as a UM decision or a care plan, need to be communicated very quickly to the beneficiary. The need for translation must be balanced with the need to provide many non-standard communications quickly. Turnaround times would be the most challenging element of this requirement. For accessible formats and auxiliary aids—given the complexity of audio, data, and braille conversion—the request for a unique document to be converted can take two to four weeks to complete. For unique documents to be translated into another language, the turnaround time is one to two weeks. This completion time runs counter to the need to provide many unique communications quickly. If CMS is intent on finalizing this requirement relative to non-standard communications, it would be critical that CMS first establish multi-stakeholder workgroups on how language translations and conversions to aids could be accomplished more quickly for nonstandard communications.



7. **Can CMS produce a definitive list of required materials?** Is 42 CFR 422.2267(e)(1) the current and complete list of materials that CMS expects to be translated or available in alternative formats? Some of these are categories rather than uniquely identified materials. We are concerned that we may not feel a document is called out in the list, but in actuality CMS still expects it translated.

8. **Medicaid requirements.** Also, within the rule, CMS is proposing that plans be required to adhere to both Medicare and state specific Medicaid requirements for a wide variety of plan types. We are requesting that CMS incorporate these state specific requirements into HPMS, along with the Medicare requirements. This will save plans from having to find the information themselves and keep everyone consistent in the languages they are using.

9. **Standing Basis.** CMS should clarify its expectations around what "on a standing basis" means. PBMs receive eligibility files from plan sponsors with language indicators. In one month, the file may list a language, and then the following month it may be missing. Are PBMs obligated to honor the original language indicator, in perpetuity?

***PCMA recommendation*: CMS should finalize this proposal but only with respect to standard documents, which CMS could ideally produce models for to streamline delivery. Plans will still need time to translate specific situational communications beyond what CMS would otherwise allot. CMS should delay any requirements on those types of communications pending further stakeholder feedback.**

E. Medicare Advantage (MA) and Part D Marketing (Subpart V of Parts 422 and 423)

In this rule, CMS is addressing several years of growing concerns regarding the marketing approaches taken by plans and their contracted third-party marketing organizations (TPMOs). PCMA supports CMS's effort and offers additional justification for the codification of these and other similar national standards. CMS's proposed actions in this rule will make clear to the market there is a single enforcer of a clear, beneficiary-focused standard.

1. **Uniform national standards are needed.** While state partnership is important, it is critical to preserve and strengthen the role of standardized, federal rules to ensure consistency in addressing misleading marketing materials across the country. A patchwork of state regulations on MA and Part D marketing materials would undermine strong and consistent federal standards and risk inconsistent enforcement regimes. Many of CMS's concerns are around television advertising. State-based differences could provide for loopholes or uneven enforcement. This is clearly the outcome Congress intended when it included the broad federal pre-emption clause in the MA and Part D authorizing statute.



2. **CMS should go beyond this proposal and codify additional Part C and D marketing requirements that exist elsewhere.** Since the regulatory and subregulatory requirements currently in effect related to marketing are not published in one place for stakeholders to reference, we recommend CMS compile and codify the various marketing requirements that exist within the Medicare Communications and Marketing Guidelines (MCMG) and clarifying HPMS memos. As with this rulemaking, CMS should provide the public with an opportunity to comment.

***PCMA recommendation*: We support CMS's efforts to protect beneficiaries from false and misleading advertising and ask that it further codify its other marketing guidance in the future.**

F. Changes to an Approved Formulary (§§ 423.4, 423.100, 423.104, 423.120, and 423.128)

CMS is proposing to codify its Prescription Drug Benefit Manual chapter on midyear formulary changes and the several updates it has provided to plan sponsors outside of the Manual via HPMS.[56] PCMA is fully supportive of codifying these changes, to create a single national standard. **We ask that CMS also extend the final rule to allow the immediate substitution biosimilars of the reference product as well.** If a reference product must compete directly with a biosimilar, beneficiaries and the Medicare program will achieve the potential of savings at a much quicker pace. The prescriber and patient community are looking to CMS to definitively state that biosimilars are safe and effective for the Medicare population. The status quo merely protects innovator reference biologics, at the expense of the Medicare program and its beneficiaries.

We acknowledge that FDA's interchangeability designation is enshrined in the ACA and in federal regulation. However, those regulations are about drug manufacturer approval pathways, and represent a further example of big drug companies erecting barriers to competition, rather than meaningful clinical distinctions across products. Many drugs that are "mere" biosimilars here are treated as wholly interchangeable in Europe for more than a decade. We point CMS to a recent report released by IQVIA that demonstrates that the introduction of an interchangeable biosimilar dramatically reshaped the insulin market, in a way that predecessor biosimilars did not.[57] CMS's formulary regulations should step outside of FDA's shadow and recognize that FDA-licensed biosimilars are safe and effective. Formulary regulations should also recognize that biosimilars of the same reference product are biosimilars of each other, and biosimilars are therapeutic substitutes for other reference products in the same therapeutic class.

[56] See Q5 in HPMS, CY 2022 Formulary Information, December 27, 2021.
[57] IQVIA Institute for Human Data Science, "Biosimilars in the United States 2023-2027." January 31, 2023. Available at https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2023-2027.

***PCMA recommendation*: CMS should expand its proposal, to also allow for the immediate substitution of biosimilar products for their reference product.**

G. Part D Proposed Automatic Shipment Requirements (§ 423.505)

PCMA has a long history of supporting simplification of the Part D program's auto-ship requirements. We appreciate that CMS is tackling this issue in this rulemaking, and pulling existing guidance up to the regulatory level, which will standardize the administration of these programs across the country. In the rule, CMS proposes to adopt most of the guidance provided by manual chapter and HPMS memo since its last rulemaking (2014), with a few exceptions. We recommend CMS revise its proposal in the following ways:

1. **CMS should adopt the language used in the 2020 Final Call Letter on plan approximations.**[58] This guidance, not referenced in the proposed rule, allows for plans to provide an approximate shipping date range (e.g., two to three days) in lieu of an exact date. As CMS is aware, through our shared experience with the COVID-19 PHE and any number of weather-related events, exact shipping and receipt dates are an unmanageable standard to meet. The 2020 guidance further permits plans to provide approximate cost-sharing amounts for an upcoming shipment, rather than the exact cost-sharing amount. Since beneficiaries may still be acquiring some drugs at retail pharmacies rather than through the mail, there's a chance that someone could trigger a new benefit phase while the automatic shipment is still in process.

2. **CMS should reduce the notification requirement to a single printed and mailed letter.** Plans repeatedly received phone calls from beneficiaries about receiving too much mail and confusion arises about whether something has changed when they receive a second letter.

***PCMA recommendation*: We support the codification of Part D automatic shipment requirements and recommend CMS use the 2020 Call Letter as its basis for allowing plan flexibility on shipment dates and approximate cost sharing.**

IV. Request for Comment on the Rewards and Incentives Program Regulations for Part C Enrollees (§ 422.134 and Subpart V)

CMS seeks comment on potential revisions to the MA regulations regarding rewards and incentives (R&I), based on a change in the standard of what a "cash equivalent" is according to

[58] CMS, Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, April 1, 2019. Available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf. See pages 230*ff*.



the HHS, OIG. We appreciate that CMS has made no proposal here, so plans operating in 2024 are not going to have to make sudden changes in their offerings. We continue to believe that Part D plan sponsors and their enrollees would benefit from RI designed with similar guardrails as the MA policy allows would bring an additional layer of health improvement activities to PDP enrollees. For example, under the MA Value-Based Insurance Design (VBID) CMMI model, MA plans were able to offer R&I based on enrollees meeting adherence goals for medications.[59] While we acknowledge there is not similar language in the Part D authorizing statute, we ask that CMS consider alternative authorities to achieve these aims. We suggest CMS find a way to continue to allow MA plans to offer cash equivalent R&I, and also to extend offerings to PDPs.

***PCMA recommendation*: CMS should identify a path forward to maintain or improve the ability of MA and Part D plan sponsors to offer enrollees cash equivalent rewards and incentives.**

V. Revisions to the Medication Therapy Management (MTM) Program

CMS has proposed significant structural reforms of the Medication Therapy Management (MTM) program. The current MTM program, in CMS's view, has seen decreasing enrollment and a lack of attention from Part D plan sponsors. Enrollment is voluntary, and plan and PBM outreach have not persuaded people to participate at high enough rates. Under the rule, plans would have to make a broader set of Part D enrollees eligible for MTM. CMS estimates that as many as 11 million enrollees may become eligible, up from about 4.5 million participants in MTM programs today.

PCMA is concerned about the CMS MTM program proposed changes. While PCMA supports a well-constructed MTM program, we are troubled that CMS is proposing a major expansion without considering either the significant implementation problems or other less burdensome ways to achieve a robust MTM program. Moreover, the proposal lacks a fundamental assessment as to why making more beneficiaries eligible to enroll into MTM is the optimal outcome. We also note a number of other viable options to improving MTM that CMS should consider. Rather than conduct such a wholesale swap in the midst of significant and serious changes to the Part D program under the IRA, CMS should engage the stakeholder community and determine alternative options for satisfying MTM statutory requirements, given all of the other plan offerings available today. At a minimum, we ask that CMS delay any effective date for changes to the MTM program to plan year 2025. Below we outline our concerns and offer a range of alternatives for consideration.

A. **What About Increased Engagement for Currently Eligible Beneficiaries?** CMS's drastic expansion of MTM threatens to miss an opportunity to have plans better target and engage those already eligible. If participation is low, then casting a wider net to a less

[59] RAND. Evaluation of Phase II of the Medicare Advantage Value-Based Insurance Design Model Test. Available at https://innovation.cms.gov/data-and-reports/2022/vbid-1st-report-2022.



needy population will not generate more engagement, just more participants. Withdrawing or at a minimum delaying the significant proposed MTM expansion would allow plan sponsors to focus on the existing eligible population that has the greatest need, avoid diluting the program, and be more consistent with the Administration's health equity goals.

B. **How much does it cost?** CMS acknowledges that its three-fold approach to eligibility expansion would more than double the number of MTM participants, yet states are unable to score the proposal because of unclear administrative costs. Any proposal that would increase eligibility by 6.5 million enrollees to a voluntary program – roughly the same number of Medicare beneficiaries in all of California[60] – must be "economically significant" regardless of presumed administrative costs and require a burden estimate before CMS can reasonably expect meaningful public input. In the final rule, CMS should offer such an analysis while delaying any action on the proposal itself.[61] Importantly, any additional costs incurred as a result of the expansion of the MTM program would be in addition to premium pressures from other policies that will go into effect in 2024 including changes from the IRA and the change in the definition of negotiated price – or pharmacy DIR at point-of-sale.

C. **How will CMS know what works and what doesn't?** The three-fold approach to expansion also means that CMS will be unable to determine which part of their expansion "worked" or "failed" when it is evaluated.[62] The metrics for MTM success for CMS (vaguely defined as related to reducing medication errors, improving health outcomes, and "maintaining a reasonable cost criterion") are ill-defined. If plans are not able to reduce medication errors beyond today's reductions with the expanded eligibility, is it because so many new enrollees had fewer than eight medications? Or maybe the

[60] Per https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/mcradvpartdenroldata/monthly/monthly-enrollment-state-2023-01, there are 6.7 million Medicare beneficiaries eligible for MA or Part D plan enrollment in California as of January 2023.

[61] Such an estimate should include costs such as: (a) information system changes and testing; (b) myriad plan operational and policy changes (e.g. need to go to specified sources for determination of maintenance drugs); (c) changes to enrollee materials, handbook, and mailings; (d)new training materials for employees; and (e) new education and training content for MTM providers. This list is of course in addition to the cost of conducting more CMRs which CMS has projected to be in the range of $336 million annually.

[62] CMS did not reference the CMMI "Part D Enhanced MTM Model" (eMTM Model) which ended in 2021. eMTM sought to test "whether modifications to traditional MTM requirements incentivize better medication management interventions and thereby lead to improved therapeutic outcomes and reductions in Medicare expenditures." [see: Part D Enhanced Medication Therapy Management Model | CMS Innovation Center. The Fourth Evaluation Report found that there were limited if any benefits from the various eMTM interventions to expand MTM to a broader population.[see: Evaluation of the Enhanced Medication Therapy Management (MTM) Model: At a Glance (cms.gov)]. There does not appear to be a final eMTM evaluation. In any event, due to the consistency of what the Model was looking at and the current CMS goals to improve MTM, at a minimum, CMS should conduct a "lessons learned" type assessment based on the eMTM Model findings.



baseline for errors is exceedingly low when the cost threshold invites participants on five stable, low-cost generic medications, whose potential errors have already been worked out. CMS will not know, yet PBMs will have expended millions of dollars in resources – yielding higher premiums for all Part D enrollees including those who participate in MTM – with no clear reason as to why. CMS also fails to address the main threshold question with MTM, which is how to engage unwilling eligible enrollees. In the final rule, CMS should instead consider a staged expansion, in a design that tests which facet yields the best outcomes. For instance, requiring eligibility based on a reduced number of drugs, first, could test whether Comprehensive Medication Reviews (CMRs) are effective for a broader set of individuals.

In addition to failing to recognize the earlier CMMI demo on enhanced MTM in the proposed rule, CMS also does not discuss the more recent expansion of MTM to include all at-risk or potentially at-risk beneficiaries (ARBs and PARBs) who are concurrently enrolled in Drug Management Programs (DMPs). ARBs and PARBs have a demonstrated claims history indicating they may have been prescribed a significant level of opioids. Under the SUPPORT Act, CMS was to design a DMP to monitor both the beneficiary and their prescribers and inform them of the risks. All DMP beneficiaries were automatically enrolled in MTMs beginning in 2021. Has CMS conducted any evaluation of this mandatory expansion? Did MTM build upon or distract from the purposes of the DMP?

D. **What about Star Ratings?** MTM participation affects Star Ratings in a number of ways, most directly through the CMR measure, which would need to be moved to display status given all the changes, but also through complaints tracking, adherence itself, and other chronic disease measures. While a change that affects all plans would seem to have a monotonic effect on all plans' Star Ratings, that is not the case, given the highly variable enrollment and mix of chronic conditions across the country. Further, reduced quality bonus payments would have the result of reducing the availability of MA supplemental benefits that target improvements in health equity-aligned measures.

E. **What about all the other programs in operation?** In our view, one concern CMS may be expressing is that much of what they considered to be MTM programming is occurring outside of the formal program. MA-PDs – which have a much more aligned incentive to achieve MTM goals than standalone PDPs – often employ case management and social determinant of health (SDOH) programming that incorporates the core concepts of MTM, and more, for populations beyond those enrolled in their formal MTM programs. They are achieving significant health outcomes improvements, though the results are not matriculating to MTM. In other cases, much of what MTM covers can be conducted in an automated fashion, without individual participant at all, e.g., drug-drug interaction (DDI) analyses, which are performed routinely outside of CMRs. Could CMS instead consider redefining what counts as MTM and accepting a broader conception of case



management as being compliant with the Part D requirements? In a similar vein, since the incentives for MA-PDs to operate MTM and MTM-like case management are clear, could CMS devise ways for PDPs to share in any Part A and B fee-for-service (FFS) medical benefits savings they generate?

F. **Can CMS help individuals understand the value of MTM or similar programs?** As CMS is aware, many individuals eligible for MTM choose not to participate. Could CMS consider changes to MPF that would highlight the value added by specific plans' MTMs? Would CMS consider their own outreach during the Annual Enrollment Period to potentially eligible enrollees providing them guidance on why selecting plans based on MTM program specifics may be beneficial? Beneficiary groups could be engaged to determine what changes may help make enrollees more receptive to participating in CMRs.

G. **CMS should engage the stakeholder community through a working group.** There is a recent precedent for convening a broad and diverse group. CMS in 2019-2020 engaged plans, PBMs, developers, and patient groups on how to improve MPF which resulted in major improvements supported by a wide range of interested parties. Plans and PBMs could be engaged to determine what other programs they have that currently substitute for the MTM program, to determine whether MTM expansion is warranted.

H. **CMS should re-issue any initiative it is considering to expand the MTM program as a Request for Information (RFI).** There are several questions CMS asks in the proposed rule that should be understood before any proposal is offered. CMS should ask these questions in a future RFI to inform the stakeholder workgroups we are recommending. These questions include those on eligibility criteria (e.g., whether to include cancer as a monolith core chronic condition), the effect of including any additional core chronic diseases on specialized MTM provider training and program size, and whether MTM services are an effective mechanism for management of certain diseases (e.g., those with high use of Part B drugs or frequently changing medication regimens). These seem to be questions CMS should understand prior to proposing a several-hundred-million dollar increase in plan expenditures and premium increases on beneficiaries.

***PCMA recommendation*: CMS should not finalize this proposal. It should instead undertake a stakeholder engagement exercise to determine which aspects of the MTM program are worth going forward. In addition, CMS should provide more flexibility to help plan sponsors reach the thousands of beneficiaries who are already MTM eligible but not yet engaged.**

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VI. Revisions to the Medicare Overpayment Provisions of the Affordable Care Act (§§ 422.326(c), 423.360(c), (§ 401.305(a)(2))

CMS has proposed to revise the standards by which a plan sponsor identifies an overpayment, by adopting the False Claims Act definition of "knowing" and "knowingly." Under the proposed rule, an MA organization or Part D sponsor has identified an overpayment if it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment. The context for this change is related to litigation over earlier rulemaking on overpayments in 2014, and confusion over revisions made in 2016 that sought to address the litigation. We appreciate CMS's efforts to clarify this important area of program integrity, but a few questions remain.

First, we ask that CMS clarify that there is still a need for an investigation period. While a plan may identify, or be made aware of, a potential overpayment, only through further investigation would it be able to identify the reason and make corrective action.

Second, we appreciate that CMS is working to align the MA and Part D regulations with the FFS regulations promulgated in 2016. However, in capitated models like MA and Part D, it's not clear how a repayment to CMS would work outside of annual reconciliation programs. MA and Part D plans are paid a risk adjusted per-member per-month (PMPM) amount by both CMS and the beneficiary. Beneficiaries then pay cost sharing to providers and pharmacies for covered items and services. (This simplifies an obviously more complicated process). An identified overpayment by beneficiaries as cost sharing is more readily actionable by plans than an overpayment by CMS or beneficiaries as subsidies or premiums, since the PMPM payments are not paying for specific items.

***PCMA recommendation*: CMS should clarify the continued need for an investigation period and further clarify how plans that receive overpayments on capitated rates would calculate and return these amounts.**

VII. Proposals intended to streamline the adoption of electronic health information interchange

A. Standards for Electronic Prescribing (§ 423.160)

CMS proposes updates to the standards that Medicare Part D plans will use for electronic prescribing (e-prescribing). CMS notes that it is proposing a "novel approach" to updating e-prescribing standards by cross-referencing relevant standards adopted by the Office of the National Coordinator for Health Information Technology (ONC) and those adopted in the Health Insurance Portability and Accountability Act (HIPAA). CMS states that the NCPDP SCRIPT standard version 2022011 offers important updates and efficiencies for the healthcare industry and would be a suitable e-prescribing standard for the Medicare Part D

program. CMS also proposes this NCPDP SCRIPT standard for the Part D medication history transactions and electronic prior authorization (e-PA) transactions, following a transition period from July 1, 2023 until January 1, 2025. Use of NCPDP SCRIPT version 2022011 would have a mandatory compliance deadline of January 1, 2025. CMS also notes that NCPDP has developed a Real-Time Prescription Benefit (RTPB) standard for use with an electronic real-time benefit tool (RTBT) and that NCPDP RTPB standard version 12 is designed for prescribers, not RTBT applications used by beneficiaries. CMS proposes that prescribers' RTBTs must comply with NCPDP RTPB standard version 12 by January 1, 2025. CMS emphasized, however, that it is not proposing that the NCPDP standard be required for beneficiary RTBTs.

PCMA has long-supported both e-prescribing and e-PA and believes that both tools increase transparency for health care consumers. E-prescribing ensures that each prescription is written by a valid prescriber and filled by a legitimate pharmacy, which improves patient safety and quality by reducing medication errors. Similarly, e-PA can streamline the PA process, saving both prescribers and PBMs administrative costs, while helping to prevent fraud, waste, and abuse. PCMA fully supports the use of e-PA as a means to improve provider and patient satisfaction and reduce inefficiencies in care delivery, such as access to prescribed medications and treatment.

***PCMA recommendation*: CMS should update the e-PA standard to NCPDP SCRIPT version 2022011, with a transition period for NCPDP SCRIPT from July 1, 2023 until January 1, 2025. CMS should not delay the mandatory compliance deadline beyond this date.**

B. Adoption of Health IT Standards (45 CFR 170.205)

ONC proposes to adopt standards for e-prescribing and other relevant activities on behalf of HHS, including for use by the Part D program. The new department-wide approach is intended to increase alignment within HHS and to reduce regulatory burden for stakeholders. Prior to this effort, the ONC Health IT Certification program and the Medicare Part D program have had separate standards for e-prescribing, medication history, and e-PA for prescription drugs. ONC and CMS are pursuing a new approach whereby ONC and CMS would adopt the same standards and align the requirements for use of those standards within each of their programs. CMS notes that alignment across the standards will provide for consistent regulatory requirements for Part D plan sponsors, health care providers, and health IT developers. CMS proposes that during a transition period – from the effective date of a final rule until January 1, 2025 – both the 2017-01 and 2022011 versions of the NCPDP SCRIPT standard would be available for use, with only the 2022022 version being available on or after January 1, 2025. CMS seeks comment on whether it should allow for a transition period up to January 1, 2026 or longer.

***PCMA recommendation*: CMS should align the standards and requirements for electronic prescribing and related activities across the Part D program and ONC Health IT Certification program. CMS should also allow for a transition period which should not be extended beyond 2026.**

C. Other Considerations-Updating NCPDP Telecommunication Standard Implementation Guide, Version F6 Standards and Competing Priorities

CMS's alignment of standards and requirements should include the proposed adoption of the NCPDP Telecommunication Standard Implementation Guide, Version F6 (Version F6) and equivalent NCPDP Batch Standard Implementation Guide, Version 15 (Version 15) in relation to all other changes taking place within the Medicare program.

PCMA agrees that implementation of Version F6 and Version 15 will mitigate existing inefficient workarounds, allow for more robust data exchanges between LTC providers and payers, improve coordination of benefits information, improve controlled substances reporting, codify clinical and patient data, harmonize with related standards, and improve plan benefit transparency. Version F6 and Version 15 would provide greater clarity in data exchanges between pharmacies and payers, improve reporting for various programs, eliminate complex workarounds, and improve plan coordination of benefits and transparency.

Given the complexity of the new F6 standard, PCMA believes that a 36-month implementation period with an additional transition period of eight months is necessary. This will allow sufficient time for IT development and internal testing, external testing, and certification, and then production deployment. For this reason, we support both a longer implementation period plus a transition period to perform stage testing, configuration, and implementation. Therefore, PCMA requests the compliance date be set 44 months after the final rule effective date for NCPDP Telecommunication Standard Version F6 and Batch Standard Version 15.

The additional time is necessary not only for successful implementation of the new standards, but also to accommodate the many changes required for successful implementation of the Inflation Reduction Act (IRA) provisions as well as other technology changes such as adoption of health IT standards, which are happening concurrently. PCMA is concerned that many of the same resources will be needed to address and implement IRA provisions affecting the Medicare program, updated health IT standards and electronic prescribing. This will create a significant challenge in terms of competing priorities and severe resource constraints, which could jeopardize the smooth implementation of both the new standards and the IRA requirements.

***PCMA recommendation*: CMS should finalize an F6 compliance date 44 months after the effective date of the final rule and ensure that stakeholders have sufficient time to develop and test changes before rolling them out.**

VIII. Changes to the Medicare Part C & D Star Ratings program

PCMA supports CMS's goals for the delivery of equitable and consistent, high-quality coordinated care to Medicare beneficiaries through measure updates, including measure additions, removals, and updates based on specification and performance changes. We applaud CMS's efforts at integrating measurement and quality with equitable care which requires the consideration and analysis of SDOH, such as geographic location, housing, transportation, co-morbidities, education, race, sex, and gender, among others. Assessment of such SDOH factors allows for integrated whole-person care that addresses medical and behavioral health needs through the lens of non-clinical social factors. However, PCMA recommends clarity of SDOH measurement goals and definitions to promote uniformity in care delivery and assessment. In addition, equity and equitable care is also affected by administrative factors such as measure weighting, guardrails, and extreme and uncontrollable circumstances.

A. Adding, Updating, and Removing Measures §§ 422.164 and 423.184

- **Proposed Measure Updates.** Medication Adherence for Diabetes Medication, Medication Adherence for Hypertension (RAS Antagonists), Medication Adherence for Cholesterol

CMS is proposing a substantive update to implement risk adjustment based on sociodemographic characteristics regarding medication adherence for three measures: (1) diabetes medication; (2) hypertension medication (RAS antagonists); and (3) cholesterol medication (statins). CMS proposes to implement risk adjustment based on measure specifications recommended by the Pharmacy Quality Alliance (PQA). If finalized, these risk adjustment adherence measures would be display measures for two years beginning with the 2026 Star Ratings, then replace the legacy measures as Star Ratings in 2028.

In addition to risk adjustments to the three adherence measures, CMS proposes to eliminate adjustments for In-Patient (IP)/Skilled Nursing Facility (SNF) stays. These inpatient stays do affect Proportion of Days Covered (PDC) calculations and disproportionately disadvantage vulnerable populations with sicker and medically complex members. Therefore, this is as much a measurement issue as it is a SDOH issue. Without risk adjustments offsetting this potential impact, we cannot support this proposal. Given that LTC facility staff manage this complicated population with scarce



resources, alignment is needed with respect to who is accountable once a patient enters LTC.

From a patient care lens, interactions with LTC facility staff are often unnecessary and take time away from actual patient care. Moreover, LTC facilities are held to quality standards that are measured which includes medication reviews by clinical staff. Given this duplication, we would suggest that CMS exclude members residing in LTC facilities, since these members are being managed by professional care teams and medications are actively monitored. Additionally, LTC billing practices like batch billing play more of a role in declining PDC calculations than lapses in doses and complicates the true view of adherence.

PCMA appreciates CMS's continued commitment to further exploring sociodemographic status (SDS) measures. However, we recommend that CMS not finalize the proposed updates for the reasons that follow. The agency's proposed rule references a June 28, 2020, Office of the Assistant Secretary for Planning and Evaluation (ASPE) Report to Congress[63] which recommended the implementation of social risk factors (SRFs) but does not provide insight into a definition of success regarding adherence measures. Perfect adherence is not attainable, and there is no discussion of a "ceiling" of adherence that would translate into a rating. Therefore, the lack of specificity surrounding an identifiable goal for the measure would harm beneficiaries.

In addition, removal of the stand-alone Part C Medication Reconciliation Post-discharge measure will have a negative impact on adherence, as post-discharge medication reconciliation is one of the best opportunities for intervention to ensure adherence. PCMA also believes that the proposed changes would place beneficiaries in a precarious position, as the proposed change would dissuade plans from taking on sicker populations with SDS characteristics associated with poor adherence. In addition, we do not support the proposed removal of the post-discharge medication reconciliation measure.

***PCMA recommendation*: CMS should not make the proposed substantive changes to the diabetes medication, hypertension medication, or cholesterol medication adherence measures for the 2026 Star Ratings measurement year.**

[63] Second Report to Congress on Social Risk and Medicare's Value-Based Purchasing Programs, *ASPE*, https://www.aspe.hhs.gov/reports/second-report-congress-social-risk-medicares-value-based-purchasing-programs.

PCMA

B. Proposed Measure Additions

- **Kidney Health Evaluation for Patients with Diabetes (Part C)**

CMS is proposing to add a kidney health evaluation for MA patients with diabetes to the 2026 Star Rating year. CMS began reporting this measure as a display measure for the 2022 Star Ratings. PCMA is strongly supportive of this measure, as it aligns with NCQA's Healthcare Effectiveness Data and Information Set (HEDIS) portfolio measure.[64]

***PCMA recommendation*: CMS should adopt the Kidney Health Evaluation for Patients with Diabetes measure for the 2026 Star Ratings.**

- **Concurrent Use of Opioids and Benzodiazepines (COB), Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (PolyACH), and Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults (Poly-CNS) (Part D)**

CMS is proposing to add a new performance measure that would measure Concurrent Use of Opioids and Benzodiazepines (COB) in Part D for the 2026 Star Ratings. The measure examines concurrent use of prescription opioids and benzodiazepines in Medicare Part D beneficiaries beginning at age 18. While PCMA understands the risks of concurrent use of prescription opioids and benzodiazepines, we believe the proposed measure is overly broad and would not be effective in reducing complications and overdoses for beneficiaries.

PCMA notes that the Centers for Disease Control and Prevention's (CDC) updated opioid prescribing guidelines[65] clearly state that decisions regarding concurrent use of opioids and benzodiazepines involve several considerations between a physician and patient. Identifying "enrollees who are at risk of respiratory depression or fatal overdoses, cognitive decline, or falls and fractures"[66] was considered by CDC to be a Category B recommendation, which classifies attention to prescribing opioids and benzodiazepines as an individual-level concern that does not apply to all persons. PCMA does not believe that CMS should develop measures and incentives that are at odds with the policies of the new CDC guidelines.

PCMA also believes that any necessary interventions regarding tapering off existing medications are the role of the physician – plans and PBMs do not have control of these

[64] Kidney Health: A New HEDIS Measure, *NCQA*, https://www.ncqa.org/blog/kidneyhealth/.
[65] CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022, *The Centers for Disease Control and Prevention*, https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?s_cid=rr7103a1_w.
[66] 87 Fed. Reg. at 79619.



decisions. In addition, opioid prescribing concerns are often addressed at the physician-level through enhanced Concurrent Drug Utilization Review (CDUR) Edits. CDUR Edits require additional steps from physicians when co-prescribing an opioid and a benzodiazepine through a soft reject. This safety edit is readily used and addresses co-prescribing concerns at an effective care level.

Should CMS adopt this measure, PCMA recommends that it be more targeted to effectively reduce adverse outcomes and be limited to patients who are newly using these medications concurrently, as long-time users of both medications are significantly less likely to experience adverse events.[67] Due to the logistical difficulties of coordinating concurrent use of opioids and benzodiazepines between physicians and health plans, limiting intervention to the first 30 days of concurrent use would be the most effective and feasible window to achieve desired results.

***PCMA recommendation*: CMS should rescind its proposed addition of the Concurrent Use of Opioids and Benzodiazepines measure.**

CMS is also proposing to add two new polypharmacy measures for: (1) Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH), and (2) Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults (Poly-CNS). The Poly-ACH measure would analyze the percentage of Part D beneficiaries with concurrent use of at least two ACH medications, and the Poly-CNS measure would calculate the percentage of Part D beneficiaries using three or more CNS-active medications concurrently. If finalized, these measures would go into effect for the 2026 Star Ratings. Should CMS adopt the measure, it should be limited to patients who are newly using these medications concurrently.

Data related to polypharmacy use is difficult to collect and burdensome for providers. It is also unclear as to which metrics and outcomes would be considered successful for this measure. This lack of clear goals for measurement exacerbates our concern that these new measures would not substantially improve patient outcomes.

While the agency notes that the goal of this measure is for "plans to encourage appropriate prescribing when clinically necessary,"[68] it is unclear how plans and PBMs are well situated to improve polypharmacy use compared to prescribers, who are better situated to understand a beneficiary's medical history and medication needs. Much of the research guiding CMS's proposal to include these new polypharmacy measures cites the

[67] Hernandez I, He M, Brooks MM, Zhang Y. Exposure-Response Association Between Concurrent Opioid and Benzodiazepine Use and Risk of Opioid-Related Overdose in Medicare Part D Beneficiaries, *JAMA Network Open*, 2018;1(2):e180919. doi:10.1001/jamanetworkopen.2018.0919.
[68] 87 Fed. Reg. at 79619.

Beers Criteria for Potentially Inappropriate Medication (PIM) Use in Older Adults[69] which shows low to moderate evidence, reiterating PCMA's recommendation regarding the need to collect robust and useful data.

***PCMA recommendation*: CMS should revoke its proposal to implement the Poly-ACH and Poly-CNS measures for the 2026 Star Ratings.**

C. Measure Weights (§§ 422.166(e) and 423.186(e))

- **Patient Experience/Complaints and Access Measures (§§ 422.166(e)(1)(iii) and (iv), 423.186(e)(1)(iii) and (iv))**

Beginning with the 2026 Star Ratings, CMS is proposing to decrease the weight of patient experience and complaint measures to two. In its final rule in 2020, CMS had increased the weight of patient experience and or complaints from two to four for the 2023 Star Ratings. In this proposed rule, CMS states that it has reconsidered its position from the 2020 final rule and now believes that these measures currently are receiving an undue weight in the Star Ratings. PCMA concurs with CMS's assessment.

***PCMA recommendation*: CMS should decrease the current weighting of patient experience and / or complaints measure from four to two.**

D. Guardrails §§ 422.166(a)(2)(i) and 423.186(a)(2)(i)

CMS is proposing to eliminate the guardrails that restrict the maximum allowable movement of non-Consumer Assessment of Healthcare Providers and Systems (CAHPS) cut points. This would modify the cut points for non-CAHPS measure stars. The guardrails have been in place so that the cut points for these measures did not increase or decrease more than the cap amount from year to year. If finalized, the guardrails would be removed for the 2026 Star Ratings.

With this proposed change, we believe that CMS must redefine its goals for success to adequately obtain the reward factor associated with CAHPS measures. Additionally, the lack of guardrails generates questions about an appropriate adherence percentage for cut points, as 100 percent adherence, for example, would not be an achievable goal for a 5-star rating.

***PCMA recommendation*: CMS should redefine its goals for success to adequately obtain the reward factor associated with CAHPS measures.**

[69] American Geriatrics Society 2019 Beers Criteria Update Expert Panel. Updated AGS Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc. 2019 Apr;67(4):674–694. PMID: 30693946.



E. Health Equity Index Reward (§§ 422.166(f)(3) and 423.186(f)(3))

CMS has created a Health Equity Index (HEI), which it proposes to use in the Part C and D Star Ratings that would reward plans with high scores for their enrollees with certain SRFs. CMS states that the HEI reward is designed specifically to create an incentive for plans to reduce disparities in care and improve health equity. CMS proposes to define HEI as "an index that summarizes contract performance among those with specified [SRFs] across multiple measures into a single score." CMS would replace the current reward factor with the new HEI reward starting with the 2027 Star Ratings.

PCMA has long supported efforts to increase quality for Medicare beneficiaries. Part D plans invest considerable resources on a long-term basis to increase plan performance and make improvements in their Star Ratings. We support CMS's efforts to improve health equity, though we suggest that the agency further clarify how the HEI would be applied and its impact on Star Ratings. In addition, it is critical that plans have access to the data that CMS utilizes in order to ensure that appropriate populations are being analyzed. In order for CMS to achieve its equity goals in an effective and efficient manner, we believe that more work needs to be done to target populations that can most benefit. In its current form, the proposal does not specify which SRFs would be leveraged or a specific intended outcome for the HEI measure.

In its discussion regarding the HEI reward, CMS notes that it agrees with the definition of SRFs that was established by the National Academies of Sciences, Engineering, and Medicine (NASEM). This definition is vague and would compound the unanswered questions surrounding the HEI definition. [70] A lack of specificity and clarity regarding a potential HEI measure and SRFs could also create an adverse incentive for cherry picking and beneficiary selection based on SRFs, and the reward factor would likely penalize plans that already have robust SDOH mechanisms integrated into their services.

In short, we believe that there is too much ambiguity surrounding the proposed HEI measure and definition to move forward with the agency's proposal at this time and that more work needs to be done to improve the HEI measure reward.

Should the agency maintain its support of the measure, we recommend a two-year display measure period to gather additional information on the HEI's impact, ways to achieve data goals, which populations to target, how to reconcile the reward factor for plans that already have robust SDOH initiatives in place, and the ultimate outcome goal for the measure.

Should CMS decide to move forward with the HEI measure, PCMA recommends a transition period for implementation, where the HEI measure would be a display measure for two years

[70] Social Risk Factors: Definitions and Data Accounting for Social Risk Factors in Medicare Payment, *The National Academies Press*, https://nap.nationalacademies.org/read/23635/chapter/4.



while CMS assesses the above issues. We also believe that a hold harmless provision would be appropriate to avoid adverse impacts on plans that already engage in SDOH efforts.

PCMA recommendation: CMS should withdraw the proposed HEI measure.

F. Improvement Measure Hold Harmless §§ 422.166(g)(1) and 423.186(g)(1)

CMS is proposing to lift the hold harmless provision for 4- and 4.5-star contracts due to the fact that those plans still have the potential to improve and increase their measure scores and Star Ratings, leaving the hold harmless to apply only to 5-star plans. If finalized, this provision would be applied to the 2026 Star Ratings.

PCMA applauds CMS for its sustained dedication to encouraging plan improvement as a means to better serve beneficiaries. However, we think CMS needs to consider a range of issues before finalizing this change. CMS should be aware that this change will cause the Tukey method to pull down total Star Rating scores since outliers are more commonly low-performing data points. This change will undoubtedly have a negative impact on plans and beneficiaries, as maintaining Star Ratings will become more difficult and require more plan resources.

Historically, we have found the known threshold cut points at the 4-star level provided the utmost clarity and predictability for plans. Fluctuating goalposts surrounding cut points not only enhances uncertainty but also does not provide adequate time to fully realize the adverse consequences of these changes. Constant methodological changes such as this proposed change systematically deprive beneficiaries of plan improvement to comply with new standards that risk further decreasing plans' ratings.

Additionally, performance is often driven at a regional level even if Star Ratings are scored at a national level. Factors like culture, demographics/social determinants of health, infrastructure, differences in healthcare administration, prescriber behavior, etc., drive quality performance. While there are areas of the country that tend to perform well and drive cut points on the high end, there are areas of the country, especially in areas that were heavily impacted by COVID and have not fully recovered. For these areas a 4- or 4.5-star may be the highest achievable rating. Therefore, a hold harmless on plans achieving a 4-star or above allows some cushion to account for those regional differences.

PCMA recommendation: CMS should revoke its hold harmless proposal to maintain consistency and predictability and not drain resources from plans.

PCMA

G. Extreme and Uncontrollable Circumstances §§ 422.166(i)(9)(i), 422.166(i)(10)(i), 423.186(i)(7)(i), and 423.186(i)(8)(i)

CMS is proposing to remove its extreme and uncontrollable circumstances rule, which applied when 60 percent or more of a contract's enrollees were in individual assistance areas designated by the Federal Emergency Management Agency (FEMA). CMS would limit the rule to Star Ratings for 2025 and earlier. CMS states that, for non-CAHPS measures in 2026 and beyond, if a contract is affected by an extreme and uncontrollable circumstance and has a significantly lower score on a measure, the score would be removed if it is an "extreme outlier." CMS states that removal of the 60 percent rule will simplify the Star Ratings calculations. Given that CMS has not provided a definition of extreme outlier and the percentage of enrollees affected by this change is unknown, more data is needed prior to removing the extreme and uncontrollable circumstances rule.

PCMA recommendation: CMS should not remove the extreme and uncontrollable circumstances rule without undertaking a comparative analysis of the data.

H. Calculation of Star Ratings §§ 422.166(a)(2)(i) and 423.186(a)(2)(i)

CMS is proposing to maintain its previously published final rule[71] to implement Tukey outlier deletion beginning with the 2024 Star Ratings, though the agency intends to finalize a technical change to rectify a codification error from that final rule. PCMA disagrees with the impending implementation of the Tukey outlier deletion, as it will have a negative impact on Star Ratings, as exemplified in the Tukey Outlier Deletion Simulations data file.[72] Hurdles to improving scores will likely impact plans' attitudes towards goals of improving scores.

PCMA recommendation: CMS should withdraw its proposed Tukey outlier deletion for the 2024 Star Ratings as it will create new hurdles for plans that are trying to improve their ratings.

IX. Transitioning away from Public Health Emergency (PHE)-related policies for Coronavirus-19 covered items and services

On January 30, 2023, the White House announced that the current COVID-19 PHE will expire effective May 11, 2023.[73] This announcement did not address the level of leftover government procured vaccines and antivirals, nor did it address commercial access and procurement given

[71] 87 FR 27766
[72] Tukey Outlier Deletion Simulations (ZIP), Part C and D Performance Data, *CMS.gov*, https://www.cms.gov/files/zip/tukey-outlier-deletion-simulations.zip.
[73] CMS, Current Emergencies, see https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page. Last updated February 2, 2023.

that these products are still being used under the Emergency Use Authorization (EUA) designation. Moreover, commercial access is dependent on full FDA approval of products with the availability of necessary NDC codes.

Since the start of the COVID-19 pandemic, access to antiviral therapeutics and COVID vaccines has been facilitated by and dependent on the PHE declaration, FDA EUA designations, and government-purchased supply of both products. FDA EUAs and government purchase and distribution of EUA tests and therapeutics eased access for insured and uninsured individuals. These federally procured products are provided at zero cost to all regardless of coverage, including with respect to copays and coinsurance.

Given that the PHE is ending, plans and PBMs will need guidance and confirmation of CMS's outlook on coverage and cost sharing for COVID-19 tests, vaccines, and treatments. As plan sponsors are constructing their plan offerings for 2024, some but not all COVID-19 tests, vaccines, and treatments (or indications thereof) will be either available only under an EUA or as government-purchased stock. Since the commercial pricing of these items remains unknown, CMS should clarify for manufacturers what level of UM (including but not limited to PA and cost sharing) Part D plan sponsors may impose on these services once commercially available.

With the end of the PHE set for May 2023, CMS should focus on tracking of government procured supply of both vaccines and antiviral medications as those supplies get depleted and replaced by commercially procured supplies. CMS should also address coverage with regards to FDA approval status of vaccines and antivirals, including copay and coinsurance parameters.

Moving forward coverage will also be affected by the 2023 Omnibus Bill Sec. 4131[74] which encourages continued coverage of oral antiviral drugs available only under an FDA EUA and dispensed pursuant to a prescription through December 31, 2024. PBMs will continue to facilitate appropriate clinical use of these therapies. These operational considerations mostly stem from the emergence of new COVID variants, changes in clinical guidance, and practice recommendations, false positive and negative test results. The role of UM post-COVID will be to help providers and pharmacists with respect to clinical appropriateness given that they may not be able to keep up with the clinical changes in real time.

Apart from coverage and access, the other important issue relates to the transition period from PHE to post-PHE period. Since the PHE is ending in May 2023, documents, operational, and administrative processes should not change midyear. The focus of unwinding should be on plan year 2024 materials post-PHE for minimizing beneficiary confusion and operational burdens. This will help the facilitation of commercial units throughout 2023 as government supplies get depleted and PBMs ready themselves for new administrative processes post-PHE.

[74] H.R.2617 - 117th Congress (2021-2022): Consolidated Appropriations Act, 2023. (2022, December 29). https://www.congress.gov/bill/117th-congress/house-bill/2617

***PCMA recommendation*: We recommend that CMS align COVID PHE unwinding with plan year 2024 and formally acknowledge the appropriateness of UM for commercial units of the oral antivirals and monoclonal antibodies for the Medicare program.**

CMS Is Not Required By the Inflation Reduction Act of 2022 to Revise the Current Regulatory Definition of Gross Covered Prescription Drug Costs

Section 11001 of the Inflation Reduction Act of 2022 (IRA)[1] requires the Department of Health and Human Services (HHS) to negotiate the prices Medicare pays for certain prescription drugs under Part B and Part D. In describing the drugs that are eligible for negotiation, the statute defines "total expenditures" by referencing, for Part D drugs, total "gross covered prescription drug costs (as defined in section 1860D-15(b)(3))."[2] Congress also cross-referenced the gross covered prescription drug costs definition to implement the Manufacturer Discount Program in the IRA.[3]

The term "gross covered prescription drug costs" has, since 2005, been interpreted by the Centers for Medicare & Medicaid Services (CMS) to mean "those **actually paid** costs incurred under a Part D plan, excluding administrative costs, but including dispensing fees, during the coverage year."[4] The "actually paid costs" include the share of actual costs actually paid by the Part D plan, nominal cost-sharing paid by or on behalf of an enrollee, and all amounts paid under the Part D plan by or on behalf of an enrollee.[5] In the Medicare Contract Year 2024 Policy and Technical Changes Proposed Rule,[6] CMS proposes to amend the definition of "gross covered prescription drug costs" to remove the phrase "actually paid."

We have been asked whether CMS is required by the IRA to amend its definition of "gross covered prescription drug costs" to remove the phrase "actually paid." We believe the answer is no, CMS is not required to amend its definition of gross prescription drug costs. As explained below, it is reasonable to conclude that Congress was aware of, and accepted, CMS' established definition of gross covered prescription drug costs, including the phrase "actually paid," when it cross-referenced the definition for purposes of the new programs.

Our opinion is limited to the issues specifically identified herein and does not address any other issues. The analysis and conclusions expressed in this opinion are based upon the laws, regulations, rulings and decisions currently in effect, all of which are subject to change, and are

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[1] P. L. 117-169.

[2] Social Security Act § 1191(c)(5), as added by § 11001 of the IRA; 42 U.S.C. § 1320f.

[3] Social Security Act § 1860D-14C, as added by § 11201 of the IRA; 42 U.S.C. § 1395w-114c.

[4] 42 C.F.R. § 423.308 "Gross covered prescription drug costs" (emphasis added).

[5] 42 C.F.R. § 423.308.

[6] Centers for Medicare & Medicaid Services, Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications, Proposed Rule, 87 Fed. Reg. 79452 (Dec. 27, 2022) (Proposed Rule).

subject to the limitations and qualifications set forth herein. It is possible that a court or HHS could reach conclusions different from our own.

I. Legal Background

A. Medicare Part D

In 1965, Congress amended the Social Security Act, through the Health Insurance for the Aged Act, to create Medicare.[7] Originally, Medicare consisted of Part A (hospital coverage) and Part B (supplementary coverage–*e.g.*, physician services). Those eligible for Medicare coverage included individuals who are age 65 or over and are eligible for Social Security retirement (or would be eligible for such benefits if certain government employment were covered employment under such title) or under the railroad retirement system. Outpatient prescription drug coverage was not part of the original Medicare program.

The Medicare program was amended in 2003 to add voluntary prescription drug coverage (Part D).[8] CMS issued a final rule in 2005 implementing the new Part D benefit,[9] and has issued rules implementing and revising requirements periodically since that time.

One Part D program feature is subsidized coverage for certain eligible beneficiaries.[10] In 2003, Congress created two subsidies: a direct subsidy and a "subsidy through reinsurance." The reinsurance-based subsidy

> is an amount equal to 80 percent of the allowable reinsurance costs (as specified in paragraph (2)) attributable to that portion of gross covered prescription drug costs as specified in paragraph (3) incurred in the coverage year after such individual has incurred costs that exceed the annual out-of-pocket threshold specified in section 1395w-102(b)(4)(B) of this title.[11]

"[A]llowable reinsurance costs," in turn, means

> with respect to **gross covered prescription drug costs** under a prescription drug plan offered by a PDP sponsor or an MA-PD plan offered by an MA organization, the part of such costs that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or organization or by (or on behalf of) an enrollee under the plan, but in no case more than the part of such costs that would have been paid under the plan if the prescription drug coverage under the plan were basic

[7] P.L. 89-97.

[8] Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA; P.L. 108-173)

[9] Centers for Medicare & Medicaid Services, Medicare Prescription Drug Benefit, 70 Fed. Reg. 4193 (Jan. 28, 2005).

[10] Social Security Act § 1860D-15.

[11] Social Security Act § 1860D-15(b)(1) (2003).

> prescription drug coverage, or, in the case of a plan providing supplemental prescription drug coverage, if such coverage were standard prescription drug coverage.[12]

And "gross covered prescription drug costs"[13] means

> with respect to a part D eligible individual enrolled in a prescription drug plan or MA-PD plan during a coverage year, the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year and costs relating to the deductible. Such costs shall be determined whether they are paid by the individual or under the plan, regardless of whether the coverage under the plan exceeds basic prescription drug coverage.[14]

B. Inflation Reduction Act

Among many other things, the IRA created a program under which HHS is required to negotiate prices with pharmaceutical manufacturers for certain Medicare-covered drugs (the Drug Price Negotiation Program). In creating and implementing this program, Congress amended the Part D subsidy definitions described above and, in the Drug Price Negotiation Program, cross-referenced the statutory definition of "gross covered prescription drug costs."

1. Gross covered prescription drug costs amendments

When Congress amended section 1860D-15 (the Part D subsidy provision) in 2010 and again in 2020, it did not make any substantive changes to the definition of gross covered prescription drug costs.[15] In 2022, however, Congress amended section 1860D-15 substantively. In the IRA, Congress changed the subsidy payment percentage amounts, changed the definition of allowable reinsurance costs, and changed the definition of gross covered prescription drug costs (used to determine allowable reinsurance costs).

Following the IRA, the gross covered prescription drug costs provision reads (changes in italics):

> *Subject to paragraph (2)(B),* for purposes of this section, the term "gross covered prescription drug costs" means, with respect to a part D eligible individual enrolled in a prescription drug plan or MA-PD plan during a coverage year, the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year and costs relating to the deductible. Such costs shall be determined whether they are paid by the individual or under the plan *(or, with respect to 2025 and subsequent years, in the case of an applicable drug, as defined in section 1395w-114c(g)(2) of this title, by a manufacturer)*, regardless of whether the coverage under the plan exceeds basic prescription drug coverage.

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[12] Social Security Act § 1860D-15(b)(2) (2003) (emphasis added).

[13] "Gross covered prescription drug costs" is sometimes abbreviated by CMS as GCPDC.

[14] Social Security Act § 1860D-15(b)(3) (2003).

[15] Pub. L. 111-148, Title VI, § 6402(b); Pub. L. 116-206, Div. CC, Title 1, § 112(a).

And, for these purposes, "applicable drug" means a covered Part D drug, but does not include a drug selected by HHS for negotiation during a specified period.[16]

2. Drug Price Negotiation Program

The Drug Price Negotiation Program requires HHS to negotiate the prices Medicare pays for certain prescription drugs under Part B and Part D. The IRA directs HHS to select "negotiation eligible" drugs.[17] In establishing the Program, Congress provided definitions of various terms used in the Program, including "total expenditures."

> The term "total expenditures" includes, in the case of expenditures with respect to part D of subchapter XVIII, the **total gross covered prescription drug costs (as defined in section 1395w-115(b)(3) of this title)**. The term "total expenditures" excludes, in the case of expenditures with respect to part B of such subchapter, expenditures for a drug or biological product that are bundled or packaged into the payment for another service.[18]

(emphasis added). The cross-reference, section 1395w-115(b)(3), is the definition of "gross covered prescription drug costs" described above. Congress included a similar cross-reference in the Manufacturer Discount Program included in the IRA.[19]

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[16] 42 U.S.C.A. § 1395w-114c

> (2) Applicable drug
>
> The term "applicable drug", with respect to an applicable beneficiary--
>
> (A) means a covered part D drug--
>
> (i) approved under a new drug application under section 355(c) of Title 21 or, in the case of a biologic product, licensed under section 262 of this title; and
>
> (ii)(I) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA-PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in;
>
> (II) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA-PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in; or
>
> (III) is provided through an exception or appeal; and
>
> (B) does not include a selected drug (as referred to under section 1320f-1(c) of this title) during a price applicability period (as defined in section 1320f(b)(2) of this title) with respect to such drug.

[17] 42 U.S.C.A. § 1320f-1.

[18] 42 U.S.C.A. § 1320f.

[19] Social Security Act 1860D-14C, as added by IRA § 11201(c); 42 USC § 1395w-114c.

C. Agency Interpretation

1. Gross covered prescription drug costs

CMS issued rules shortly after the Part D program was created, interpreting the Part D drug subsidy requirements, including the gross covered prescription drug cost.[20] And in 2005, when the first Part D rule was issued, it defined gross covered prescription drug costs as

> those **actually paid costs** incurred under a Part D plan, excluding administrative costs, but including dispensing fees during the coverage year and costs relating to the deductible. They equal-
>
> (1) All reimbursement paid by a Part D sponsor to a pharmacy (or other intermediary) or to indemnify an enrollee when the reimbursement is associated with an enrollee obtaining drugs under the Part D plan; plus
>
> (2) All amounts paid under the Part D plan by or on behalf of an enrollee (such as the deductible, coinsurance, cost-sharing, or amounts between the initial coverage limit and the out-of-pocket threshold) in order to obtain drugs covered under the Part D plan. These costs are determined regardless of whether the coverage under the plan exceeds basic prescription drug coverage.[21]

In March of 2009, the gross covered prescription drug cost definition was amended.[22] At the time, CMS explained that the revision was necessary to "ensure that nominal PAP copayments are included in 'gross covered prescription drug costs' and allowable reinsurance costs."[23] CMS further explained that "Any cost incurred by a Part D sponsor under the Medicare Part D program which does not represent "gross covered prescription drug cost" incurred by the sponsor to purchase or reimburse the purchase of Part D drugs is considered an "administrative cost"."[24]

CMS further explained that the amendment to the definition of gross covered prescription drug costs was necessary to exclude certain expenses paid by the plan:

> We proposed revising the definitions of "gross covered prescription drug costs" and "allowable risk corridor costs" to establish that the amount received by the dispensing pharmacy or other dispensing provider (whether directly or through an intermediate contracting organization) and not the amount paid by the Part D sponsor to the PBM, is the basis for determining the drug costs that must be reported to CMS. This change will

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[20] Centers for Medicare & Medicaid Services, Medicare Prescription Drug Benefit, 70 Fed. Reg. 4193 (Jan. 28, 2005).

[21] 42 CFR § 423.308 (2005)(emphasis added)

[22] Centers for Medicare & Medicaid Services, Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions, 74 Fed. Reg. 1493 (Jan. 1. 2009).

[23] Centers for Medicare & Medicaid Services, Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions, 74 Fed. Reg. 1493, 1504 (Jan. 1. 2009).

[24] Centers for Medicare & Medicaid Services, Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions, 74 Fed. Reg. 1493, 1514 (Jan. 1. 2009).

> ensure that all administrative costs incurred by Part D sponsors, including the "risk premium" paid to PBMs to mitigate market risk around the cost of drugs, are excluded from the drug costs used to determine reinsurance and risk sharing payments.[25]

CMS justified the change, in part, by saying that "the proposed changes to the definitions of "gross covered prescription drug costs" and "allowable risk corridor costs" would increase transparency by ensuring that CMS and Part D sponsors are aware of actual Part D drug costs."[26]

In October of 2009, CMS proposed to revise the definition of gross covered prescription drug costs again, this time to "replace the term 'negotiated price' with the term 'actual cost,'" and to correct a technical error in the March 2009 definition which failed to reference usual and customary prices for out-of-network drugs.[27] CMS finalized the proposal in 2010, explaining that "our intent was to clarify that Part D sponsors must use the amount received by the

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[25] Centers for Medicare & Medicaid Services, Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions, 74 Fed. Reg. 1493, 1514 (Jan. 1. 2009).

[26] Centers for Medicare & Medicaid Services, Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions, 74 Fed. Reg. 1493, 1514 (Jan. 1. 2009). The rule read as follows (changes in italics):

> Gross covered prescription drug costs *mean* those actually paid costs incurred under a Part D plan, excluding administrative costs, but including dispensing fees, during the coverage year. They equal *the sum of the following:*
>
> (1) The share of negotiated prices (as defined by § 423.100 of this part) actually paid by the Part D plan that is received as reimbursement by the pharmacy, or other dispensing entity, reimbursement paid to indemnify an enrollee when the reimbursement is associated with an enrollee obtaining covered Part D drugs under the Part D plan, or payments made by the Part D sponsor to other parties listed in § 423.464(f)(1) of this part with which the Part D sponsor must coordinate benefits, including other Part D plans, or as the result of any reconciliation process developed by CMS under § 423.464 of this part.
>
> (2) Nominal cost-sharing paid by or on behalf of an enrollee which is associated with drugs that would otherwise be covered Part D drugs, as defined in § 423.100 of this part, but are instead paid for, with the exception of said nominal cost-sharing, by a patient assistance program providing assistance outside the Part D benefit, provided that documentation of such nominal cost-sharing has been submitted to the Part D plan consistent with the plan processes and instructions for the submission of such information.
>
> *(3)* All amounts paid under the Part D plan by or on behalf of an enrollee (such as the deductible, coinsurance, cost sharing, or amounts between the initial coverage limit and the out-of-pocket threshold) in order to obtain *Part D drugs that are covered under the Part D plan. If an enrollee who is paying 100 percent cost sharing (as a result of paying a deductible or because the enrollee is between the initial coverage limit and the out-of-pocket threshold) obtains a covered Part D drug at a lower cost than is available under the Part D plan, such cost-sharing will be considered an amount paid under the plan by or on behalf of an enrollee under the previous sentence of this definition, if the enrollee's costs are incurred costs as defined under § 423.100 of this part and documentation of the incurred costs has been submitted to the Part D plan consistent with plan processes and instructions for the submission of such information.* These costs are determined regardless of whether the coverage under the plan exceeds basic prescription drug coverage.

[27] Centers for Medicare & Medicaid Services, Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 75 Fed. Reg. 19677, 19786 (April 15, 2010).

dispensing pharmacy or other dispensing provider as the basis for determining the drug costs that must be reported to us."[28]

Thus, the current rule defining gross covered prescription drug cost is more detailed than the original 2005 definition, but retains the "actually paid costs" phrase, just as it did in the original 2005 rule:

> Gross covered prescription drug costs mean those **actually paid costs** incurred under a Part D plan, excluding administrative costs, but including dispensing fees, during the coverage year. They equal the sum of the following:
>
> (1) The share of actual costs (as defined by § 423.100 of this part) actually paid by the Part D plan that is received as reimbursement by the pharmacy, or other dispensing entity, reimbursement paid to indemnify an enrollee when the reimbursement is associated with an enrollee obtaining covered Part D drugs under the Part D plan, or payments made by the Part D sponsor to other parties listed in § 423.464(f)(1) of this part with which the Part D sponsor must coordinate benefits, including other Part D plans, or as the result of any reconciliation process developed by CMS under § 423.464 of this part.
>
> (2) Nominal cost-sharing paid by or on behalf of an enrollee which is associated with drugs that would otherwise be covered Part D drugs, as defined in § 423.100 of this part, but are instead paid for, with the exception of said nominal cost-sharing, by a patient assistance program providing assistance outside the Part D benefit, provided that documentation of such nominal cost-sharing has been submitted to the Part D plan consistent with the plan processes and instructions for the submission of such information.
>
> (3) All amounts paid under the Part D plan by or on behalf of an enrollee (such as the deductible, coinsurance, cost sharing, or amounts between the initial coverage limit and the out-of-pocket threshold) in order to obtain Part D drugs that are covered under the Part D plan. If an enrollee who is paying 100 percent cost sharing (as a result of paying a deductible or because the enrollee is between the initial coverage limit and the out-of-pocket threshold) obtains a covered Part D drug at a lower cost than is available under the Part D plan, such cost-sharing will be considered an amount paid under the plan by or on behalf of an enrollee under the previous sentence of this definition, if the enrollee's costs are incurred costs as defined under § 423.100 of this part and documentation of the incurred costs has been submitted to the Part D plan consistent with plan processes and instructions for the submission of such information. These costs are determined

[28] Centers for Medicare & Medicaid Services, Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 75 Fed. Reg. 19677, 19787 (April 15, 2010).

regardless of whether the coverage under the plan exceeds basic prescription drug coverage.[29]

2. Actually paid

In 2005, CMS also defined "actually paid."[30] CMS explained that "[a]ctually paid means that these costs must be net of any discounts, chargebacks, and average percentage rebates, and will exclude any amounts not actually incurred by the sponsor."[31] The formal definition of actually paid reads:

> "Actually paid means that the costs must be actually incurred by the sponsor and must be net of any direct or indirect remuneration (including discounts, chargebacks or average percentage rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred by the sponsor for the drug."[32]

The current definition of "actually paid" reads:

> Actually paid means that the costs must be actually incurred by the *Part D* sponsor and must be net of any direct or indirect remuneration (including discounts, *charge backs* or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred *under the Part D plan. Direct and indirect remuneration includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers, pharmacies or similar entities obtained by an intermediary contracting organization with which the Part D plan sponsor has contracted, regardless of whether the intermediary contracting organization retains all or a portion of the direct and indirect remuneration or passes the entire direct and indirect remuneration to the Part D plan sponsor and regardless of the terms of the contract between the plan sponsor and the intermediary contracting organization*.[33]

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[29] 42 CFR § 423.308 (2023).

[30] Centers for Medicare & Medicaid Services, Medicare Prescription Drug Benefit, 70 Fed. Reg. 4193 (Jan. 28, 2005).

[31] Centers for Medicare & Medicaid Services, Medicare Prescription Drug Benefit, 70 Fed. Reg. 4193, 4311 (Jan. 28, 2005).

[32] *See, e.g.*, Centers for Medicare & Medicaid Services, Medicare Prescription Drug Benefit, 70 Fed. Reg. 4193, 4398 (Jan. 28, 2005).

[33] 42 CFR § 123.308 "Actually paid" (2023)(emphasis added).

The italicized terms show the differences between the 2005 and 2023 definition; the additions were made in 2009 when CMS decided to codify then-current guidance to clarify what direct and indirect remuneration includes.[34] In that rule, CMS favorably quoted a comment that said "rebates retained by PBMs and price concessions received from manufacturers should be treated as part of the true drug cost."[35] CMS further noted that "actually paid" was intended, in part, to assist Part D sponsors identify the most cost effective drugs and help Part D sponsor in negotiations with manufacturers and PBMs.[36]

3. Proposed rule amendments to gross covered prescription drug cost

The Proposed Rule would amend the current definition so that it reads:

> Gross covered prescription drug costs means those costs incurred under a Part D plan, excluding administrative costs, but including dispensing fees, during the coverage year. They equal the sum of the following:
>
> (1) The share of actual costs (as defined by § 423.100 of this part) paid by the Part D plan that is received as reimbursement by the pharmacy, or other dispensing entity, reimbursement paid to indemnify an enrollee when the reimbursement is associated with an enrollee obtaining covered Part D drugs under the Part D plan, or payments made by the Part D sponsor to other parties listed in § 423.464(f)(1) of this part with which the Part D sponsor must coordinate benefits, including other Part D plans, or as the result of any reconciliation process developed by CMS under § 423.464 of this part. …

CMS explains that gross covered prescription drug costs (also referred to in the preamble as GCPDC) is statutorily defined, and that the statutory definition of "allowable reinsurance costs"

> specifies that such costs are the subset of GCPDC that are "actually paid (net of discounts, chargebacks, and average percentage rebates)," the statutory definition of GCPDC at paragraph (3) of that provision does not use the phrase "actually paid" or otherwise specify that such costs must be net of all DIR.[37]

CMS concludes that

> This distinction, coupled with the use of the modifier "gross" to describe these costs indicates that the best reading of section 1860D-15(b)(3) of the Act is that GCPDC should reflect gross costs, not net costs that reflect all DIR that a Part D sponsor may receive. As stated above, CMS's use of the phrase "actually paid" in the current regulatory definition of GCPDC was intended to emphasize that all DIR would be netted

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[34] Centers for Medicare & Medicaid Services, Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions, 74 Fed. Reg. 1493, 1512 (Jan. 1. 2009).

[35] Centers for Medicare & Medicaid Services, Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions, 74 Fed. Reg. 1493, 1512 (Jan. 1. 2009).

[36] Centers for Medicare & Medicaid Services, Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions, 74 Fed. Reg. 1493, 1512 (Jan. 1. 2009).

[37] Proposed Rule, 87 Fed. Reg. 79452, 79611.

> out in the calculation of costs eligible for Part D reinsurance consistent with the plain language of the statute, which requires that the reinsurance payment amount be based on net drug costs. While the use of the phrase in the current regulatory definition of GCPDC is consistent with the statute for this reason, we recognize that that it may have led to ambiguity as to when the DIR would be netted out. We also recognize that the use of the phrase could create ambiguity when GCPDC is referenced outside of the reinsurance context (as it now is by the IRA).[38]

As a result, CMS believes, it is necessary to remove the two references to "actually paid" from the regulatory provision implementing the statutory definition, "to clarify that GCPDC are not net of all DIR."[39] CMS emphasizes, however, that the change

> would have no impact on Part D payment calculations or reporting requirements. Consistent with section 1860D-15(b)(2), the reinsurance payment amount would continue to be calculated based on drug costs net of DIR.[40]

CMS further noted that, because of a new definition of ""negotiated price" effective January 1, 2024, all price concessions from network pharmacies will continue to be reflected in the negotiated price which is reflected in the gross covered prescription drug cost.[41]

CMS does not appear to be proposing to remove or amend the regulatory definition of "actually paid" from the CFR, so the phrase continues to have meaning.

II. Analysis

We have been asked if the IRA requires CMS to change its long-standing regulatory definition of gross covered prescription drug cost to remove "actually paid." In short, we believe the answer is no, the IRA does not require CMS to change its definition of gross covered prescription drug costs.

A. Text of the IRA does not require CMS to reinterpret gross covered prescription drug costs

In establishing the Drug Price Negotiation Program in the IRA, Congress defined "total expenditures" in relation to the gross covered prescription drug cost statutory definition. Specifically, for purposes of the Negotiation Program, total expenditures includes total gross covered prescription drug costs (with an exception for certain bundled, Part B drugs).[42] The IRA

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[38] Proposed Rule, 87 Fed. Reg. 79452, 79611.

[39] Proposed Rule, 87 Fed. Reg. 79452, 79612.

[40] Proposed Rule, 87 Fed. Reg. 79452, 79612.

[41] Proposed Rule, 87 Fed. Reg. 79452, 79612.

[42] 42 USC § 1320f(c)(5) ("The term "total expenditures" includes, in the case of expenditures with respect to part D of subchapter XVIII, the total gross covered prescription drug costs (as defined in section [1860D-15(b)(3)] 1395w-115(b)(3) of this title). The term "total expenditures" excludes, in the case of expenditures with respect to part B of such subchapter, expenditures for a drug or biological product that are bundled or packaged into the payment for another service.)

also amended the Part D drug subsidy program and, in that amendment, referenced total gross covered prescription drug costs. In the Manufacturer Discount Program established in the IRA, Congress also cross-referenced total gross covered prescription drug costs when defining total expenditures (with the same definition as under the Negotiation Program).[43]

Thus, Congress clearly referenced the definition of gross covered prescription drug costs multiple times. These cross-references did not, however, require CMS to change its current interpretation of the gross covered prescription drug costs term. If Congress had intended for CMS to change its interpretation, it could have and it had multiple opportunities to do just that. In fact, Congress did clearly limit the definition of "total expenditures" in the Negotiation Program to "gross covered prescription drug costs" *excluding* certain bundled drugs, demonstrating that Congress understood the term that it cross-referenced and chose to modify it for Negotiation Program purposes.[44] Despite this, Congress did not modify CMS' gross covered prescription drug costs definition to exclude "actually paid" costs.

B. Congress legislates against the background of current interpretation

CMS has interpreted gross covered prescription drug cost to include "actually paid" since 2005. Importantly, "where, as here, Congress adopts a new law incorporating sections of a prior law, Congress normally can be presumed to have had knowledge of the interpretation given to the incorporated law, at least insofar as it affects the new statute."[45]

Here, of course, Congress is cross-referencing a definition, but that definition is thus incorporated into the new programs Congress created in the IRA. It is reasonable to conclude that, because CMS has interpreted the definition consistently for nearly 20 years, Congress "had knowledge of the interpretation" of the definition. Moreover, for purposes of the new program, as explained above, Congress was careful to exclude certain bundled drugs from "total expenditures," which is otherwise the total gross covered prescription drug cost, ensuring that the new Negotiation Program operates as Congress intends. Absent affirmative direction from Congress, it is reasonable to conclude that Congress was aware of CMS' established definition and did not intend, via a cross-reference, to suggest to CMS it must change its longstanding interpretation of gross covered prescription drug cost to include "actually paid" costs.

C. Congress actually amended this provision without changing the definition

CMS first included "actually paid" in the regulatory definition of gross covered prescription drug costs in the fall of 2005. Congress has, since that time, amended the Part D program generally, and section 1860D-15 (the statutory section with the "gross covered prescription drug cost"

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[43] 42 USC § 1395w-114c(g)(4)(D).

[44] The IRA's definition of "total expenditures" for purposes of the Drug Price Negotiation Program is the "total gross covered prescription drug costs" as defined in Part D, but "excludes, in the case of expenditures with respect to part B [of the Medicare title], expenditures for a drug or biological product that are bundled or packaged into the payment for another service." 42 U.S.C. § 1320f(c)(5).

[45] *Lorillard v. Pons*, 434 U.S. 575, 581 (1978).

definition) specifically, and has not changed CMS' definition or otherwise suggested that CMS' interpretation was incorrect.[46]

Perhaps most important for these purposes, Congress also actually amended the definition of "gross covered prescription drug costs" *in the IRA* to provide that, with respect to "applicable drugs" (which are generally those not selected by HHS for negotiation) costs include those paid by a manufacturer. This suggests that, at a minimum, Congress considered how the term "gross covered prescription drug costs" would need to be modified for purposes of the drug subsidy pro in light of the relevant new IRA programs. Nonetheless, Congress did not amend the applicable language to require that gross covered prescription drug costs not be interpreted to reflect "actually paid" costs.

Courts will at times place significant, even dispositive, weight on the fact that Congress has amended a provision.[47] Similarly, courts have also at times concluded that Congress adopts a settled interpretation when it reenacts a statute that had been consistently interpreted.[48] As the Supreme Court explained

> Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it reenacts a statute without change.[49]

In this case, Congress actually made a change to the very definition at issue, but did not correct, modify or in any way suggest that CMS' long-standing definition of the provision was improper.[50]

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[46] *See* I.B.1 and note 15, above.

[47] *Stone v. INS*, 514 U.S. 386, 397 (1995) ("When Congress acts to amend a statute, we presume it intends its amendment to have real and substantial effect."); *Pierce Cnty., Wash. v. Guillen*, 537 U.S. 129, 145 (2003)(rejecting a reading of a statute that would render an amendment an "exercise in futility.").

[48] *Lorillard v. Pons*, 434 U.S. 575, 581 (1978); *see also, Pierce v. Underwood*, 487 U.S. 552, 567 (1988)(in "a situation in which Congress reenacted a statute that had in fact been given a consistent judicial interpretation … [s]uch a reenactment, of course, generally includes the settled judicial interpretation."); *Bragdon v. Abbott*, 524 U.S. 624, 645 (1998) ("When administrative and judicial interpretations have settled the meaning of an existing statutory provision, repetition of the same language in a new statute indicates, as a general matter, the intent to incorporate its administrative and judicial interpretations as well.").

[49] *Merrill Lynch, Pierce, Fenner & Smith v. Curran*, 456 U.S. 353, 382 n.66 (1982)(concluding that when Congress re-examines and leaves a statutory provision intact that had been substantively interpreted by courts, it does so intentionally)

> "Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change, see *Albemarle Paper Co. v. Moody*, 422 U.S. 405, 414, n. 8, 95 S.Ct. 2362, 2370, n. 8, 45 L.Ed.2d 280 (1975); *NLRB v. Gullett Gin Co.*, 340 U.S. 361, 366, 71 S.Ct. 337, 340, 95 L.Ed. 337 (1951); *National Lead Co. v. United States*, 252 U.S. 140, 147, 40 S.Ct. 237, 239, 64 L.Ed. 496 (1920); 2A C. Sands, Sutherland on Statutory Construction § 49.09 and cases cited (4th ed. 1973). So too, where, as here, Congress adopts a new law incorporating sections of a prior law, Congress normally can be presumed to have had knowledge of the interpretation given to the incorporated law, at least insofar as it affects the new statute." *Lorillard v. Pons*, 434 U.S. 575, 580–581, 98 S.Ct. 866, 869–871, 55 L.Ed.2d 40 (1978).

[50] As the First Circuit concluded, when one statute was amended, but another related statute was not, "subsequent Congressional inaction may signal acquiescence to an agency interpretation." *Com. of Mass. v. Sec'y of Health & Hum. Servs.*, 899 F.2d 53, 60 (1st Cir. 1990), cert. granted, judgment vacated sub nom. *Sullivan v. Massachusetts*, 500 U.S. 949 (1991), and abrogated by *Rust v. Sullivan*, 500 U.S. 173 (1991).

In other words, this is not a case of Congress simply failing to act to correct an interpretation. By amending the definition specifically to function properly in Part D (after the newly enacted Programs) and by clarifying the exclusion of bundled drugs as the definition is used in the newly created the Drug Negotiation Program, Congress clearly and intentionally reaffirmed the statutory definition, and by implication, its long-standing interpretation.

D. Agency authority to continue long-standing interpretation

HHS, and its division CMS, has general authority to issue "such regulations as may be necessary to carry out the administration of the insurance programs under" Medicare.[51] Courts "generally will defer to a permissible interpretation espoused by the agency entrusted with its implementation."[52] And "[o]f particular relevance is the agency's contemporaneous construction which 'we have allowed ... to carry the day against doubts that might exist from a reading of the bare words of a statute.'"[53] Here we have CMS' contemporaneous interpretation of gross covered prescription drug costs and that interpretation has been consistently maintained for nearly twenty years. This suggests that courts would be inclined to uphold the current definition of gross covered prescription drug costs, absent evidence that Congress rejected it (which we do not have).

In addition,

> "[t]he Supreme Court has made clear that courts must give heightened deference to [an agency's] interpretation of a 'complex and highly technical regulatory program' such as Medicare."[54]

Here, the gross covered prescription drug costs definition is not only an operative definition in Part D, but a definition applicable to the Part D reinsurance subsidy, a technical part of the complex Part D program. As CMS explained in the preamble to the 2024 Proposed Rule, CMS included "actually paid" in its regulatory definition of gross covered prescription drug costs to "to emphasize that DIR [direct and indirect remuneration] would be netted out in the calculation of costs eligible for Part D reinsurance as required by the statute."[55] In other words, CMS read the definition in the context of the reinsurance subsidy required under Part D and interpreted the term in harmony with the context, a perfectly supportable interpretation.[56] CMS notes that the

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[51] Social Security Act § 1871(a)(1); 42 USC § 1395hh(a)(1).

[52] *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 414 (1993).

[53] *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 414 (1993).

[54] *Washington Reg'l Medicorp v. Burwell*, 813 F.3d 357, 362 (D.C. Cir. 2015)(quoting *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1229 (D.C.Cir.1994) which was in turn quoting *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512, 114 S.Ct. 2381, 129 L.Ed.2d 405 (1994)).).

[55] Proposed Rule, 87 Fed. Reg. 79452, 79611.

[56] *Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 666 (2007)("It is a 'fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall

current definition—which includes "actually paid"—"is consistent with the statute …".[57] Indeed, CMS believes that even absent the phrase "actually paid" in the definition of gross covered prescription drug costs, "GCPDC would continue to be reduced by POS [point-of-service] DIR reflected in negotiated prices."[58]

However, after the passage of the IRA, and its cross-references to the gross covered prescription drug costs definition, CMS now believes that its long-standing definition "could create ambiguity when GCPDC is referenced outside of the reinsurance context (as it now is by the IRA)."[59] Yet, as we have seen above, there was no indication by Congress that it believed the long-standing definition was ambiguous, could cause any ambiguity in the new programs, or even that CMS' established interpretation of the statutory term should be revised simply because newly created programs now cross-reference it.

In short, CMS' contemporaneous interpretation of gross covered prescription drug costs was justifiable at the time it was issued and there is no evidence that Congress either objected to CMS' definition or that, in cross-referencing the term in the IRA, that Congress intended CMS to change its long-standing definition.

III. Conclusion

We believe the answer to the question of whether CMS is required by the IRA to amend its definition of "gross covered prescription drug costs" to remove the phrase "actually paid" is no. As explained above, the text of the IRA does not direct CMS to change its definition, and it is reasonable to conclude that Congress was aware of, and accepted, CMS' established definition of gross covered prescription drug costs, including the phrase "actually paid," when it cross-referenced the definition for purposes of the new programs. Moreover, Congress actually amended the definition at issue in the IRA to accommodate the newly created programs that cross-reference the definition and did not at that time "correct" CMS' interpretation. As a result, we do not believe that the IRA requires CMS to change its long-standing definition of gross covered prescription drug costs.

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statutory scheme.' ") This is also supported by the fact that this is a long-standing interpretation that Congress has not felt it needed to change.

[57] Proposed Rule, 87 Fed. Reg. 79452, 79611.

[58] Proposed Rule, 87 Fed. Reg. 79452, 79612.

[59] Proposed Rule, 87 Fed. Reg. 79452, 79611.

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Comment On: CMS-2022-0191-0001
Medicare Program: Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, etc.

Document: CMS-2022-0191-0740
Comment on CMS-2022-0191-0001

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General Comment

Elevance Health appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') "Contract Year 2024 Policy and Technical Changes to the Medicare Advantage (MA) Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications," proposed rule, published on December 27, 2022. Please see our attached comments.

Attachments

Elevance Health Comments_2024 MAPD Proposed Rule(2023-02-13)

Submitted via Federal e-Rulemaking Portal: http://www.regulations.gov

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

February 13, 2023

Re: Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications

Administrator Brooks-LaSure,

Elevance Health appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') "Contract Year 2024 Policy and Technical Changes to the Medicare Advantage (MA) Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications," proposed rule, published on December 27, 2022.

Elevance Health is a lifetime, trusted health partner fueled by its purpose to improve the health of humanity. We support consumers, families, and communities across the entire care journey – connecting them to the care, support, and resources they need to lead healthier lives. Elevance Health's companies serve approximately 119 million people through a diverse portfolio of industry-leading medical, digital, pharmacy, behavioral, clinical, and complex care solutions. Elevance Health serves over 2.5 million Medicare beneficiaries through our MA plans, nearly 1.5 million of the beneficiaries we serve are in MA-Part D (MA-PD) plans, and about 600,000 beneficiaries are full or partial-benefit dual eligibles.

Executive Summary

With the continued growth of the Medicare program and the success and popularity of MA and Part D, we urge CMS to implement policies that support the overall stability of the programs to enable plans to continue providing access to the affordable, high-quality care beneficiaries want and rely upon every day. We urge CMS to reconsider the magnitude of the

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changes they have proposed across recent regulatory and sub-regulatory actions. When combined, they will result in significant disruption to the program and, more importantly, these changes will negatively impact nearly 50% of Medicare beneficiaries.

Nearly half of Medicare beneficiaries choose MA because it delivers better services, better access to care, and better health outcomes.[1] The value MA plans deliver to beneficiaries include out-of-pocket spending protections, reductions in cost-sharing and Part B premiums, access to prescription drug benefits – often at no additional cost, and important supplemental benefits like dental, vision, hearing, transportation, nutrition, and in-home support services. The value-based MA model outperforms Fee-For-Service (FFS) Medicare on clinical quality measures, improves survival rates, and reduces hospital readmissions.[2] [3] [4] Beneficiaries are also overwhelmingly satisfied with the MA and Part D programs as evidenced by surveys where 90% of respondents were satisfied with their coverage and would recommend MA to their friends and family.[5]

Below are: (1) Elevance Health's recommendations on key issues at a high level; (2) key issues we would highlight as CMS considers policies to implement the Inflation Reduction Act (IRA); and (3) detailed comments and recommendations.

Star Ratings

The MA Star Rating system was created by CMS in 2007 to measure MA and Part D performance based on specific measures on a 1 to 5 scale.[6] The system incentivizes quality improvement and public accountability and provides beneficiaries with a valuable tool to assist in choosing a high-quality health plan. A comparable comprehensive quality measurement system does not exist in FFS Medicare.

The Star Rating system continues to increase the quality of the health plans available, and the care provided to MA and Part D beneficiaries.[7] A robust body of research has shown that

[1] https://www.ajmc.com/view/quality-health-and-spending-in-medicare-advantage-and-traditional-medicare
[2] https://pubmed.ncbi.nlm.nih.gov/29130269/
[3] https://www.ajmc.com/view/value-based-contracting-innovated-medicare-advantage-healthcare-delivery-and-improved-survival
[4] https://pubmed.ncbi.nlm.nih.gov/29944655/
[5] https://www.affordableprescriptiondrugs.org/resources/americans-opinions-on-the-elimination-of-rebates-in-medicare-part-d.
[6] Sprague L.: *The Star Rating System and Medicare Advantage Plans*. Washington (DC): National Health Policy Forum; 2015 May 5. (Issue Brief, No. 854.): www.ncbi.nlm.nih.gov/books/NBK560455/
[7] O'Neill Hayes T: *Primer: The Medicare Advantage Star Rating System* (June 2015): www.americanactionforum.org/print/?url=https://www.americanactionforum.org/research/primer-the-medicare-advantage-star-rating-system

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MA delivers significantly better care, leading to better outcomes and lower costs compared to FFS Medicare.[8] [9] [10]

Health plans with Star Ratings of at least 4-Stars receive bonus payments that must be used to offer additional benefits and lower cost-sharing for beneficiaries. We support improvements to the Star Rating system that appropriately incentivize high performance and quality improvement. However, we are concerned that taken together, the significant changes in the proposed rule would amount to a nearly $25 billion cut to the Star Ratings program. These cuts would lead to benefit cuts and cost increases for beneficiaries and undermine the Administration's health equity goals.

Eliminating the Hold Harmless for Star Rating Improvement Measures Would Negatively Impact Beneficiaries

We are concerned CMS' proposal to remove the hold harmless provision for the Star Rating improvement measures would harm beneficiaries by limiting the availability of high-quality plans and would lead to more out-of-pocket costs and access to fewer benefits for beneficiaries, impacting plans' ability to address social drivers of health. When CMS implemented the Quality Improvement (QI) measure, the agency acknowledged that the approach would create an unintended consequence: the QI measure for high-quality plans would drop once their ratings improved because—as plans improve their scores—it gets more difficult to produce a statistically-significant improvement year-over-year. In other words, a contract's Star Rating could drop due to a drop in the QI score, even if the plan continued to improve and make gains in each measure, but not enough to be statistically significant. Because of this unintended consequence, CMS implemented its existing hold harmless policy for plans who earn 4- and 4.5-Stars. This ensures a recognized high-quality health plan is not penalized for only making modest gains after reaching the 4-Star threshold. In turn, beneficiaries have more opportunities to enroll in high-quality contracts with at least 4 Stars and received additional benefits and reduced cost-sharing.

[8] DuGoff E, Tabak R, Diduch T, Garth V: Quality, Health, and Spending in Medicare Advantage and Traditional Medicare. The American Journal of Managed Care (September 2021): www.ajmc.com/view/quality-health-and-spending-in-medicare-advantage-and-traditional-medicare
[9] Timbie JW, Bogart A, Damberg CL, Elliott MN, Haas A, Gaillot SJ, et al.: Medicare Advantage and Fee-for-Service Performance on Clinical Quality and Patient Experience Measures: Comparisons from Three Large States. Health Services Research (December 2017): www.pubmed.ncbi.nlm.nih.gov/29130269/
[10] Mandal AK, Tagomori GK, Felix RV, Howell SC: Value-Based Contracting Innovated Medicare Advantage Healthcare Delivery and Improved Survival. The American Journal of Managed Care (February 2017): www.ajmc.com/view/value-based-contracting-innovated-medicare-advantage-healthcare-delivery-and-improved-survival

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Removing the QI Hold Harmless for 4- and 4.5-Star Ratings Devalues Quality Improvement

By proposing to change the hold harmless policy and only applying it to 5-Star plans, CMS would introduce the unintended consequence it originally sought to avoid. Plans that achieve 4- and 4.5-Stars and continue to make modest gains (but not enough to achieve 5-Stars) would see their QI measures score drop, despite continuing to be high-quality plans. This change would significantly decrease the number of contracts obtaining 4 or more Stars, increasing the volatility of Star Ratings, and reducing the incentive for quality improvement. The QI measures are intended to evaluate year-over-year improvement in contracts, not the number of measures that achieve 5-Stars as compared to other health plan contracts.

The Proposed Policy Would Lead to Lower Star Ratings Undermining Health Equity Goals

The existing hold harmless policy for the QI measures that apply to 4-Stars and above has driven quality improvement across measures. Achieving the 4-Star threshold increases the benchmark against which MA plans bid, and a portion of the savings between the bid and the benchmark are used to enhance benefit offerings and lower costs for beneficiaries.

The enhanced benefit offerings made possible by the current policy support work addressing health equity. Health plans that obtain the quality bonus payment for achieving 4-Stars or higher are able to offer more robust supplemental benefits such as dental, vision, and hearing coverage that improve whole-person health. Special Supplemental Benefits for the Chronically Ill (SSBCI) such as nutritious meals, transportation, and in-home supports go even further to help address social drivers of health.

By CMS' own estimate, the elimination of the hold harmless provision for 4- and 4.5-Star plans would result in over $19 billion in cuts over the next ten years, which are not mandated by Congress. A significant portion of these savings would come from supplemental benefits. Removing those benefits would directly harm the Administration's health equity goals. For these reasons, we urge CMS to withdraw this proposal.

Improve Health Equity Index (HEI) Reward Framework to Address Health Disparities

Elevance Health supports CMS' ongoing efforts to ensure the right incentives exist to promote the goal of addressing health disparities. We have implemented many strategies to improve

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health equity, including working with a variety of stakeholders, such as community-based organizations, to provide innovative supplemental benefits like non-medical transportation, nutritious food, and home-safety services.

We agree that the existing reward factor should be improved to better gauge how measures can account for social risk factors in the Star Ratings program. However, CMS' proposal would drastically change the current reward factor so that it becomes a two-sided, net-zero, approach. We believe a system that focuses exclusively on rewards and is equitable for all plans to participate is the best approach.

CMS' proposal would create the following challenges:

- CMS proposes enrollment thresholds for the HEI reward that disqualify smaller contracts which would discourage the enrollment of beneficiaries with social risk factors in smaller tailored plans that best meet their needs, such Chronic Condition Special Needs Plans (C-SNPs);
- Create an incentive for contract enrollment gaming where health plans could target or avoid cohorts of beneficiaries, particularly dually eligible beneficiaries, and beneficiaries with chronic conditions, because CMS is not proposing any corrections (similar to risk adjustment) that would ensure contracts are fairly scored relative to the different populations in each contract, and its "net zero" approach would incentivize selection for the purpose of maximizing the HEI reward.; and,
- Undermine improvements in health equity in the majority of Group Retiree contracts. Group Retiree contracts will be too small to quality for the HEI reward, which directly impacts the resources available to address health-related social needs.

For these reasons, we recommend CMS withdraw this proposal and instead propose an improved framework that continues to take a reward-only approach (instead of a mix of rewards and penalties). If CMS moves forward with this proposal, we urge the agency to establish a transition period that phases-in the approach. The phase-in should ensure the revised approach is tested with data for at least three years, consistent with CMS' standard practice for display measures, plus one year considering the different Health Outcomes Survey (HOS) measurement years. CMS should ensure the current reward factor is still in place for three years, and then the revised approach could be phased-in during the following four years (for example, 25% in Y4, 50% in Y5, 75% in Y6, and 100% in Y7).

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Coverage Determinations and Prior Authorization

The application of health plan medical policy is one of the most effective ways to ensure the right care is provided at the right place and the right time. Experts have found that hundreds of billions of dollars are wasted every year in healthcare – and that beneficiaries often receive care that is costly, inappropriate, or unnecessary.[11] [12] Elevance Health's medical policies are developed by over 100 physicians and clinicians that have expertise in their specialties and are based on both peer-reviewed studies in medical literature and guidelines that reflect a strong clinical consensus among the medical specialty communities. By ensuring care is aligned with evidence-based medicine, Elevance Health drives towards improved health outcomes and reduced emergency department readmissions to align with CMS' strategic pillars to protect the Medicare program, drive innovation, and foster excellence.[13]

We appreciate CMS' efforts to ensure coverage determinations (including Utilization Management [UM] and Prior Authorization [PA]) are made using transparent medical policy and overseen by Medical Directors or other appropriate healthcare professionals with the appropriate experience. Focusing on these areas helps build beneficiary and provider trust in the market. To that end, Elevance Health supports CMS' proposals to require health plans to:

- Only use internal coverage criteria to the extent it is made publicly available;
- Involve Medical Directors or other appropriate healthcare professionals to ensure the clinical accuracy of medical necessity decisions where appropriate; and,
- Ensure staff reviewing coverage determinations have the appropriate expertise based on the item or service being requested.

Conforming MA Medical Policy to FFS Medicare would Undermine Health Outcomes and Increase Costs

CMS' proposal to require health plans to adopt the medical policy used by FFS Medicare fails to recognize that the application of FFS Medicare's medical policy may lead to worse health outcomes for beneficiaries and would have other negative implications. The FFS Medicare requirements are often incomplete, out of date, and do not contain the latest clinical

[11] Ricardo Alonso-Zaldivar: *Health-care system wastes $750 billion a year* (accessed January 2023): csmonitor.com
[12] Johns Hopkins Medicine: *Unneeded Medical Care is Common and Driven by Fear of Malpractice, Physician Survey Concludes* (accessed January 2023): hopkinsmedicine.org
[13] Centers for Medicare & Medicaid Services: *CMS Strategic Plan* (accessed January 2023): cms.gov

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guidance from medical specialty communities. The shortcomings of FFS Medicare's medical policy include the following:

- **Lack of specificity in key areas:** FFS Medicare has a number of coverage policies that are vague and do not provide appropriate guidance, meaning the proposed regulation may have the practical impact of inhibiting any coverage denials in those areas, even in cases where the service being provided presents a safety risk.
- **Nonexistent medical policies in key areas:** In addition to those areas of medical policy that are vague, there are key benefit areas where FFS Medicare has no medical policy. While the proposed regulation would allow health plans to use their own medical policies in such circumstances, the rule appears to not allow guidelines built upon a clinical consensus that has not yet been incorporated into the published medical literature.

By proposing that MA plans conform their more up to date and complete coverage policies to FFS Medicare, CMS is working against a number of its stated goals to drive innovation and promote value-based, person-centered care in the following ways:

- **Worse health outcomes:** FFS Medicare coverage guidelines can be vague or fail to reflect the latest medical research in key areas; requiring health plans to adopt them would eliminate guidelines that are proven to improve health outcomes and reduce health risks for beneficiaries;
- **Reduced beneficiary choice:** Removing differentiation on coverage guidelines between health plans and FFS Medicare (and between health plans themselves) takes away an important element of beneficiary choice;
- **Lower value care:** Health plans work with providers on medical management policies to achieve better health outcomes and improvements in the Star Rating quality measures, affordability, and product design through value-based care arrangements; and,
- **Higher costs:** Health plan coverage guidelines are proven to help reduce costs; eliminating UM tools would increase costs to the Medicare program and result in higher premiums and/or reduced benefits.

CMS proposes to go even further than requiring health plans to conform to FFS Medicare guidelines by also proposing to prohibit the application of medical policies that requires one item/service to be furnished prior to another item/service. This proposal runs counter to one of the most important elements of medical policy: ensuring that a medical item or service is provided at the right time (that is, the right step in the course of treatment). Medical policy is often designed to ensure that a less invasive item/service is furnished prior to a more invasive

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item/service, such as requiring an ultrasound prior to a Computed Tomography (CT) scan to limit unnecessary radiation exposure.

If CMS' proposals were finalized in this area, it would result in worse health outcomes, lower quality care, less beneficiary choice, and higher costs that would be passed on to beneficiaries in the form of higher premiums and/or fewer benefits, while exacerbating Medicare's financial challenges. For these reasons—and as explained in more detail below—we request CMS withdraw these proposals.

Medication Therapy Management (MTM) Eligibility Expansion

As a national MTM provider, Elevance Health has firsthand knowledge of how high-quality MTM services can make a difference in improving health outcomes, and we are supportive of finding opportunities to expand this service. However, instead of a thoughtful incremental expansion that would identify the beneficiaries most likely to benefit, CMS' proposed eligibility expansion would more than double those eligible for MTM services, diluting and devaluing the program for those who need it most and undermining the Administration's health equity goals.

Significant MTM Expansion Would Devalue MTM Services through Over-Expansion

As noted in the rule's preamble, the impact of implementing all the eligibility changes proposed would increase beneficiary eligibility from 4.5 million (9% of the Medicare population) to 11 million (23% of the Medicare population). Plan sponsors could not meet this substantial increase in volume overnight by simply scaling existing program elements. Due to pharmacy provider shortages, the strict administrative requirements of the program, and challenges engaging certain hard to reach beneficiary cohorts, without flexibility the proposal would undermine the effectiveness of the program for current beneficiaries.[14]

[14] National Community Pharmacists Association: *Survey: Three-Quarters of Community Pharmacies Report Staff Shortages* (accessed January 2023): ncps.org

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Undermining Health Equity Goals through Lower Star Ratings

Because Star Ratings help health plans provide supplemental benefits that address social drivers of health and support the Administration's health equity goals, it is important to consider how changes to the MTM program would impact Star Ratings. Elevance Health goes to great lengths to engage the existing MTM eligible population to maximize the Part D Comprehensive Medical Review (CMR) completion rate measure. Despite these significant efforts, we have difficulty reaching a percentage of existing eligible beneficiaries. Increasing the volume of MTM beneficiaries would result in even more difficulty achieving the 4- , 4.5-, or 5-Star Rating. Driving down Star Ratings would have the result of reducing the availability of supplemental benefits that help support health equity.

CMS Should Support Engagement of Currently Eligible Beneficiaries

We urge CMS to consider a different approach to expanding MTM services or, at a minimum, take a more incremental approach to the targeting criteria to ensure the potential expansion of this critical service is successful. We recommend CMS withdraw its existing proposal and provide more flexibility to help plan sponsors reach the beneficiaries who are already MTM eligible but not yet engaged. Specifically, we encourage CMS to move the new measure to display given the significant methodology changes and increase the chronic condition disease states incrementally by requiring plans to implement MTM for 6 chronic conditions versus 9. Withdrawing, or at a minimum delaying the significant proposed MTM expansion would allow plans to focus on the existing eligible population that has the greatest need, avoid diluting the program, and be more consistent with the Administration's health equity goals.

Payment Definitions: Gross Covered Prescription Drug Costs

CMS is proposing to change its definition of "Gross Covered Prescription Drug Costs" (GCPDC) to remove the phrase "actually paid." While CMS indicates in the rule's preamble that this proposed change intends to remove any ambiguity that may arise from the current definition, we are concerned it would have a significant, detrimental financial impact to the Medicare

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program to the extent it flows into the selection of drugs for which CMS will negotiate prices pursuant to the IRA.

CMS Should Clarify Intent to Select Drugs for Negotiation Based on Costs Net of Rebates

If CMS finalizes this proposal, the agency could select drugs for negotiation irrespective of rebates, and thus, select drugs that would be duplicating the efforts of plan sponsors that already successfully negotiate with manufacturers. These negotiations reduce costs and offer more affordable and comprehensive prescription drug benefits to Part D beneficiaries. This in turn would lead to higher premiums, Medicare program costs, and taxpayer spending, which contradicts the intent of the IRA that is designed to produce savings, by targeting high-cost drugs lacking in any type of competition, including competition from other branded agents.

We recommend CMS withdraw this proposal and instead clarify that it intends to select drugs for negotiation based on costs net of rebates. Further, CMS should target single source drugs without any therapeutic competition, rather than only drugs without generic or biosimilar competition. Although often less discussed than generic-to-brand competitive dynamics, brand-to-brand competition can create leverage points for negotiations with manufacturers in the period before generics are able to enter a market. When therapeutic alternative drugs are available with the same efficacy, plan sponsors and their Pharmacy Benefit Managers (PBMs) are able to leverage this competition to negotiate price concessions from drug manufacturers, which results in lower costs for beneficiaries. Therefore, we urge CMS to refrain from selecting drugs with direct competitors—whether they are generics, brands, or biosimilars.

Marketing Requirements

Elevance Health strongly believes all MA and Part D marketing must be clear, accurate, and compliant with CMS regulations and sub-regulatory guidance. All marketing entities must meet standards to ensure beneficiaries are able to make the best healthcare choices that meet their needs. To best meet this objective, we have industry-leading processes in place that include not only ensuring our own materials and practices are compliant, but also monitoring the activities of contracted Third-Party Marketing Organizations (TPMOs).

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Marketing Accuracy is Important to Foster Trust in the Medicare Program

We support CMS' continued focus on closing marketing loopholes and targeting bad actors that mislead beneficiaries, cause abrasion, and reduce trust in the Medicare program. We appreciate policymakers' acknowledgement that a majority of the problems are not health plans or plan sponsors themselves, but rather a relatively small subset of third-party downstream entities and lead generators that may not have a direct contractual relationship with health plans.[15] Attempting to regulate TPMOs and other third parties through health plans results in the following challenges:

- TPMOs and other third parties typically market the plan options of a large number of health plans. Health plans may continue using marketing materials even when a single organization opts-out through the Health Plan Management System (HPMS) due to concerns that the activity does not meet all CMS requirements; and,
- Health plans cannot take collective actions against third-party bad actors due to antitrust constraints.

As bad actors may not have contracts with health plans or plan sponsors, CMS should have the appropriate regulatory authority and staffing to directly regulate those entities. We recommend CMS work with stakeholders and Congress to ensure the right framework exists to regulate third parties, which could include requiring all individuals/entities marketing MA and Part D to register with CMS (and be subject to direct audits and fines), along with fines for not being registered.

Within its existing authority, as explained in the detailed section of this letter, we recommend CMS take the following additional steps to mitigate non-compliant marketing of third parties:

- Preserve federal Medicare preemption to ensure consistency in addressing misleading marketing materials across the country;
- Create a consolidated document containing all marketing requirements with examples for stakeholders to reference since the regulatory requirements related to marketing are not published in one place today;
- Revise the process for TPMO material approval such that one lead health plan approves the final materials once to resolve edits quickly through a CMS review;

[15] U.S. Senate Committee on Finance: *Deceptive Marketing Practices Flourish in Medicare Advantage* (accessed January 2023): finance.senate.gov

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- Establish a compliance resolution process for reports of potentially non-compliant marketing materials or tactics; and,
- Perform trainings targeted at TPMOs and downstream entities.

Several CMS Marketing Proposals Could Close Loopholes

Elevance Health appreciates CMS' efforts to close marketing loopholes to protect beneficiaries and make sure beneficiaries make the most informed coverage decisions. We are supportive of several of CMS' proposals with clarifications that:

- Prohibit TPMOs selling information to other TPMOs, while clarifying contact information can still be provided to an entity, including to health plans for follow-up;
- Modify the TPMO standard notice, while streamlining the language to avoid beneficiary confusion;
- Prohibit advertising that markets something as "savings" in a misleading way, with examples of scenarios and language that is appropriate;
- Require health plans to have an agent/broker monitoring and oversight plan, with an acknowledgement that health plans cannot monitor another organization real-time due to beneficiary privacy concerns;
- Establish required questions that must be asked prior to enrollment, with an appropriate number of streamlined questions;
- Extend the existing requirement to record calls, with flexibility if a beneficiary refuses to be recorded; and,
- Prohibit the use of superlatives without concurrent data backing up the claim.

Proposals Could Prevent Face-to-Face Sales and Exacerbate Health Inequity

CMS is proposing two significant changes that would have the effect of limiting face-to-face sales interactions: (1) a 48-hour wait time between a Scope of Appointment (SOA) being filled out and the appointment, and (2) separating sales events from educational events. Both of these changes would add additional burden, which would result in fewer face-to-face sales interactions overall.

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Many of our sales are conducted through face-to-face interactions with beneficiaries, and we have found that a substantial portion of beneficiaries prefer face-to-face sales. Studies have similarly concluded that older adults strongly prefer in-person interactions and demonstrated that beneficiaries are most likely to enroll in the best plan that meets their needs following a face-to-face conversation.[16] [17]

For these reasons, as explained in more detail later in this letter, we urge CMS to withdraw the two proposals that would inhibit in-person sales conversations. Instead of prohibiting or inhibiting certain types of sales interactions, we urge CMS to instead focus on targeting the bad actors and closing marketing loopholes, irrespective of the type of sales interaction.

Exacerbating Health Inequity

While we have found that many Medicare beneficiaries prefer face-to-face interactions, the opportunity is especially critical for beneficiaries who are dually eligible for Medicaid and Medicare. In our experience, a larger share of dually eligible beneficiaries prefer face-to-face encounters given a lower level of access to technology. Undermining access to face-to-face sales would create more barriers for dually eligible beneficiaries (as compared to older adults earning higher incomes) to choose the best plan for them, undercutting efforts to improve health equity.

It is also important to consider the extra burden that each of these proposed rules would create for dually eligible beneficiaries seeking to have a face-to-face sales interaction. Instituting a 48-hour wait time between an SOA being filled out and the appointment would create a requirement for two in-person interactions. CMS' proposed change would require beneficiaries to gain additional access to transportation in a different location and devote additional time to have a second conversation, which can be challenging. Separating educational events from sales events would similarly be placing a heavy burden on beneficiaries to find additional time and transportation to have a second in-person sales interaction.

Expanding Gaps in Coverage

According to our internal data, 25% of beneficiaries wait until the last 7 days of open enrollment to have a sales conversation and enroll. Instituting a 48-hour wait time between an SOA being filled out and the appointment would essentially shorten the annual open

[16] Rivera-Hernandez M, Blackwood KL, Mercedes M, Moody KA: Seniors don't use Medicare.Gov: how do eligible beneficiaries obtain information about Medicare Advantage Plans in the United States?: BMC Health Services Research (February 2021): doi.org/10.1186/s12913-021-06135-7

[17] Shupei Y, Syed AH, Kayla DH, Shelia RC: What do they like? Communication preferences and patterns of older adults in the United States: The role of technology, Educational Gerontology, 42:3, 163-174, (2016): doi.org/10.1080/03601277.2015.1083392

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enrollment period by two days. This creates a workload challenge with sales agents working to ensure those seeking to enroll at the last-minute do so with the best information possible. Many beneficiaries would not be aware of the mandated 48-hour waiting period, and if they fill out the SOA within the last few days of the enrollment period, they will likely not have an opportunity to enroll, creating a gap in coverage, undermining beneficiary access to care, care continuity, and satisfaction. This dynamic would also increase beneficiary complaints as additional abrasion would be created by the arbitrary 48-hour waiting period.

Increasing Disenrollments

Elevance Health is aligned with CMS' efforts to reduce disenrollments and ensure uninterrupted access to care. In our review of disenrollments by source of enrollment, we have found that those who enroll as part of face-to-face interactions exhibit the lowest proportion of disenrollments as compared to beneficiaries who enroll through other sources. The data demonstrate that—if a major goal is to decrease disenrollments—face-to-face interactions should be encouraged, not discouraged, as would be the effect of the proposed regulation.

Escalating Complaints

Elevance Health is aligned with CMS' efforts to limit and address beneficiary complaints to the largest extent possible. In our internal review comparing beneficiary complaints to source of enrollment, we found that beneficiary complaints are lowest among the cohort of beneficiaries that enrolls following a face-to-face sales interaction. This supports evidence in other areas that demonstrates beneficiaries receive the best information in face-to-face interactions, and those interactions should be encouraged instead of discouraged, as would be the case if these proposed provisions go into effect.

Mental Health (MH) and Network Adequacy

The U.S. is continuing to experience a dramatic increase in Mental Health and Substance Use Disorder (MH/SUD) needs in the wake of the COVID- 19 pandemic.[18] This persistent increase in demand has outpaced the supply of MH/SUD professionals. The Government Accountability Office's (GAO's) October 2022 report on the MH/SUD workforce in the U.S. in 2022 included the following conclusions:

- Approximately half of counties in the U.S. did not have an active psychiatrist or addiction medicine specialist;

[18] National Academies of Sciences, Engineering, and Medicine: Mental Health and Substance Use Disorders in the Era of COVID-19 - The Impact of the Pandemic on Communities of Color: Proceedings of a Workshop—in Brief. National Academies Press (March 2021): ncbi.nlm.nih.gov/books/NBK569170/ doi: 10.17226/26102

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- More than 150 million people live in federally designated MH professional shortage areas; and,
- In the near future, the U.S. will be short between 14,280 and 31,109 MH/SUD providers.[19]

A recent report from the American Psychological Association reinforces the fact that demand for services exceeds the supply of MH professionals. Nearly half of 2,300 psychologists surveyed said they were unable to meet demand for treatment, while 60% have no more openings for new patients, and 42% have waitlists of at least 10 patients.[20]

- Given that a major challenge for all stakeholders is—foundationally—there are currently not enough MH/SUD providers in the U.S. As an alternative, Elevance Health supports policymaker efforts to increase the supply of MH/SUD providers over time to better meet increasing demand by: allowing peer support specialists to be eligible for Medicare reimbursement;
- Expanding the types of services and providers eligible to receive federal/state funds. For example, payment of asynchronous care, coaching, texting, and wellness services should be evaluated; and,
- Examining scope of practice/physician oversight/supervision rules to increase access to a broad array of providers and services.

Implement Policy Flexibilities Due to Shortage of MH/SUD Providers

Amid this shortage of MH/SUD providers, CMS is proposing to put more pressure on health plans by: (1) establishing network adequacy requirements for three types of MH/SUD providers, and (2) extending existing wait time standards to these services. These proposed requirements do not account for the foundational shortfall of MH/SUD providers and would not increase the supply of providers. If the standards cannot be met, beneficiaries would have fewer choices to the extent health plans are forced to reduce their footprint or avoid planned expansions. The proposals also could result in retaining low-quality providers in networks as health plans attempt to meet the new requirements, which would negatively impact beneficiary experience.

With respect to wait time standards, CMS does not have a reasonable and efficient framework for assessing appointment availability, and existing audits do not generate

[19] Government Accountability Office: Behavioral Health: *Available Workforce Information and Federal Actions to Help Recruit and Retain Providers* (October 2022): https://www.gao.gov/products/gao-23-105250
[20] American Psychological Association: *Psychologists Struggle to Meet Demand Amid Mental Health Crisis* (November 2022): apa.org/pubs/reports/practitioner/2022-covid-psychologist-workload.pdf

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objective, consistent outcomes that would generate proof of compliance. This lack of a workable framework creates uncertainty for health plans, exacerbating the likelihood that health plans could curtail offerings, impacting beneficiary choice.

Health plans would also need time to collaborate with providers to develop a reporting system that allows health plans to collect appointment wait time data. The Fast Healthcare Interoperability Resource (FHIR) is the industry interoperability standard that allows health data, including clinical and administrative data, to be quickly and efficiently exchanged between entities. Currently, appointment scheduling information cannot be included in the FHIR record. Any attempt to implement new appointment wait time standards without a reporting system that is workable for both health plans and providers, including modifications to the FHIR standard so that appointment scheduling information can be included in the FHIR record, would lead to significant provider abrasion, discouraging provider participation in plan networks.

Because of these challenges and negative implications for beneficiaries, we recommend CMS:

- **Add flexibility to any new MH/SUD network adequacy standards:** We recommend CMS provide flexibility for any additional network adequacy justifications that would account for the fact that these standards would be new and implemented during a MH/SUD provider shortage;
- **Reconsider stringent wait time standards:** Wait times cannot be perfectly measured and are enforced using audits that do not generate perfect, objective results. Given the MH/SUD provider shortage, such audits would generate inconsistent results and needlessly increase administrative costs that would be passed on to beneficiaries. Instead, we encourage CMS to reconsider the wait time standards and work with stakeholders on accurately measuring and implementing such standards with appropriate flexibilities to avoid provider abrasion that could discourage participation with MA plans; and,
- **Help address the MH/SUD provider shortfall:** We request CMS work collaboratively with stakeholders to develop a comprehensive strategy to address the foundational shortfall of MH/SUD providers.

If CMS is intent on moving forward with new wait time standards, we request CMS delay the implementation of such standards until FHIR standards can be updated to help create a more efficient and effective way of demonstrating compliance.

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IRA Implementation

Incorporate Stakeholder Feedback and Work with Stakeholders to Educate Beneficiaries

Medicare Part D is a model of consumer choice and market competition that is improving access to prescription drugs and reducing out-of-pocket costs for more than 50 million beneficiaries.[21] Large scale changes such as Part D redesign in plan year 2025 will have broader program impacts given that that nearly 90% of beneficiaries are in MA-PD plans.[22] The Part D policy changes are expected to lead to reduced benefits, increased cost-sharing, and increased premiums for MA beneficiaries.

Given the significant volume of changes that will be implemented in the Part D program as a result of the IRA, it is critical that CMS continues to partner with plans and stakeholders to avoid issues with beneficiaries accessing medications and customer service challenges and ensure affordability and a positive beneficiary experience. Elevance Health is committed to working with CMS to implement the provisions within the IRA to ensure beneficiaries have uninterrupted access to their benefits. We appreciate CMS' acknowledgement of the need to work with stakeholders to ensure successful implementation of the law. Given the significant volume of changes that will be implemented in the Part D program, this collaboration will be critical to the operational success of any new requirements.

To that end, we have outlined our recommendations on key steps and questions CMS should consider to ease implementation challenges. We would like to work collaboratively with the agency to implement the significant changes to the Part D benefit required by the IRA. As CMS prepares to implement these changes, we recommend the agency:

- Collaborate with stakeholders to educate beneficiaries about the IRA changes and encourage CMS to display the latest information on www.CMS.gov and give health plans the option of adding links to health plan websites instead of requiring updates to model member materials;
- Defer enforcement on IRA-related complaints and audits through December 2023. This should apply to the Complaints Tracking Module (CTM), appeals and grievances, and Star Ratings given that the law was signed by President Joe Biden on August 16, 2022, after plan year 2023 bids were submitted on June 6, 2022, and implementation continues; and,

[21] https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/medicare-monthly-enrollment
[22] https://www.kff.org/medicare/issue-brief/medicare-advantage-2022-spotlight-first-look/

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- To smooth the transition, we encourage CMS to provide a comment opportunity on proposed Part D risk adjustment model changes. Any potential changes to the risk adjustment model should be proposed with at least a 60-day comment period and 12 months in advance of the June bid deadline.

Given the volume of changes to Part D expected in the coming years, it is critical for plans and stakeholders to partner with CMS to educate beneficiaries, ensuring the delivery of robust benefits and quality care through the MA and Part D programs.

Detailed Comments

Star Ratings

The Star Rating system incentivizes quality improvement and public accountability and provides beneficiaries with a valuable tool to assist in choosing a high-quality health plan that best suits their personal needs and preferences. Any changes to the Star Rating system should not undermine the ability of health plans to deliver access to high-quality care to the millions of Medicare beneficiaries who rely on the program.

HEI Reward

Elevance Health supports CMS' ongoing efforts to ensure the right incentives exist to promote the goal of addressing health disparities in the Star Ratings system. Elevance Health has implemented many strategies to improve health equity and address health-related social needs, including working with a variety of stakeholders, such as community-based organizations, to expand access to non-medical transportation, nutritious foods, and accessible housing.

We agree that the existing reward factor could be improved to better gauge how measures can account for social risk factors in the Star Ratings system, and we believe a system that focuses exclusively on rewards (instead of a combination of rewards and penalties) is the best approach.

We are concerned that the proposal in its current form would undermine the Administration's health equity goals due to the significant negative consequences of the multiplier on health plan Star Ratings. CMS' proposal would drastically change the current reward factor so that it

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becomes a two-sided, net-zero approach that looks at each measure and breaks contracts into thirds, with the top third of contracts receiving 1 point, the middle third of contracts receiving 0 points, and the bottom third of contracts receiving -1 point.

While we commend CMS for working to improve the reward factor, CMS' proposed revised framework would create the following perverse incentives and unintended consequences:

- **Working against health equity goals by lowering Star Ratings and reducing revenue available to help beneficiaries:** CMS' proposal to modify the HEI reward to be a two-sided approach would have the net impact of making it more difficult for plans to fairly receive the higher Star Ratings they have earned. These Ratings help generate the revenue for supplemental benefits—such as medically tailored meals, transportation, and in-home supports—that go even farther to address health-related social needs. CMS' penalties would reduce revenue for the plans that serve the beneficiaries who need these resources the most.
- **Discouraging enrollment of beneficiaries with social risk factors in C-SNPs:** C-SNPs are designed to provide targeted and tailored access to care and care coordination for beneficiaries with specific CMS-defined chronic conditions. Because CMS proposes enrollment thresholds for the HEI reward that disqualify smaller contracts, the proposed revisions would create an incentive for health plans to enroll certain beneficiaries in larger non-SNP contracts, who would be best served by the tailored care coordination available in SNPs.
- **Undermining improvements in health equity in majority of Group Retiree contracts:** As detailed above, under the proposed enrollment thresholds for beneficiaries with social risk factors, some contracts would not have access to the HEI reward, even if they are advancing health equity. By potentially rendering these contracts as ineligible for the reward, it would be more difficult for these contracts to achieve high Star Ratings. Any revisions to the HEI reward framework should ensure Group Retiree contracts qualify to ensure plans that are improving health equity can appropriately achieve high Star Ratings.[23]
- **Creating an incentive for beneficiary selection:** CMS has worked to mitigate any incentive for health plans to target or avoid cohorts of beneficiaries in its contracts. CMS' proposed "net zero" approach would incentivize selection for the purpose of maximizing the HEI reward, which would work against CMS' goal of eliminating incentives to enroll specific cohorts of beneficiaries in the risk adjustment program.

[23] https://repositorio.uc.cl/xmlui/bitstream/handle/11534/47031/Precarious%20Employment.pdf

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Recommendation: Elevance Health recommends CMS implement an HEI reward framework that exclusively rewards health plans for improving health outcomes of historically marginalized populations. Such an approach would mitigate the unintended consequences previously detailed in this letter. Specifically, we recommend CMS implement an approach that applies to all contracts (that is, removes enrollment thresholds) and is not two-sided.

However, if CMS moves forward with the proposed approach, we request CMS:

- Establish a transition period that phases in the proposed approach. The phase-in should ensure the revised approach is tested with data for at least three years, consistent with CMS' standard practice for display measures, plus one year considering the different HOS measurement years. CMS should ensure the current reward factor is still in place for three years, and then the revised approach could be phased in during the following four years (e.g., 25% in Y4, 50% in Y5, 75% in Y6, and 100% in Y7); and,
- Provide additional data to health plans to improve readiness for the policy change should CMS proceed with the significant methodological change. For health plans to be able to model the proposed policy change, we encourage the release of additional baseline and national performance data to enable health plans to make more informed investments in quality and health equity improvements. Specifically, we request the following information for each health plan for Star years 2021, 2022, and 2023:
    - The blended Social Risk Factor (SRF) population of Low-Income Subsidy/Dual Eligible (LIS/DE) and Disabled by contract;
    - The top 3rd, bottom 3rd, and middle 3rd cut points for all measures;
    - Blended measure rates for SRF population by contract;
    - National performance rates;
    - National SRF population levels;
    - How rates will be determined for the two-year combined rates;
    - How beneficiaries in a health plan for one year will be handled;
    - How survey measures will be addressed and whether they will be blended given that LIS/DE stratification reports do not include calculated values for Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures;
    - How Healthcare Effectiveness Data and Information Set (HEDIS) hybrid measures will be addressed;
    - Clarity on which measures are included and why certain measures are removed from the calculation;

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- Sample calculation models that show the calculation of the HEI and reward values; and,
- How the reliability scoring in the LIS/DE and Disabled stratification reports are determined and used, and which values represent the 0.7 reliability level.

Improvement Measure Hold Harmless

Elevance Health is concerned about CMS' proposal to apply the hold harmless policy to the Health Plan and Drug Plan QI measure to contracts with only 5-Stars beginning with the 2026 Star Ratings, instead of contracts with 4-Stars and above. CMS' proposal would lead to billions in cuts from the MA program, directly impacting older adults and people with disabilities and which would undermine the Administration's health equity goals.

Undermining the Incentive to Improve Star Ratings and Devaluing the QI Measure

CMS has stated the goals of the Parts C and D Star Ratings are to drive quality improvement for plans and providers and empower beneficiaries or their caregivers to make healthcare decisions that best suit each individual's personal needs and preferences.[24] [25] [26] [27] CMS implemented the QI measure to create an extra incentive for health plans to improve measure scores, supporting increased access to high-quality health plans. Each measure is evaluated to determine if there was a statistically significant improvement year-over-year, and those scores are added together to create the QI score.

As the QI measure was implemented, CMS acknowledged that the approach would create an unintended consequence: the QI measure for high-quality plans would drop once their ratings improved because—as plans improve their scores—it gets more difficult to produce a statistically-significant improvement year-over-year. In other words, a contract's Star Rating could drop due to a drop in the QI score, even if the plan continued to improve and make gains in each measure, but not enough to be statistically significant.

[24] https://public-inspection.federalregister.gov/2022-26956.pdf
[25] https://www.cms.gov/newsroom/news-alert/cms-releases-2023-medicare-advantage-and-part-d-star-ratings-help-people-medicare-compare-plans#:~:text=Plans%20are%20rated%20on%20a,Part%20D%20prescription%20drug%20plans.
[26] https://www.cms.gov/Medicare/Health-Plans/Medicare-Advantage-Quality-Improvement-Program/Downloads/Quality_Strategy_061212.pdf
[27] https://www.cms.gov/newsroom/press-releases/medicare-announces-quality-bonus-payment-demonstration-medicare-health-plans

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Because of this unintended consequence, CMS implemented its existing hold harmless policy for plans with 4-Stars or above. This ensures a recognized high-quality health plan is not penalized for only making modest gains after reaching the 4-Star threshold.

CMS has acknowledged that plans reaching 4, 4.5, and 5-Stars offer high-quality access to healthcare, supports, and services. According to a CMS press release on 2023 Star Ratings, "[a]pproximately 72% of people currently in Medicare Advantage plans that offer prescription drug coverage are enrolled in a plan that earned four or more stars in 2023. Approximately 51% of Medicare Advantage plans that offer prescription drug coverage will have an overall rating of four stars or higher in 2023."[28] CMS highlighting this data indicates that the agency believes 4-Star performance or higher is above-average level and should not be penalized.

This proposed change would significantly increase the volatility of the Star Ratings and undercut the incentive for improvement. In the Star Ratings system, we expect that health plans with higher Star Ratings will have more 5-Star measure ratings, with fluctuations based upon the calculation of cut points as a byproduct of overall industry performance. This enables even 5-Star contracts to improve. The QI measures are intended to evaluate year-over-year improvement in contracts measure scores, not the number of measures that achieve 5-Stars as compared to other contracts.

Undermining Health Equity Goals

As outlined above, the existing hold harmless policy for the QI measure that applies to 4-Stars and above has created the right incentive to drive quality improvement across measures. Those 4-Star and 4.5-Star plans can continue to make modest gains and not be penalized for continually improving scores year-over-year. Achieving the 4-Star threshold increases the benchmark against which an MA plan bids, and a portion of the savings between the bid and the benchmark is used to enhance benefit offerings and lower costs for beneficiaries.

The enhanced benefit offerings made possible under the existing hold harmless approach is contributing to advancing health equity, in support of the Administration's goals. Traditional supplemental benefits such as dental and vision coverage address whole health needs. Additional supplemental benefits such as medically tailored meals, transportation, and in-home supports go even farther to address health-related social needs.

According to CMS' own estimate, the elimination of the hold harmless provision for 4-Star and 4.5-Star plans would result in over $19 billion in cuts over the next ten years.[29] A significant

[28] https://www.cms.gov/newsroom/news-alert/cms-releases-2023-medicare-advantage-and-part-d-star-ratings-help-people-medicare-compare-plans
[29] https://public-inspection.federalregister.gov/2022-26956.pdf

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portion of these savings would come from the elimination of supplemental benefits being provided to historically marginalized populations, including dental, vision, nutritious food, transportation, and in-home supports.

Recommendation: Elevance Health urges CMS to maintain the current improvement measure hold harmless provision for contracts with 4-Stars and above. Any changes to the Star Ratings should improve the long-term stability of the MA program and avoid undermining the ability of MA plans to deliver access to high-quality care to millions of older adults and people with disabilities. The CMS proposal would lower the incentive for health plans to make quality-improvement investments and would result in fewer rebate dollars available for supplemental benefits that address social drivers of health such as transportation, nutritious food delivery, and in-home services and supports, compounding disparities in health outcomes.[30] [31]

Quality Bonus Payment Rules

CMS is proposing to prohibit MA organizations from appealing measures that are based on feedback or surveys that come directly from plan beneficiaries. The survey data collected for CAHPS and HOS measures are subjective, and the collection methods for these surveys may result in bias due to the diverse beneficiary responses and differences in survey and digital literacy across member populations. We encourage CMS to allow MA organizations to retain the right to raise methodological questions about the accuracy of survey measure scores given that the measures are case mix adjusted, the potential for incorrect adjustments, and invalid responses from beneficiaries.

Additionally, we encourage CMS to increase transparency around the underlying calculations at a contract-level for CAHPS. We are concerned the additional calculations CMS performs for CAPHS measures do not undergo external audit, and unlike the HEDIS measures, these measures are not generated from a certified rules engine.

Recommendation: We ask CMS to continue to allow MA organizations to appeal survey measure scores in the calculation of the quality bonus payments given that the measures are case mix adjusted, the potential for incorrect adjustments, and invalid responses from beneficiaries.

[30] JAMA. "Patient Characteristics Associated with Telemedicine Access for Primary and Specialty Ambulatory Care During the COVID-19 Pandemic." December 2020. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774488.
[31] AJMC. "Differences in the Use of Telephone and Video Telemedicine Visits During the COVID-19 Pandemic." January 14, 2021. http://tinyurl.com/2or2482g.

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We also encourage CMS to increase transparency around the underlying calculations at a contract-level for CAHPS, which may help avoid such appeals of survey measure scores in the calculation of the quality bonus payments.

Removal of Star Ratings Measures through Sub-Regulatory Guidance

CMS proposes to allow for removal of Star Ratings through sub-regulatory guidance if a third-party steward (for example, National Committee for Quality Assurance [NCQA]) retires the measure.

Recommendation: Elevance Health supports this proposal. To support increased transparency, we also recommend CMS:

- Maintain a chart on its website that shows which measures are being scored in which years and each measure's associated weight in scoring. This would reduce administrative costs across the MA program, as all health plans currently need to maintain and track which measures are scored in which year; and,
- Provide a table in each proposed and final rule that includes the measure being added/retained/removed for each rating year, each measure's weight, if the measure will be scored or simply included for display-only, and footnotes to indicate if the measure is endorsed by a consensus-based entity (such as the National Quality Forum [NQF]) or was recently added/removed from the Star Ratings.

Consumer Experience, Complaints, and Access Measure

CMS proposes to reduce the weight of the patient experience/complaints and access measures by half (from a weight of 4 to 2) for the 2026 Star Ratings (which is the 2024 measurement period). Elevance Health appreciates CMS willingness to listen to concerns regarding the challenges associated with CAHPS surveys and outcomes that are not directly within the control of the health plan and not based on objective, clinical measures. Given the timing and resources invested in these measures, Elevance Health believes those elements directly within the control of the health plan should continue to be emphasized with the full weighting.

In CMS' proposed HEI, the agency states the focus of the measurement is on measures within the health plan's control – for example, the appeals and call center measures focus on the

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plan and its operations rather than on beneficiary perceptions. We support CMS drawing this distinction between measures with beneficiary-level information like the CAHPS survey data that is more subjective, and those that more objectively measure health plan actions.

For this reason, we support an alternative where patient experience/complaints and access measures are divided into two categories: (1) those which are out of the health plan's direct control, such as the CAHPS survey, which would be weighted as a 2; and (2) those related to beneficiary experiences and access to their health plan that are within the direct control of the health plan, which would be weighted at 4. This approach would better align the measure weights based on the extent to which the outcomes are within the control of the health plan.

Recommendation: Elevance Health recommends the consumer experience, complaints, and access measure set is divided into two categories starting in Star Ratings Year 2023: (1) CAHPS measures that are subjective survey questions that demonstrate the experience the beneficiary has with the provider [lower to 2-weight]; and (2) the measure elements that are related to health plan operations and access [maintain at the current 4-weight].

This approach would continue to hold health plans accountable with respect to elements that are directly in the health plans control while lowering the weight of the survey measures, which are more subjective, not directly within the control of the health plan and based more on the CAHPS which is flawed due to the decreasing response rates and the lack of objective clinical measures. Should CMS disagree with this approach, we encourage the agency to consider a compromise in which all of the consumer experience, complaints, and access measures are weighted as a 3.

Removing Star Rating Guardrails

CMS is proposing to remove guardrails when determining measure-specific thresholds (cut points) for non-CAHPS measures. Because CMS implemented the mean rescoring methodology for 2023 Star Ratings and intends to add the Tukey outlier deletion to the hierarchical clustering methodology beginning with the 2024 Star Ratings to improve the predictability and stability of cut points, CMS believes that guardrails are no longer needed. Under this proposal, guardrails for non-CAHPS measures would only be effective through the 2025 Star Ratings and not apply for the 2026 Star Ratings or later.

We oppose the removal of the guardrails. The guardrails policy provides known data elements prior to the performance year improving the overall predictability of cut points. Instead, we support the removal of the Tukey outlier deletion, which undermines the predictability of cut points. We have concerns with the implementation of the Tukey outlier

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deletion process, and its impact on the calculation of cut points for Star Ratings as the process is executed after the measurement year has ended and all performance indicators have been reported. While Tukey fences are generally considered effective at detecting outliers, deletion of outlier data is a controversial practice particularly in instances where a normal distribution cannot be assumed. Normally this practice is used when outliers result in a data error, which is not an issue in the Star Rating measures given the data validation processes used to calculate final scores. We provide an analysis of our concerns with the Tukey outlier deletion in Appendix I of this letter.

We encourage CMS to put the Tukey outlier deletion policy on hold to further evaluate whether the policy is necessary if the guardrails remain in place. Should the agency move forward, we support a delay in the removal of the guardrails to provide CMS an opportunity to determine whether any unintended consequences materialize from the implementation of the Tukey outlier. We also emphasize the need for flexibility and exceptions in instances with unforeseen consequences, such as natural disasters or another pandemic. In these situations, it may be important to account for the volatility in cut points as these policies could have a negative impact on beneficiaries' access to high-quality plans.

Recommendation: Elevance Health requests CMS modify this proposal as follows:

- Maintain the guardrails, while removing the Tukey outlier deletion process to improve the predictability and stability of cut points;
- Should the agency move forward, we support a delay in the removal of the guardrails to provide CMS an opportunity to determine whether any unintended consequences materialize from the interaction of guardrail and Tukey outlier policies; and,
- Allow for flexibility in the event of significant unforeseen circumstances, such as natural disasters or another pandemic, where guardrails or exceptions may reduce potential volatility to improve beneficiaries access to high-quality health plans.

Weighting of Measures with a Substantive Specification Change

CMS proposes to clarify that when a measure with a substantive update moves back to Star Ratings from the display page following rulemaking, it is treated as a new measure for weighting purposes and therefore would receive a weight of 1 for its first year back in the Star Ratings program.

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Recommendation: Elevance Health supports this change, as it would result in a phase-in and reduce potential volatility.

Recommendations to Improve the Star Ratings

Elevance Health appreciates CMS' willingness to take a collaborative approach on improving the Star Ratings. We have the following recommendations on ways to further improve the program to support high-quality plan options for beneficiaries:

- **Avoid significant year-over-year changes:** It can take years of focused efforts and investments to improve even one Star Rating measure. We encourage CMS to look at Star Ratings changes in aggregate and avoid significant disruptions that undermine the system, and beneficiary access to supplemental benefits and reduced cost-sharing.
- **Provide advance warning when measures are likely to change:** While CMS often provides updates and comment opportunities when it is considering changing some measures, we encourage increased communication and transparency from CMS on future actions and goals for the Star Rating system. For example, we have seen proposed changes on pharmacy-related measures (such as this year), where the industry had minimal warning. If the industry has advance warning, health plans can start making investments to reach CMS' updated objectives more quickly and efficiently to support beneficiary access to healthcare, supports, and services.
- **Increase the reliability of survey data:** Elevance Health supports CMS' interest in increasing response rates for the MA and Prescription Drug Plan (PDP) CAHPS surveys as well as potential new questions. We would like to collaborate with CMS and measure stewards like the Agency for Healthcare Research and Quality (AHRQ) and NCQA to update and improve the survey to ensure it provides an accurate portrayal of the beneficiaries' experience and considers the evolving healthcare system, health equity and the diversity of the MA population, and the growing use of technology resulting from the COVID-19 pandemic.

Part D Proposed Changes

MTM Eligibility Expansion

CMS proposes several changes that would substantially expand the program, including:

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- Requiring Part D plan sponsors to include all core chronic diseases when identifying beneficiaries who have multiple chronic disease (from 5 to 9) and adding HIV/AIDS to the list;
- Decreasing the maximum number of Part D drugs that a Part D plan sponsor may require from 8 to 5;
- Defining maintenance drugs (for targeting criteria) such that the Part D plan sponsors would no longer be allowed to target only specific Part D drug classes, but would be required to target all Part D maintenance drugs; and,
- Lowering the cost threshold to the average annual cost of 5 generic drugs.

The MTM program currently targets and is tailored to beneficiaries who would benefit the most from support. We are concerned the proposed changes would dilute this targeted approach. Instead, we urge CMS to work with Part D plan sponsors and stakeholders to ensure the beneficiaries who would benefit the most from MTM services are successfully engaged in the program.

Diluting and Devaluing MTM Services through Over-Expansion

We commend CMS for continuing to focus on the MTM program and the agency's focus on health equity. As a national MTM provider, we have firsthand knowledge and experience with how high-quality MTM services can make a difference in supporting beneficiaries and improving health outcomes. Beneficiaries may benefit from a letter intervention to improve medication adherence if they cannot be reached by phone, but the efficacy of the program across the newly proposed chronic conditions is largely unproven.[32] While we support appropriate expansions of the MTM program based on clinical evidence, this should be done in an incremental way to ensure its success for any new cohorts of beneficiaries while not diluting and devaluing the program for existing eligible beneficiaries.

In the proposed rule, CMS states the impact to implementing all the criteria changes would increase beneficiary eligibility from 4.5 million (9% of the Medicare population) to 11 million (23% of the Medicare population). Plan sponsors could not meet this substantial increase in volume by simply scaling existing program elements. There are currently provider shortages, and the expansion would place additional stress on pharmacists able to conduct MTM CMRs. Such a rapid expansion could lead to lower-value MTM programs that undermine investments in the more targeted care management programs currently in place.

[32] https://www.pharmacytimes.com/view/cost-effectiveness-of-medication-therapy-management-in-part-d-diabetic-enrollees

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Undermining Health Equity Goals through Lower Star Ratings

Given that Star Ratings help high-quality health plans provide supplemental benefits that support health equity, it is important to consider how changes to the MTM program will impact the Part D MTM CMR Completion Rate measure. Despite significant outreach efforts, health plans have difficulty reaching a percentage of existing eligible beneficiaries. Given the ongoing challenges with higher measure-level cut points to obtain a 4-, 4.5, or 5-Star Rating, and the guardrails policy that could interact with this proposal as detailed previously in this letter, increasing the volume of MTM eligible beneficiaries would result in even more difficulty achieving the 4-, 4.5-, or 5-Star Rating. Driving down Star Ratings would have the result of reducing the availability of supplemental benefits and lower costs for beneficiaries.

Recommendation: Elevance Health recommends CMS withdraw its proposal to expand MTM eligibility. We recommend the focus remains on beneficiaries who are currently eligible and most likely to benefit—but are not engaged—instead of expanding eligibility. Given the difficulty reaching certain cohorts of existing eligible beneficiaries despite significant effort, we recommend the following changes to improve the success rate of outreach:

- Relax the existing requirement that beneficiaries be reached within 59 days to allow for continued outreach; and,
- Allow CMRs to be completed via mail or email. We recognize this runs counter to CMS' proposal to codify the requirement for CMRs to be performed in real-time with the beneficiary, but for those beneficiaries who do not engage despite several attempts, a CMR being mailed and/or emailed may still allow a plan sponsor to connect with a beneficiary on their terms.

If CMS pursues the proposed MTM eligibility expansion, we recommend the agency:

- Take an incremental approach and delay implementation to enable stakeholders to prepare for implementation given the shortage of pharmacists. Specifically, CMS should move the new measure to display so that it is monitored in parallel with the existing measure to compare outcomes across all contracts; and,
- Increase the chronic condition disease states incrementally, by requiring plan sponsors to implement MTM for 6 chronic conditions versus 9 based on the groups the MTM program is best equipped to serve.

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Payment Definitions: Gross Covered Prescription Drug Costs

CMS is proposing to change its definition of "Gross Covered Prescription Drug Costs" (GCPDC) to remove the phrase "actually paid." While CMS indicates in the preamble that this proposed change is to remove any ambiguity that may arise from the current definition, we are concerned it could have a significant, detrimental financial impact to the program, to the extent it flows into the selection of drugs for which CMS will negotiate prices pursuant to the IRA. By removing the phrase "actually paid," CMS could be removing the impact of rebates, which have been found to lower Part D program costs[33]

If CMS were to select drugs for negotiation irrespective of rebates, it could be selecting the wrong drugs and duplicate efforts of plan sponsors that already successfully negotiate with manufacturers. In addition, if gross, rather than net prices, will determine whether a drug is selected for negotiation under the IRA, manufacturers are unlikely to agree to rebates with Part D plans as those price concessions will not be accounted for when the federal government selects drugs for negotiation under the IRA. This would hamper Part D plans' ability to secure prices concessions, which in turn would lead to higher premiums, program costs, and taxpayer spending, which contradict the intent of the law that is designed to produce savings by targeting high-cost drugs lacking in any type of competition, including competition from other branded agents. We are particularly concerned about specific drug classes, including oncology, HIV, and anti-psychotics drugs, which have extremely high levels of aggregate spending and little willingness from manufacturers to negotiate price concessions. CMS should address high-drug expenditures within these classes.

Recommendation: Elevance Health recommends CMS withdraw this proposal and instead clarify that it intends to select drugs for negotiation based on costs net of rebates. Further, CMS should target single source drugs without any therapeutic competition, rather than only drugs without generic or biosimilar competition. Although often less discussed than generic-to-brand competitive dynamics, brand-to-brand competition can create leverage points for negotiations with manufacturers in the period before generics are able to enter a market. When therapeutic alternative drugs are available with the same efficacy, plan sponsors and their PBMs are able to leverage this competition to negotiate price concessions from drug manufacturers, which results in lower costs for patients. Therefore, we urge CMS to refrain from selecting drugs with direct competitors—whether they are generics, brands, or biosimilars.

[33] Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization | U.S. GAO.

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Overpayment Look-Back for Prescription Drug Event (PDE) and Direct and Indirect Renumeration (DIR)

Regarding the process used to recoup overpayments associated with PDE and DIR, CMS also proposes to modify the timeframe for a "reopening for good cause" from within four years to within six years.

While Elevance Health does not have a conceptual problem with expanding the timeframe for overpayments associated with PDE and DIR, we are concerned that looking back more than four years would result in administrative costs that exceed the value of the recoupments. We recommend CMS pursue an analysis to determine if this proposed change adds value to the program, in support of the Medicare Trust Fund.

Recommendation: Elevance Health recommends CMS withdraw this proposal unless an analysis demonstrates that the expanded timeframe would result in recoupments that exceed increased administrative costs.

De minimis Threshold for Refunds and Recoveries

Within its proposal on mid-year benefit changes, CMS proposes to establish a de minimis threshold for refunds and recoveries associated with incorrect collections of premiums and cost-sharing.
Elevance Health supports this proposal as we have found that exceedingly small refunds generate abrasion with beneficiaries and complaints asserting the plan sponsor is being wasteful.

Recommendation: Elevance Health recommends CMS finalize this proposal to limit administrative costs, creating savings that can be passed along to beneficiaries.

Shortages of Formulary Drug Products During a Plan Year

CMS proposes requiring Part D plan sponsors to permit beneficiaries affected by a drug shortage to obtain coverage for a therapeutically equivalent or interchangeable non-formulary alternative without requiring those beneficiaries to meet formulary exception requirements.

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Recommendation: Elevance Health recommends CMS define "affected enrollee" for the purposes of formulary drug shortages as a beneficiary with a history of taking the drug within a minimum of 108 days. We encourage CMS to ensure this requirement does not apply to a beneficiary who presents a new prescription for the drug due to operational challenges. Currently, we have no way to proactively identify these beneficiaries, or direct them at the point-of-sale to a more affordable and therapeutically equivalent alternative. If this proposal applies to new starts, we would require additional time to implement the policy change and recommend it apply no earlier than the 2025 plan year.

Changes to an Approved Formulary

Clarify CMS Requirements Around Cost of Immediate Drug Substitutions

CMS states that Section 11001 of the IRA allows the government to negotiate certain drug prices and requires that a drug for which a maximum fair price is in effect must be included on a plan's formulary. In § 423.120I(2)(i), CMS proposes to permit immediate substitutions, which would mean Part D sponsors could:

- Immediately make generic substitutions as well as substitute a new "interchangeable biological product" for its corresponding reference product;
- Substitute a new "unbranded biological product" for its corresponding brand name biological product; and,
- Substitute a new "authorized generic" for its corresponding brand name equivalent.

Given that the definition of maximum fair price is broad, we encourage CMS to provide health plans with the flexibility to determine the lowest price of the drug.

Recommendation: We encourage CMS to further clarify expectations for when a drug is removed from the formulary and give health plans the flexibility on a drug-by-drug basis, to determine the lowest price of the drug.

Enable Clinical Experts Outside of P&T Committee to Identify Appropriate Formulary Alternatives

CMS proposes changes to obtaining approval to make updates to a formulary already approved by CMS, and the requirements for providing notice of such updates. Specifically, for notice of negative immediate changes, we appreciate CMS removing the requirement that the alternative drugs must be in the same therapeutic category or class. However, we are concerned about the requirement that the Part D plan sponsor's Pharmacy and Therapeutics

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(P&T) Committee must identify clinically appropriate formulary alternatives at the time the formulary change is being evaluated.

Elevance Health strongly encourages CMS to allow other qualified clinical experts from the health plan to identify appropriate formulary alternatives. We are concerned that putting the responsibility on the P&T Committee, which is only required to meet quarterly, would put health plans at risk of failing the meet CMS' 30-day beneficiary notification requirement for notices of maintenance and non-maintenance changes.

Recommendation: We encourage CMS to allow Part D clinical experts from the health plan to identify appropriate alternatives in the event of an update to an approved formulary. Putting the responsibility solely on the P&T Committee, which is only required to meet quarterly, would put health plans at risk of failing the meet CMS' 30-day beneficiary notification requirements.

Health Equity, Dual Eligibles, and SNPs

C-SNP Chronic Conditions

CMS proposes to expand the list of chronic conditions C-SNPs can target. This expansion would include additional condition categories and additional diseases within existing categories.

As a health plan that serves beneficiaries with chronic conditions through C-SNPs, Elevance Health greatly appreciates CMS' commitment to expanding eligibility for C-SNPs to include additional conditions. Our C-SNPs have helped improve health outcomes for beneficiaries, and we are eager to expand our tailored care to additional chronic conditions. We particularly appreciate opportunities to help additional beneficiaries with Chronic Kidney Disease, where the care coordination offered by C-SNPs would help beneficiaries better manage their disease and delay, or even avoid, progression to End-Stage Renal Disease.

Recommendation: We recommend CMS finalize the proposed expansion of chronic conditions in C-SNPs.

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Additional Provider Directory Elements Related to Health Equity

Creating a National Provider Directory

Elevance Health shares CMS' commitment to ensuring provider directories meet the needs of all beneficiaries, particularly historically marginalized populations who may experience more barriers accessing the care they need. We also commend CMS for acknowledging that health plans do not have full control over their provider directories and are largely reliant upon providers to share accurate and timely information. Providers experience significant burden reporting information to all health plans with which they do business, and the response rate from providers to health plans about provider directories is low. Therefore, Elevance Health is supportive of CMS' effort to create a National Directory of Healthcare Providers and Services (NDH). Creating an NDH that acts as a single source of truth for provider directories is the most efficient way to ensure health plans have all information needed for accurate, comprehensive provider directories.

Recommendation: Elevance Health recommends CMS and stakeholders focus provider directory efforts on creating an NDH rather than establishing any new piecemeal requirements that would draw resources away from focusing on the NDH and would have limited value in the interim while creating additional provider abrasion.

Languages Spoken by Providers

CMS proposes provider directories include an element related to non-English languages spoken by the provider. Elevance Health supports CMS' efforts to ensure beneficiaries can easily identify providers who speak non-English languages. Given that CMS has already deemed this a best practice, in our provider directories, we already identify non-English languages spoken by providers (to the extent we are aware), and it is the first data element listed under the provider's name.

The biggest challenge associated with this proposed requirement is obtaining the information from the provider. We understand the value of providing this information to our Medicare beneficiaries; therefore, our current practice is to provide a list of languages providers speak in our directories. However, currently we are only able to provide languages for nearly 30% of our providers who have indicated they speak a non-English language.

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Recommendation: Elevance Health recommends CMS delay this requirement and instead focus on obtaining the data from providers to support beneficiaries in making educated decisions about their healthcare:

- As detailed above, deploy an NDH that collects language information for providers on behalf of all health plans;
- Add a data element to the National Provider Identifier (NPI) for providers to indicate non-English languages that are spoken;
- Conduct a provider directory education campaign to encourage providers to respond to questions from health plans related to provider directories; and,
- Provide an audit safe harbor if a health plan can show a good faith effort to collect and list the languages a provider speaks in our directories, but the provider did not share that information.

Provider and Location Accessibility

CMS proposes to require provider directories include data elements related to provider and location accessibility for people with physical disabilities.

Elevance Health supports CMS' efforts to ensure provider and location accessibility. In our provider directories, we already identify providers with Americans with Disabilities Act (ADA) accessibility (to the extent providers share that information) for beneficiaries with physical disabilities. We work to list this information in our directories; however, currently only approximately 6% of our providers share ADA access information to help us populate our provider directories.

Recommendation: We have the following recommendations to improve health plan and provider data for inclusion in our directories:

- As detailed above, deploy an NDH that collects data elements on providers' ability to accommodate beneficiaries with disabilities;
- Add a data element to the NPI to capture providers' ability to accommodate beneficiaries with disabilities;
- Conduct a provider directory education campaign to encourage providers to respond to questions from health plans related to provider directories; and,
- Provide an audit safe harbor if a health plan can show a good faith effort to collect provider accessibility information for our directories, but the provider did not share that information.

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Searchable by Every Data Element

CMS proposes to require a health plan's provider directory be searchable by every element. We currently work to ensure our directories are searchable by the data elements that are most useful for beneficiaries. For example, our directories are searchable by provider name, NPI, specialty type, and many more data elements can be filtered to narrow search results. However, there are certain data elements that would not be helpful to beneficiaries such as contract number or provider email address.

Recommendation: Elevance Health recommends CMS withdraw this proposal and instead propose a list of search elements that is prioritized based on elements beneficiaries currently use in their searches. Specifically, we would support prioritizing beneficiary preferences such as name, NPI, gender, provider specialty, procedure, provider type (for example, hospital, lab, etc.), telehealth availability, and location.

Materials in Alternative Languages and Auxiliary Aids

CMS proposes to require health plans to provide materials to beneficiaries on a standing basis in non-English languages and accessible formats upon receiving a request for the materials in that language/format. In the preamble, CMS notes this means that once a plan learns of a beneficiaries' preferred language and/or need for auxiliary aids and services—at any touchpoint with the beneficiary—the plan must provide required materials in that language and/or accessible format until the beneficiary requests that the plan provide required materials in a different manner.

Elevance Health supports beneficiaries who are limited-English proficient or require auxiliary aids. In all written communications, we include the Babel sheet that offers over 15 translation languages. Our partners can fulfill requests in over 170 languages. We also include a statement about offering materials in alternate formats (Braille, audio, etc.) at no cost on request.
For all of our written communications, we strive to create base content at a 5th grade reading level or lower, using plain language. Simple language, clear graphics, and white space all lead to content that is easier to comprehend, both in English as well as translated languages.

We agree with CMS that health plans and plan sponsors should acknowledge a beneficiary's preferred language/accessible format and carry that preference forward when practicable. There are many standard notices and documents where health plans have already translated and created auxiliary aids that can and should be used once a beneficiary has made their preference known.

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However, there are also many communications sent to beneficiaries that are not standard notices, and are also unique to a specific situation, which would need to be separately translated into a language/aid as its own document. Many of these communications, such as a UM decision or a care plan, need to be communicated quickly and within required timelines.

Turnaround times would be the most challenging element of this requirement. For accessible formats and auxiliary aids—given the complexity of audio, data, and Braille conversion—the request for a unique document to be converted can take 2-4 weeks to complete. For unique documents to be translated into another language, the turnaround time is 1-2 weeks. This completion time runs counter to the need to provide many unique communications quickly.

Recommendation: Elevance Health recommends CMS finalize this proposal only with respect to model materials. For non-standard communications, we strongly urge CMS first establish a multi-stakeholder workgroup to address how language translations and conversions to aids could be accomplished for non-standard communications within the required timelines and develop best practices to support beneficiaries.

Digital Health Literacy & Telehealth

CMS proposes to add requirements for health plans to develop and maintain procedures to identify and offer digital health education to beneficiaries with low digital health literacy to assist them with accessing any medically necessary covered telehealth benefits. We support CMS' digital health literacy goals to enable Medicare beneficiaries to access benefits. Digital access is a key social driver of health. Digital health literacy, as defined by the World Health Organization (WHO), is the ability to seek, find, understand, and appraise health information from electronic services and apply the knowledge gained to addressing or solving a health problem.[34]

Barriers to health literacy and digital health literacy negatively impact health outcomes, reduce adherence and treatment recommendations, and increase medical costs. We are working to ensure beneficiaries have the right tools to make the best healthcare decisions by making health information easier to understand and act upon. Consistent with research, we have found that many Medicare beneficiaries prefer audio-only telehealth because it's easier to access.[35] In addition, Black and Hispanic/Latino beneficiaries, as well as dually eligible beneficiaries with multiple complex conditions, are less likely to have access to video and

[34] National Library of Medicine. An Introduction to Health Literacy (accessed January 2023): shorturl.at/bJZ18
[35] Elevance Health Public Policy Institute. "Virtual Healthcare Use Among Medicare Advantage Members Before and During the COVID-19 Pandemic." November 2020. tinyurl.com/3ppyfuxc.

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audio technologies than other groups of MA beneficiaries, potentially compounding disparities in outcomes.[36] [37]

We are committed to leveraging digital technologies to improve efficiency and beneficiary experiences, convert data into insights, and create a platform that connects stakeholders across the health ecosystem to improve health equity. Under our member-centric Sydney platform and mobile app, our focus is broader than telehealth as health-related competencies and digital literacy are interwoven and mutually dependent. We are leveraging health literacy data to help identify rural areas, where health literacy and digital literacy needs are significant, to focus our work.[38] We have prioritized digital health literacy as a key lever in closing the digital divide for our beneficiaries and defined digital determinants of health based on three key components:

- **Broadband Access:** Pew Research found that 43% of adults with incomes below $30,000 a year report not having home broadband services;[39]
- **Smartphone Dependence:** According to Pew Research, for about 1 in 6 Americans, a mobile device is their only access to the internet while at home;[40] and,
- **Digital Health Literacy:** The U.S. Centers for Disease Control and Prevention (CDC) reports that, "[w]hile 75% of [those surveyed] said they had skills to evaluate online health resources, only 60% reported confidence in evaluating the quality of these resources and making health decisions based on that information."[41]

This strategic undertaking has involved assessing the current state of digital health literacy among Elevance Health beneficiaries and developing programs and procedures to improve digital health literacy. We are working to meet beneficiaries where they are and empower them through processes and approaches to get care quickly, improve beneficiary knowledge and experience, and increase access to high-quality care. To achieve these goals, we are:

- Developing educational materials that are accessible, written in plain language, and encourage peer-to-peer learning. For example, our Live Health Online platform has a video educating beneficiaries about how telehealth may be able to help them avoid an Emergency Room (ER) visit;
- Helping beneficiaries understand their benefits and how to access services digitally;

[36] AJMC. "Differences in the Use of Telephone and Video Telemedicine Visits During the COVID-19 Pandemic." January 14, 2021. tinyurl.com/2or2482g.
[37] PubMed.gov. "Disparities in the Use of In-Person and Telehealth Primary Care Among High- and Low-Risk Medicare Beneficiaries During COVID-19." December 13, 2021. https://pubmed.ncbi.nlm.nih.gov/34926805/.
[38] healthliteracymap.unc.edu
[39] Vogels, Emily. Pew Research Center. Digital divide persists even as Americans with lower incomes make gains in tech adoption. (June 2021): https://www.pewresearch.org/fact-tank/2021/06/22/digital-divide-persists-even-as-americans-with-lower-incomes-make-gains-in-tech-adoption/
[40] Pew Research Center. Mobile Fact Sheet. (Accessed January 2023): https://www.pewresearch.org/internet/fact-sheet/mobile/
[41] Centers for Disease Control and Prevention. eHealth Literacy. (Accessed January 2023): cdc.gov/healthliteracy/researchevaluate/eHealth.html

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- Engaging providers in digital health learning tools to help build trust within the Medicare population;
- Improving access to digital health resources and telehealth benefits through digital health navigators and care coordinators;
- Helping beneficiaries gain broadband and internet access; and,
- Creating how-to videos for our Sydney Health app and our digital health programs.

By offering simple, transparent beneficiary experiences, we are working to build confidence, increase patient satisfaction, and support beneficiaries who need education and assistance to engage digitally to use their benefits. We are committed to collaborating with CMS to understand and improve Medicare beneficiaries' level of health and digital health literacy.

Recommendations: We encourage CMS to confirm that the agency is using the WHO definition to measure digital health literacy and provide flexibility as health plans innovate to expand access to telehealth, digital access, and digital literacy in the Medicare population. Given that there are currently different definitions, standards, and vocabulary around digital health literacy, we encourage CMS to convene a working group to develop research-driven standards and further studies. We also encourage the government to do annual assessments of digital health literacy across the Medicare population to help inform best practices in the working group using the eHealth Literacy Scale (eHEALS). The last such national study was published in 2003. We have found the eHEALS 8-item measure of consumers' knowledge, comfort, and perceived skills at finding, evaluating, and applying electronic health information to health problems is a helpful benchmark to inform our work.[42] [43]

Coverage Determinations and Prior Authorizations

The application of health plan medical policy is one of the most effective ways to ensure the right care is provided at the right place at the right time. Experts have found that hundreds of billions of dollars are wasted every year in healthcare – and that beneficiaries often receive care that is costly, inappropriate, unneeded, ineffective, or unnecessary. Elevance Health's medical policies are developed by over 100 physicians and clinicians that have expertise in their specialties and are based on both peer-reviewed studies in medical literature and guidelines that reflect a strong clinical consensus among the medical specialty communities. By ensuring care is aligned with evidence-based medicine, Elevance Health drives towards

[42] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1794004/#:~:text=The%20eHEALS%20is%20an%208,health%20information%20to%20health%20problems.
[43] https://www.jmir.org/2006/4/e27

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improved outcomes and reduced readmissions in a way that is aligned with both the goals of the Administration and Stars Rating quality measures.

Elevance Health acknowledges that that the application of medical policies—such as in the case of prior authorizations—can create friction and frustration for providers and patients. That is why we have been a leader in both transparency (as described below) and using technology to make the process of obtaining an approval as fast and as efficient as possible. To this end, we continue to develop and offer solutions to streamline prior authorization processes for our care provider partners with technology that makes prior authorization submissions easier and decisions faster. We also offer innovative programs that reward those providers taking downside risk and adhering to evidence-based standards, by relaxing or eliminating prior authorization requirements, so that providers may focus on rendering care, which will improve the quality of care.

Elevance Health also supports the goals of promoting electronic Prior Authorization (ePA) and has invested in developing electronic solutions to facilitate the ease and speed of medical management processes as well as working with industry stakeholders to develop ePA solutions. For example:

- **The DaVinci Project / HL7.** We are highly active with public-private partnerships to enhance the timely and actionable exchange of health data such as Health Level Seven (HL7) International. Elevance Health's activity includes participating in the development of new FHIR data standards for ePA, taking part in FHIR "Connect-athons," the U.S. Realm Steering Committee, the Attachments Work Group, the Payers/Providers Work Group, and The DaVinci Project, which was highlighted in the CMS presentation to the Office of the National Coordinator of Health Information Technology (ONC) as a tool to help reduce physician burden.
- **Participation in Electronic Data Interchange Working Group.** Elevance Health participates in the Attachments & Prior Authorizations Support work groups at the Workgroup for Electronic Data Interchange (WEDI), which serves in an advisory role to the Secretary of the U.S. Department of Health and Human Services (HHS) on matters related to the use of electronic transactions in healthcare. WEDI's work has contributed to other CMS rulemaking on the Health Insurance Portability and Accountability Act (HIPAA) X12 electronic standard transactions for referral certification and authorization (278) and healthcare attachments (275).[44]

[44] Proposed rule, Administrative Simplification: Adoption of Standards for Healthcare Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard, 87 Fed. Reg. 78438 (Wednesday, December 21, 2022).

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We also remain flexible to the care circumstances of our beneficiaries. For example, in response to the COVID-19 pandemic, we waived prior authorization requirements for Skilled Nursing Facility transfers and other services in order to free up hospital bed capacity. We work within federal and state guidelines, collaborating with stakeholders to appropriately adjust our care management programs for the benefit of our members.

Transparency of Medical Policies

Elevance Health supports the transparency of medical policies used to determine whether specific items and services are covered (and under which circumstances) and has made its medical policies available on its public website for over a decade.[45] Publicly publishing medical policies helps demonstrate that decisions are being made based upon clinical evidence, which helps build beneficiary and stakeholder trust.

Recommendation: Elevance Health supports the transparency provisions in the proposed regulation. This includes the requirement for MA plans to only use internal coverage criteria to the extent it is made publicly available, and requiring:

- A publicly accessible summary of evidence that was considered during the development of the internal coverage criteria;
- A list of the sources of such evidence; and,
- An explanation of the rationale supporting the adoption of the coverage criteria.

Ensuring all health plans operate with this transparency will help ensure beneficiary trust in the program.

Involvement of Medical Directors or other Appropriate Healthcare Professionals in Medical Policy and Decisions

CMS proposes that the MA organization's Medical Directors be involved in ensuring the clinical accuracy of medical necessity decisions where appropriate. Elevance Health believes the direct involvement of Medical Directors or other appropriate healthcare professionals is a critical element of the medical necessity process, and Elevance Health follows this practice today.

[45] Our medical policies are available at this site: https://www.anthem.com/provider/policies/clinical-guidelines/

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Recommendation: Elevance Health supports this provision and recommends CMS finalize it. This provision would help build trust for the program.

Qualifications of Staff Making Medical Necessity Decisions

CMS proposes that the existing general requirement that the physician or other appropriate healthcare professional have sufficient medical and other expertise be replaced by a requirement linking the requisite expertise of the reviewer to the specific service that is the subject of the organization determination request. Elevance Health strongly believes the health plan should have the ability to determine which physician or healthcare professional is qualified to conduct the initial organization determination, including what specific expertise is required for the service requested, and Elevance Health already takes this approach.

But Elevance Health does not believe there should be an exact match between the service requested and the qualifications of the reviewer. CMS gives as an example in the proposed rule a prior authorization request for a home nebulizer, which CMS states would be appropriate for a respiratory therapist to review.[46] However, respiratory therapists are not physicians, and they cannot order a home nebulizer, while physicians can. Internal medicine physicians are familiar with the reasons why a home nebulizer might be medically necessary, such as for severe asthma or Chronic Obstructive Pulmonary Disease (COPD). If, as CMS states, review of a request for referral to a surgeon for excision of a thyroid nodule does not require review by a surgeon, so too a request for a home nebulizer need not be reviewed by a pulmonologist or allergist when an internal medicine physician has familiarity with nebulizers.

Recommendation: Elevance Health supports this provision and recommends CMS finalize it, with the caveat that CMS should not require that there be an exact match between the service requested and the qualifications of the reviewer. This provision would help build trust in the program.

Conforming MA Coverage Policy to FFS Medicare

FFS Medicare's Medical Policy Falls Short of Ensuring Appropriate Care

CMS' existing definition of medical necessity requires that the service be safe and effective and furnished in accordance with the accepted standards of medical practice. Unfortunately,

[46] 87 Fed. Reg. at 79510.

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CMS' existing medical policy used in the FFS Medicare program falls short of this objective in the following ways:

- **FFS Medicare's medical policies lack specificity:** FFS Medicare has a large number of coverage policies that are vague and do not provide appropriate guidance, meaning the proposed regulation may have the practical impact of inhibiting any coverage denials in those areas, even in cases where the service being provided presents a safety risk. Specifically, the key areas of radiology and musculoskeletal conditions exhibit such a lack of specificity that health plans would be left unsure whether they could use their own policies that contain sufficient detail:
    - Current National Coverage Decisions (NCD) for CT and Magnetic Resonance Imaging (MRI) (the two most utilized advanced imaging exams) generally do not provide any condition-specific criteria for assessment of imaging appropriateness, aside from limited exceptions for relatively uncommon services. These NCDs require that services be "reasonable and necessary," but provide no detail on the criteria needed to establish that definition.
    - Health plans fill the explanatory gap by providing a definition of medical necessity (through an evidence-based appropriateness framework) via specific clinical criteria that establish appropriateness for any CT or MRI request.
    - For example, the most common reason to order an MRI of the brain is for evaluation of headache, and there is longstanding multi-specialty consensus recommending imaging only in the presence of certain clinical risk factors (a position by which MA plan guidelines are aligned).[47] However, the NCD 220.2 for MRI does not include any such criteria for this indication, instead only stating that "MRI is useful in examining the head, central nervous system, and spine… The inherent tissue contrast resolution of MRI makes it an appropriate standard diagnostic modality for general neuroradiology," perpetuating the inappropriate use of MRI against evidence-based practice in this space.
- **FFS Medicare does not have medical policies in key areas:** In addition to those areas of medical policy that are vague, there are areas of benefit classes where FFS Medicare has no medical policy. While the proposed regulation would allow health plans to use their own medical policies in such circumstances, the rule appears to not allow guidelines built

[47] National Institute for Health and Care Excellence, Headaches in over 12s: diagnosis and management, (2012) London, UK, National Institute for Health and Care Excellence; Douglas, AC, et al, Expert Panel on Neurologic Imaging. ACR Appropriateness Criteria® Headache. [Online Publication]. Reston (VA) American College of Radiology (ACR); 2013. Available at: https://acsearch.acr.org/docs/69482/Narrative/; Stephen D. Silberstein. Practice parameter: Evidence-based guidelines for migraine headache (an evidence-based review): Report of the Quality. Standards Subcommittee of the American Academy of Neurology. 2000;55;754 Neurology. (US Headache Consortium).

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upon a clinical consensus that has not yet been incorporated into the published medical literature:

- For example, there is a clinical consensus that an X-Ray or ultrasound should often be ordered before demonstrating a need for a CT scan. However, this approach is not reflected in the FFS Medicare coverage policy.

Worse Health Outcomes and Lower Quality Care for Beneficiaries

Elevance Health supports CMS' efforts to improve the health outcomes for beneficiaries. CMS has acknowledged the importance of medical policy in achieving this goal in its final 2023 Outpatient Prospective Payment System (OPPS) rule, where CMS states that "prior authorization is an effective mechanism to ensure Medicare beneficiaries receive medically necessary care."[48]

By forcing health plans to adopt vague, non-existent, or outdated medical policies, the proposed regulation would harm plan sponsor's efforts that utilize medical policies to improve beneficiaries' health. For example, there is extensive evidence that MRI of the low back should only be done for back pain after a course of non-operative management, because most uncomplicated low back pain improves with such treatment and because MRI is known to generate many false positive results in the spine (findings that are abnormal on imaging, but not the cause of pain), which often drive additional procedures/surgery and imaging.[49]

However, this approach is not reflected in the FFS Medicare coverage policy, which would expose beneficiaries to lower quality care and the potential harms of unnecessary procedures and services as compared to the application of existing health plan medical policy that aims to only use imaging when medically necessary. Potential harms of imaging overutilization include false positive imaging results leading to inaccurate diagnosis resulting in unnecessary subsequent testing and potential overtreatment. Unnecessary imaging exams also directly expose patients to harms including contrast reaction, nephrotoxicity, and exposure to unnecessary ionizing radiation.

[48] Final Rule, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; COVID–19, 87 Fed Reg 71748, 72226 (Wednesday, November 23, 2022).
[49] Chou R, Qaseem A, Snow V, et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. Ann Intern Med. 2007;147(7):478-91;
Patel ND, Broderick DF, Burns J, et al. ACR Appropriateness Criteria Low Back Pain. J Am Coll Radiol. 2016;13(9):1069-78.

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Higher Costs and/or Fewer Benefits for Beneficiaries

It is widely accepted that prior authorization reduces costs by ensuring care paid for by the plan is evidence-based. As the proposed regulation would make health plan medical policies less stringent in key areas (by requiring conformity to FFS Medicare in those areas), it would increase costs. Higher costs for MA translate to higher premiums and/or fewer supplemental benefits for beneficiaries.

Reducing Beneficiary Choice

As outlined in more detail below, MA was created as an alternative to FFS that intentionally has a more managed medical framework, including both networks and medical management. Beneficiaries place so much value on MA as an alternative that almost half of Medicare beneficiaries made a proactive choice to enroll in MA. If CMS requires MA plans to adopt the less robust medical policies in FFS Medicare—as would be required in the proposed regulation—there would be less savings available to beneficiaries which would materialize in the form of higher premiums and/or fewer benefits.

Increased Healthcare Waste and Exacerbating Medicare's Financial Challenges

CMS has agreed with the perspective that prior authorization helps reduce healthcare waste and mitigates Medicare's financial challenges. Specifically, in its final 2023 OPPS rule, CMS states that "prior authorization is an effective mechanism to ensure Medicare beneficiaries receive medically necessary care while protecting the Medicare Trust Funds from unnecessary increases in volume, by virtue of improper payments, without adding new documentation requirements."[50] A requirement that MA plans adopt FFS Medicare's less robust medical policies would exacerbate Medicare's financial challenges and run contrary to CMS' perspective outlined above.

Inconsistent with Congressional Intent for Part C

When Congress created Medicare Part C in 1997, goals included offering beneficiaries an improved option that would be different from Medicare (including through the use of medical management), would be more familiar to beneficiaries previously covered under employer-sponsored health plans, would improve care, and would reduce costs for the Medicare

[50] Final Rule, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; COVID–19, 87 Fed Reg at 72226.

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program. The MA program has successfully met those goals and is in high demand by beneficiaries, now representing nearly half of Medicare enrollment.

By proposing that MA plans conform their coverage policies to FFS Medicare, CMS is working against all of those goals stated above in the following ways:

- **Worse health outcomes:** As described in more detail below, FFS Medicare coverage guidelines can be vague or not reflect the latest medical research in key areas; requiring health plans to adopt them would eliminate guidelines that are proven to improve health outcomes and reduce health risks for beneficiaries.
- **Reduced beneficiary choice:** Removing differentiation on coverage guidelines between MA plans and FFS Medicare (and between MA plans themselves) removes an important element of beneficiary choice.
- **Lower value care:** Health plans work with providers on medical management policies to achieve better health outcomes and improvements in the Star Rating quality measures, affordability, and product design through value-based care arrangements.
- **Higher costs:** Health plan coverage guidelines are proven to help reduce costs; eliminating them would increase costs to the Medicare program and result in higher premiums and/or reduced benefits for beneficiaries.
- **Less familiarity for consumers with coverage under employer plans:** MA health plan coverage guidelines largely mirror the coverage guidelines that apply to coverage under employer-sponsored health plans. Forcing health plans to adopt FFS Medicare coverage guidelines would eliminate that element of consumer familiarity when transitioning from an employer plan to Medicare.

Recommendation: Elevance Health recommends that CMS withdraw its proposal to require health plans to conform to FFS Medicare's medical guidelines. Withdrawing the proposal will avoid (1) beneficiaries receiving worse care, higher premiums, and fewer benefits; (2) reducing beneficiary choice by devaluing MA; and (3) exacerbating Medicare's financial challenges.

Prohibiting Medical Policy that Requires One Item/Service to be Furnished Prior to Receiving the Requested Item/Service

CMS proposes to prohibit health plans from applying medical policy that requires one item/service to be furnished prior to receiving the requested item/service. One of the most

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important elements of medical policy is ensuring that a medical item or service is provided at the right time (that is, the right step in the course of treatment). Medical policy is often designed to ensure that a less invasive item/service is furnished prior to a more invasive item/service. This approach increases safety and is supported by evidence-based medicine.

For example, clinical consensus and medical literature, including Appropriate Use Criteria from the American College of Radiology, show that it is often appropriate for patients to have an x-ray or ultrasound before a CT scan or MRI, as these exams may provide sufficient diagnostic information with low or no radiation exposure. In addition, x-ray or ultrasound are often used in a complementary fashion to determine which CT or MRI imaging exam is most appropriate. If CMS' proposed provision prohibiting medical policy that requires one item/service to be furnished first were to go into effect, it would require providers to provide care that is inconsistent with evidence-based clinical consensus, potentially expose beneficiaries to more radiation or other harms of unnecessary imaging, and risk performance of diagnostically suboptimal and/or clinically redundant exams. Furthermore, requiring health plans to cover a more expensive medical test when a more cost-effective test would afford the same or better diagnostic data would increase costs for the Medicare Trust Funds and also increase costs and/or reduce benefits for beneficiaries.

Recommendation: For the above reasons, Elevance Health recommends CMS withdraw the proposal to prohibit health plans from applying medical policy requiring one item/service to be furnished prior to receiving the requested item/service. Withdrawing this proposal would avoid worse care for beneficiaries associated with the provision of potentially harmful items/services that could have been avoided, consistent with medical literature and evidence-based medicine. Withdrawing the proposal would also avoid higher premiums and/or fewer benefits for beneficiaries and exacerbating Medicare's financial challenges.

While CMS notes the agency is not proposing to revise regulations which authorize MA plans to use step therapy policies for Part B drugs, we reiterate the importance of step therapy in Part B, Durable Medical Equipment (DME), and Continuous Glucose Monitoring (CGM). Step therapy is a valuable tool to encourage beneficiaries to use clinically superior drugs that are therapeutically comparable to protect patients and taxpayers from a high-priced drug, when there is a more reasonably priced, and clinically similar alternative. It is critical to avoid additional limitations on the use of step therapy that could undermine the benefits of this valuable clinical management tool.

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Requiring Authorizations be Valid for Entire "Course of Treatment"

CMS proposes to require prior authorization approvals be valid for the entire "course of treatment." Requiring a prior authorization to be valid for the entire "course of treatment" is overly broad and may create a situation where there is no clear time limitation and potentially no limitation on a provider continuing to furnish services experts would not consider tied to the original approval. Such a policy would increase waste in the healthcare system—in some cases for multiple years for a single patient. Of note, there is nothing in the proposed provision that would differentiate between diagnostics and therapy.

It is also unclear whether an MA plan could conduct concurrent reviews for post-acute care; disallowing concurrent review in the post-acute setting would not ensure that the beneficiary was placed in the best setting. MA plans need to retain the ability to conduct concurrent reviews for post-acute care and rehabilitation, because there is a need to monitor the patient's condition. Additionally, disallowing post-acute concurrent review could potentially exhaust a beneficiary's benefits, leaving them with no remaining benefits when needed.

Recommendation: For these reasons, Elevance Health recommends that CMS withdraw its proposal to require prior authorization approvals be valid for the entire course of treatment. Withdrawing the proposal would avoid the provision of wasteful services that drive up premiums and/or reduced benefits for beneficiaries while exacerbating Medicare's financial challenges. Additionally, should this proposal apply to Part B drugs, we recommend CMS give health plans the flexibility to establish the length of the approval for therapies on a case-by-case basis. For example, the length of approval may be for the duration of the planned course of treatment or for as long as the beneficiary remains in the plan.

90-Day Transition Period when Beneficiaries Switch MA Plans

CMS proposes to require health plans to have policies for using prior authorization that provide for a minimum 90-day transition period for any ongoing course(s) of treatment when a beneficiary has enrolled in an MA plan after starting a course of treatment, even if the course of treatment was for a service that commenced with an out-of-network provider. This provision would also apply to beneficiaries who are new to Medicare.

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Elevance Health supports the general goal CMS is trying to achieve to ensure care is not disrupted when a beneficiary transitions plans. We believe this goal is already achieved through the existing practice where prior authorization approvals are "grandfathered" that allows a provider to demonstrate to the new MA plan that prior approvals already took place. In our view, this approach works well today.

CMS' proposal would switch the onus such that plans would need to continue to pay the provider—irrespective of whether the provider can demonstrate that a prior approval was achieved under the previous plan. CMS' proposal would also extend to out-of-network providers—even when the new health plan's medical policies are not being followed. This change would increase costs, leading to higher premiums and/or fewer benefits for beneficiaries, while exacerbating Medicare's financial challenges.

Recommendation: Elevance Health recommends CMS withdraw its proposal to require health plans to have policies for using prior authorization that provide for a minimum 90-day transition period for any ongoing course(s) of treatment when a beneficiary has enrolled in an MA plan after starting a course of treatment, even if the course of treatment was for a service that commenced with an out-of-network provider. CMS should instead keep in place its existing policy where prior authorization approvals are "grandfathered" that allows a provider to demonstrate to the new MA plan that prior approvals already took place. This approach would avoid increased premiums and/or fewer benefits for beneficiaries and exacerbating Medicare's financial challenges.

Utilization Management Committee

CMS proposes to require MA organizations to establish a UM committee to operate, similar to a P&T Committee, which would annually review UM policies, including prior authorization.

Elevance Health supports the concept of ensuring UM policies (including those for prior authorization) are reviewed regularly by individuals at the plan with diverse clinical experience and expertise. However, we also believe such a requirement should be applied in a way that is sufficient while minimizing duplication and administrative costs. For example, NCQA accreditation already requires accredited plans to have qualified medical personnel review UM criteria and decisions.

Recommendation: Since NCQA accreditation already requires accredited plans to have qualified medical personnel review UM criteria and decisions, Elevance Health requests that CMS avoid administrative duplication by allowing this provision to be satisfied by a plan's NCQA accreditation. Otherwise, there will be additional administrative costs and duplication

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that would increase costs, resulting in higher premiums and/or reduced benefits, and exacerbating Medicare's financial challenges. In addition, should this proposal apply to Part B drugs, in order to reduce additional administration burden on plan sponsors, we recommend CMS allow the sponsor's existing Part D P&T Committee to have oversight of certain UM coverage policies.

Request for Information (RFI): Termination of Services in Post-Acute Care

CMS states it has received complaints that allege that MA organizations are increasingly terminating beneficiaries' coverage of post-acute care before the beneficiaries are healthy enough to return home. CMS is soliciting feedback from stakeholders that have information related to this situation, and investigating internally, to get a more thorough understanding on the issue.

Upon reviewing this RFI, we reviewed our Grievance & Appeal data capturing challenges to our coverage determinations for post-acute care from January 2021 through October 2022. Our data shows the following:

- Over 92% of post-acute care appeals of our coverage decisions were upheld by the Independent Review Entity; and,
- Of those overturned, the number one reason was providers not submitting adequate information with the authorization, including documents supporting medical necessity.

This data demonstrates that Elevance Health is making post-acute care determinations consistent with evidence-based medicine. If CMS is interested in reviewing our data further and discussing the issue with our medical experts, we would be happy to do so.

Marketing

Elevance Health strongly believes all MA and Part D marketing must be clear, accurate, and compliant with CMS regulations and sub-regulatory guidance, including the Medicare Communications and Marketing Guidelines (MCMG). All marketing must meet these standards to ensure beneficiaries are able to make the best healthcare choices to meet their unique needs and preferences. To best meet this objective, we have industry-leading processes in place, including the following:

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- **Carefully generating and reviewing marketing materials that meet CMS requirements and provide clear and accurate information to beneficiaries:** Elevance Health has detailed compliance processes in place to ensure all marketing materials contain clear and accurate information and that materials meet all CMS requirements.
- **Reviewing TPMO marketing materials to the largest extent possible:** Consistent with CMS guidance, we have robust compliance programs in place to oversee the activities of TPMOs, agents, and brokers where a contract exists between Elevance Health and those individuals/entities. We also utilize CMS' HPMS process for reviewing marketing materials submitted by third-party entities, often conduct TPMO marketing reviews of documents before they are even submitted to HPMS, and opt out of any materials that contain inaccurate or potentially misleading information.
- **Quickly addressing concerns raised by any stakeholder:** We quickly investigate and work to address marketing-related complaints from sources raised through any channel, including the Complaint Tracking Module. When patterns emerge, we work with our partner organizations to quickly rectify the issue, which has included rejecting participation in certain marketing materials.
- **Consistently generating compliance education campaigns:** We consistently educate sales agents about existing and new CMS marketing requirements to ensure compliance, including the importance of reviewing all materials for accuracy and ensuring consumer confusion is mitigated to the largest extent possible. We focus on educating beneficiaries about their health plan choice, before, during, and after enrollment.
- **"Secret shopping" our sales partners:** We regularly put our own employees in the shoes of a beneficiary and go through a sales experience with our sales partners to improve beneficiaries' experience and ensure compliance with CMS requirements.

TPMO Oversight Recommendations to Reduce Abrasion and Improve Trust

Elevance Health is committed to ensuring beneficiaries have the necessary information to make the coverage choices that best meet their needs. CMS' final 2022 MA and Part D rule aimed to clarify regulations to make health plans accountable for its contractors and subcontractors engaging in marketing activities. Such an approach leaves a number of oversight challenges, including:

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- TPMOs typically market the plan options of a large number of companies and will often continue its actions even when a single plan opts-out due to concerns the activity does not meet all CMS requirements;
- Despite concerns health plans may raise about marketing accuracy, CMS may approve marketing materials leading to inconsistency and confusion about interpretations related to existing requirements;
- Health plans cannot take collective actions against third-party bad actors due to antitrust constraints; and,
- TPMOs may contract with entities which health plans have no contract or are not even aware of. For example, many of the existing marketing entities generating sales leads do not have direct or indirect contractual relationships with health plans.

Elevance Health shares policymakers' goal of protecting beneficiaries from confusing and potentially misleading Medicare marketing information that may cause beneficiary confusion or harm. In addition, we agree with policymakers' assessment that much of the confusion and abrasion is not due to health plans themselves, but rather the activity of a relatively small subset of TPMOs and their downstream entities.[51] Given these challenges, CMS is in the best position to quickly evaluate and—if necessary—stop marketing activity that does not meet CMS' requirements.

Recommendation: We recommend CMS work with stakeholders and Congress to obtain sufficient regulatory authority and staffing to ensure the activities of all marketing entities are compliant with CMS requirements with a more streamlined oversight framework. Such a framework could do the following:

- **Require all individuals/entities marketing MA and Part D to register with CMS:** Congress could establish a requirement that all entities performing an MA/Part D marketing function register with CMS and be subject to direct audits and fines for non-compliance.
- **Substantial fines for not being registered:** Because bad actors (for example, entities performing aggressive robocalls) are unlikely to do the right thing and register with CMS, Congress could mandate fines that would prevent bad actors from continuing to perform misleading marketing.

[51] Centers for Medicare & Medicaid Services: Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs (January 12, 2022): https://www.govinfo.gov/content/pkg/FR-2022-01-12/pdf/2022-00117.pdf

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While action from Congress may be needed to provide sufficient authority and staffing for CMS to directly regulate TPMOs and downstream entities, we recommend CMS take the following additional steps under its existing authority to mitigate non-compliant marketing:

- **Preserve federal Medicare preemption:** While state partnerships are important, it is critical to preserve and strengthen federal Medicare preemption protections to ensure consistency in addressing misleading marketing materials across the country. A patchwork of state regulations on MA marketing materials would undermine strong and consistent federal standards and risk inconsistent enforcement regimes. Preemption consistently applied to marketing materials in the Medicare+Choice program prior to 2003, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) reinforced and strengthened preemption.[52] The broad reach of the Congressional intent behind the Medicare Act's preemption clause must be maintained to preserve beneficiary protections.
- **Create a consolidated document containing all marketing requirements with examples for stakeholders to reference:** Since the regulatory requirements related to marketing are not published in one place for stakeholders to reference, we recommend CMS compile and codify marketing requirements through the MCMG with a comment opportunity. Until guidance is published and codified in a single place, bad actors may take advantage of a lack of clarity. Furthermore, different parts of CMS may interpret requirements differently. The compilation of requirements should include examples of compliant and non-compliant materials and tactics to improve clarity.
- **Ensure consistent enforcement:** Today, it is our experience that staff across CMS' regional offices do not provide consistent answers on whether a specific marketing material is compliant. We recommend the process for review and enforcement be centralized by CMS to provide consistent enforcement to ensure the delivery of clear and compliant information to beneficiaries.
- **Revise the process for TPMO material approval:** We recommend CMS improve the current HPMS marketing material filing approach such that material filed by TPMOs is approved by a lead plan. The lead plan would be responsible for ensuring the material meets all of CMS' standards, enforcing accountability and cutting down on duplication.
- **Establish a compliance resolution process for reports of potentially non-compliant marketing materials or tactics:** In addition to the filing process described above, we recommend CMS develop a process where stakeholders can easily report non-compliant marketing with a framework for swift resolution.

[52] CooperScully: Trends In Managed Care Preemption (2006): https://www.cooperscully.com/uploads/seminars/Leininger%20-%20Trends%20in%20Managed%20Care%20Preemption.pdf

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- **Perform TPMO-targeted trainings:** CMS should provide consistent training to TPMOs and their downstream entities to ensure understanding of marketing requirements.

Proposed Marketing Requirements Supported by Elevance Health

We appreciate CMS' efforts to close marketing loopholes in its 2024 regulation to protect beneficiaries. Specifically, Elevance Health supports CMS' proposals to:

- **Prohibit TPMOs from selling information to other TPMOs (while clarifying contact information can still be provided from TPMOs to health plans):** We generally support CMS' proposed prohibition on TPMOs selling information to other TPMOs. This would help avoid situations where bad actors pass personal contact information several times to multiple entities, creating aggravating situations for consumers.
    - However, we seek an important clarification that would ensure a TPMO can provide the relevant health plan(s) with contact information for follow-up with the consumer. For example, if a consumer expresses interest in enrolling in a particular health plan, that TPMO should have the ability to pass that information along for appropriate follow-up.
- **Modify the TPMO standard notice (with request to streamline the language):** We appreciate CMS' effort to ensure consumers understand that a TPMO may not be presenting all options available in a particular service area.
    - However, we recommend CMS streamline the language because we have found that complex disclaimers can confuse consumers. We therefore suggest CMS make the disclaimer as short as possible and reference only 1-800-MEDICARE and Medicare.gov as sources information for consumers.
- **Prohibit advertising that markets something as "savings" in a misleading way:** We support ensuring assertions made in advertising reflect accurate information. We support CMS' proposal to prohibit marketing a product as providing significant "savings" that are based on a comparison of typical expenses borne by uninsured individuals, unpaid costs of dually eligible beneficiaries, or other unrealized costs of a Medicare beneficiary. In addition, we want to ensure that health plans are not interpreting the guidance differently, so we ask CMS to provide additional examples of scenarios and what language is appropriate.
- **Require health plans to have an agent/broker monitoring and oversight plan (with needed clarifications):** We monitor the activities of our agents and brokers, including call

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monitoring and secret shopping, and we support ensuring all health plans perform that function.

- However, we request the following clarifications:
  - CMS should clarify what it means by a "healthy sampling;"
  - For an agent/broker that a health plan does not employ or have a contractual relationship with, we urge CMS to impose agent/broker fines directly; and,
  - CMS' acknowledgment that real-time monitoring cannot take place between a health plan and employees of an external organization, such as a TPMO, because systems do not exist to monitor employees of another organization in a real-time way (for example, external call center). In addition, monitored calls could involve beneficiaries enrolling in a different health plan, which would violate HIPAA privacy rules.

- **Establish required questions that must be asked prior to enrollment (with needed clarifications):** We support requiring entities go through a CMS-developed list of items that must be discussed with the beneficiary. CMS already approves Elevance Health's sales script, and we appreciate the opportunity to ensure we are being thorough with beneficiaries and compliant with CMS' requirements.
  - However, beneficiaries should only be asked a question once during the entire sales and enrollment process, not multiple times as could be the case if agents/brokers are required to ask the same questions that already exist in a pre-enrollment checklist. The scripting process is the best way to ensure these questions get asked, and we would like to work with CMS to ensure beneficiaries are asked an appropriate number of streamlined questions.
- **Clarify the existing requirement to record calls (with needed clarification):** We support CMS' proposal to clarify that the requirement to record calls is limited to calls regarding sales, marketing, and enrollment, and to extend the requirement to web-based technology.
  - However, we seek clarification that a call can continue if the beneficiary asks not to be recorded. Under existing regulation, we are concerned that the requirement to record calls could be interpreted as requiring the call be terminated if the beneficiary requests that the call is not recorded. We believe the call should be able to continue unrecorded if a beneficiary makes such a request, otherwise there would be beneficiary abrasion and complaints, as we would not be able to meet the beneficiary's needs.

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- **Prohibit the use of superlatives without concurrent data backing-up the claim:** We agree that all superlatives used in marketing materials must be backed-up with evidence. We also request CMS ensure this provision is enforced consistently across all languages as superlatives do not always translate consistently between languages.

Creating Barriers to Face-to-Face Marketing Interactions

CMS is proposing two major changes that would have the effect of limiting face-to-face sales interactions: (1) a 48-hour wait time between an SOA being filled out and an appointment being made, and (2) separating sales events from educational events. Both of these changes add waiting times, which would result in fewer face-to-face interactions, and drive more tele-sales activities.

We have found that a substantial portion of consumers prefer face-to-face sales. Particularly for older adults, face-to-face interactions are the format many consumers find to be the most helpful to build trust, gain the right information, and make the choice that best meets their needs. Telephonic sales are robust and valuable; however, relationships can be strengthened by in-person interactions and ongoing conversations.
Independent studies have similarly concluded that older adults strongly prefer in-person interaction. In a study published in 2021 by BMC Health Services Research that interviewed various cohorts of older adults concluded that:

- Most older adults have strong preferences for obtaining information in-person regarding benefits, cost, and other plan information;
- Few of those interviewed used the available internet resources, and in fact most of them mentioned that they did not have a computer/smart device with internet capabilities; and,
- Among those who used and appeared to be comfortable with navigating the internet, www.Medicare.gov was not discussed as a useful resource for making decisions regarding health insurance.[53]

Another study published in Educational Gerontology in 2016 further concluded that face-to-face communication is the most preferred method of communication for older adults in the U.S.[54] For this reason, Elevance Health is opposed to changes that would make face-to-face

[53] Rivera-Hernandez M., Blackwood K.L., Mercedes M., Moody K.A: Seniors don't use Medicare.Gov: how do eligible beneficiaries obtain information about Medicare Advantage Plans in the United States?. BMC Health Serv Res 21, 146 (February 2021): https://doi.org/10.1186/s12913-021-06135-7
[54] Shupei Yuan, Syed A. Hussain, Kayla D. Hales & Shelia R. Cotton: What do they like? Communication preferences and patterns of older adults in the United States: The role of technology, Educational Gerontology, 42:3, 163-174, (2016): https://doi.org/10.1080/03601277.2015.1083392

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sales more difficult and create an additional burden for consumers who want to decide during a face-to-face interaction.

Exacerbating Health Inequity

We have found that many sub-demographics of older adults prefer face-to-face interactions, and these interactions are especially critical for people dually eligible for Medicaid and Medicare. A larger share of dually eligible older adults enrolls through face-to-face encounters given their lower level of access to, and familiarity with, technology. Creating barriers to face-to-face sales would work against efforts to advance health equity because of dually eligible beneficiaries' heavy reliance on and preference for face-to-face interactions, which allows them to pick the best plan for their personal needs and preferences.

Increasing Disenrollments

Elevance Health is aligned with CMS' efforts to reduce disenrollments and churn that can delay and interrupt patient care and increase administrative costs. In our review of disenrollments by source of enrollment, we have found that those who enroll as part of face-to-face interactions exhibit the least proportion of disenrollments as compared to beneficiaries who enroll through other sources. Given that a quality measure for health plans is disenrollments, face-to-face interactions should be encouraged, not discouraged, as would be the effect of the proposed regulation.

Increasing Complaints

Elevance Health is focused on limiting and addressing beneficiary complaints to the largest extent possible. In our review comparing beneficiary complaints to source of enrollment, we found that beneficiary complaints are lowest among the cohort of beneficiaries that enrolls following a face-to-face sales interaction. This supports evidence in other areas that demonstrates beneficiaries feel they receive the best information in face-to-face interactions, and those interactions should be encouraged instead of discouraged, as would be the case if these proposed provisions go into effect.

48-Hour Wait Time between SOA Being Filled Out and the Appointment

CMS proposes to prohibit personal marketing appointments from taking place until after 48 hours have passed since the time the beneficiary completed the SOA. Creating an arbitrary delay when a consumer is ready to have a sales conversation would create an unnecessary burden to enrollment. This proposal would result in the following:

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- **Exacerbating health equity challenges:** As stated above, dual eligible beneficiaries have a higher share of enrollments through face-to-face encounters. These beneficiaries typically have less time to spend on Medicare enrollment and lower access to transportation and technology, making face-to-face interaction critical to ensure the beneficiary gets all of the information they need in a single interaction. Adding an arbitrary 48-hour wait time for beneficiaries earning low incomes would effectively require individuals to allocate additional time and find transportation for a second interaction, making it less likely beneficiaries would be able to enroll in the plan that best meets their personal needs and preferences.
- **Gaps in coverage:** Approximately 25% of beneficiaries wait until the last 7 days of open enrollment to have a sales conversation and enroll in coverage. This already creates a workload challenge with sales agents working as hard as possible to ensure those seeking to enroll at the last-minute do so with the best and most complete information possible. Many beneficiaries would not be aware of the mandated 48-hour waiting period, and if they fill out the SOA within the last few days the enrollment period, they will likely not have an opportunity to enroll, creating a gap in coverage and worse outcomes for the beneficiary. This dynamic would also increase beneficiary complaints as abrasion is created by the proposed arbitrary 48-hour waiting period
- **Higher numbers of disenrollments:** As explained above, face-to-face interactions exhibit the least proportion of disenrollments as compared to all other forms of marketing conversations. A large share of beneficiaries find they receive the best information in face-to-face encounters and enroll in the plan that best meets their personal needs and preferences. A 48-hour wait time would result in a lower proportion of sales occurring during face-to-face interactions, instead occurring through other mechanisms that exhibit higher proportions of disenrollments. In addition, a forced delay makes information learned during the initial interaction less fresh in the beneficiary's mind,[55] which could create additional confusion, challenges, and an increase in complaints. Furthermore, this proposal could result in more sales events and less educational events, which would make the beneficiary less informed overall and increase the chances of them enrolling in a plan that does not fit their unique needs.
- **Increasing complaints:** As explained above, the cohort of beneficiaries enrolling following a face-to-face sales interaction exhibits the highest level of satisfaction and fewest complaints. Creating a 48-hour wait time between the SOA being filled out and the appointment would result in fewer face-to-face sales interactions and CMS would see an

[55] Murman DL. The Impact of Age on Cognition. Semin Hear. (August 2015) ;36(3):111-21.: https://ncbi.nlm.nih.gov/pmc/articles/PMC4906299/

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increase in beneficiary complaints as beneficiaries shift to other sales interactions that are not face-to-face where beneficiaries exhibit a higher proportion of complaints.

Recommendation: Elevance Health recommends CMS withdraw its proposal to prohibit personal marketing appointments from taking place until after 48 hours have passed since the time the beneficiary completed the SOA. Withdrawing this proposal would help avoid exacerbating health equity challenges, increasing disenrollments, and increasing beneficiary complaints. If a 48-hour wait time were put into place, health plans will need direction on the potential removal of the SOA from enrollment kits. Instead of prohibiting *certain types of sales interactions*, we urge CMS to instead focus on:

- Targeting the bad actors using its existing authority as outlined above. Such an approach would help ensure beneficiaries have maximum opportunity for face-to-face interactions, which yields the best results; and,
- Focusing on other elements such as the pre-enrollment checklist to ensure beneficiaries receive information in key areas, irrespective of the timing or type of sales interaction.

Separating Sales Events from Educational Events

CMS proposes to reinstate the prohibition on accepting SOA cards or the collection of beneficiary contact information at educational events. This includes a proposal to prohibit marketing events from taking place within 12 hours of the educational event in the same location.

Creating separation between marketing events and sales events would result in a similar set of challenges as the 48-hour wait time described above. Sales events that occur following educational events exhibit a remarkably high level of success in terms of beneficiary satisfaction and few disenrollments. Beneficiaries obtain information at the educational event, putting them a strong frame-of-mind to meet with a sales agent to further discuss options and potentially make an enrollment decision that is best for their circumstances and health needs.

Additionally, several national surveys indicate that older adults often face transportation issues, including inadequate access to transportation services, therefore, forcing a beneficiary to travel multiple times to the same location will add to the transportation burden they might

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already be experiencing.[56] [57] We further note that we do not believe that offering food at educational events exerts pressures over beneficiaries to also attend a marketing event at the same location.

Separating sales events from educational events would create the following negative outcomes:

- **Exacerbating health equity challenges:** As previously detailed, dual eligible beneficiaries exhibit a higher share of enrollments through face-to-face encounters. Dually eligible beneficiaries typically have less time to focus on Medicare enrollment and exhibit lower access to transportation and technology that makes each engagement critical to ensure the beneficiary gets all the information needed in that one block of time and location. Separating sales events from educational events would create a barrier for beneficiaries earning low incomes who want to have a face-to-face sales interaction, which would have the effect of requiring those beneficiaries to allocate additional time and find transportation for a second interaction, making it less likely beneficiaries earning low incomes would be able to enroll in the plan that best meets their needs.
- **Exacerbating disenrollments:** As previously detailed, face-to-face interactions exhibit the least proportion of disenrollments as compared to all other forms of marketing conversations. A large share of beneficiaries find they receive the best information in face-to-face encounters and enroll in the best plan that meets their needs. Separating sales events from educational events would result in a fewer proportion of sales occurring during face-to-face interactions, instead occurring through other mechanisms that exhibit higher proportions of disenrollments.
- **Increasing complaints:** As previously detailed, the cohort of beneficiaries enrolling following a face-to-face sales interaction exhibits the highest level of satisfaction and fewest complaints. Separating sales events from educational events would result in fewer face-to-face sales interactions and CMS would see an increase in beneficiary complaints as beneficiaries shift to other sales interactions that are not face-to-face where beneficiaries exhibit a higher proportion of complaints.

Recommendation: Elevance Health recommends CMS withdraw its proposals related to separating sales events from educational events. Withdrawing this proposal would help avoid exacerbating health equity challenges, increasing disenrollments, and increasing beneficiary complaints, as would be the case by creating barriers to face-to-face sales

[56] National Association of Area Agencies on Aging Website: *National Association of Area Agencies on Aging Annual Report* (accessed January 2023): usaging.org
[57] National Aging and Disability Transportation Center Website: *Survey of Organizations that Provide Transportation Services to Older Adults and People with Disabilities* (accessed January 2023): nadtc.org https://www.nadtc.org/wp-content/uploads/KRC-NADTC-Survey-Report-11May2020.pdf

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interactions. Instead of prohibiting or inhibiting certain types of sales interactions, we urge CMS to instead focus on:

- **Targeting the bad actors** using its existing authority as outlined above; and,
- **Focusing on other elements such as the pre-enrollment checklist** to ensure beneficiaries receive information in key areas, irrespective of the type of sales interaction.

Length of Time an SOA or Business Reply Card (BRC) is Valid

CMS proposes to limit the validity of SOAs and BRCs to six months from the beneficiary's signature date. Elevance Health supports CMS' intent to ensure marketing stakeholders cannot use SOAs or BRCs as an *unlimited* source of a marketing lead with no end date. However, we would suggest a limitation of 11 months to ensure any preliminary conversations that take place during the year can be followed-up for the next open enrollment. For example, if an initial conversation takes place in February, and the beneficiary would like to follow-up during the next open enrollment period, the SOA/BRC should still be valid during the next open enrollment period. In those situations, limiting the SOA and BRC to six months would create unnecessary follow-up.

Recommendation: Elevance Health requests CMS modify this proposal to limit the validity of SOAs/BRCs to 11 months (instead of 6 months) to ensure SOAs and BRCs can always be valid for the next open enrollment.

Improper Use of Terms and Logos

Elevance Health supports prohibiting any marketing entities from using government terms and logos in a way that implies to consumers the entity is representing the government, or otherwise misusing government terms and logos. However, CMS' proposal is not clear enough on what would be permissible.

For example, even using the term "Medicare Advantage" could be considered an improper use of a government term. Bad actors may take advantage of such a lack of clarity, while making legitimate and beneficial activities more difficult for good actors.

Recommendation: If CMS finalizes this proposal, Elevance Health requests CMS make this provision extremely clear, with a large number of examples of what is permissible versus what

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is not permissible. Such specificity would not just help stakeholders, but also CMS' regional offices that respond to questions and perform enforcement.

Identifying the Name of the Organization/Marketing Name in Advertising

Elevance Health supports CMS' objective to ensure consumers must not be misled by marketing materials and must be able to understand what is being sold. However, we believe CMS' proposed requirement—to identify the name of the organization or marketing name of all plans being sold—would likely serve to confuse beneficiaries more than it would add value. This perspective is based upon the fact that much Medicare marketing involves selling a large number of plans and including all the names in materials would result in a "sea of names" in many instances.

Recommendation: Elevance Health recommends CMS withdraw this proposal to avoid increasing the complexity of marketing materials in a way that may provide more confusion than value to beneficiaries.

Summary of Benefits in MA Model Materials

CMS proposes that the Summary of Benefits be included in the top half of the first page and in the order currently listed in 422.2267(e)(5)(ii)(A)(1) through (10).

Recommendation: Elevance Health requests clarification on the meaning of to "…be included in the top half of the first page…." Our Summary of Benefits follows guidance for required medical benefits and order of information, so clarification and an example of what type of document this provision applies to and the requirements would be beneficial to understand the proposed guidance.

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Mental Health and Substance Use Disorders (MH/SUD)

Network Adequacy Standards for MH/SUD Providers

The U.S. is continuing to experience a dramatic increase in MH/SUD needs (described as behavioral health in proposed rule) in the wake of the COVID- 19 pandemic. During this time, Elevance Health (including our behavioral health management subsidiary, Beacon Health Options) has demonstrated a strong commitment to improving the mental health of our members and has continued to support laws and regulations to ensure equity between MH/SUD and medical benefits. As part of our efforts to listen to those on the front lines and offer our own data to help inform MH/SUD solutions, we recently released a report entitled *State of the Nation's Mental Health,*[58] which is based on an analysis of more than 27 million healthcare claims and a nationwide clinician survey. The survey concluded nearly 75% of mental health specialists estimate mental health repercussions from the pandemic will last three years or more.

This persistent increase in demand has outpaced the supply of MH/SUD professionals.[59] The GAO's October 2022 report[60] on MH/SUD workforce included the following conclusions:

- Approximately half of counties in the U.S. did not have an active psychiatrist or addiction medicine specialist;
- More than 150 million people live in federally designated mental health professional shortage areas; and,
- In the near future, the U.S. will be short between 14,280 and 31,109 mental health providers.

A November 2022 report from the American Psychological Association[61] reinforces the fact that demand for MH/SUD services exceeds the supply of MH/SUD professionals. Nearly half of 2,300 psychologists surveyed said they were unable to meet demand for treatment, while 60% have no more openings for new patients, and 42% have waitlists of at least 10 patients. To

[58] *Anthem's (now Elevance Health) State of the Nation's Mental Health*. May 2021. https://www.stateofthenationsmentalhealth.com
[59] https://www.modernhealthcare.com/labor/aamc-primary-care-mental-health-physician-shirtage-backlogs?utm_source=modern-healthcare-am-wednesday&utm_medium=email&utm_campaign=20230117&utm_content=article1-headline
[60] *Behavioral Health: Available Workforce Information and Federal Actions to Help Recruit and Retain Providers.* Government Accountability Office. October 21, 2022. https://www.gao.gov/products/gao-23-105250
[61] Psychologists Struggle to Meet Demand Amid Mental Health Crisis. American Psychological Association. November 2022. Available at https://www.apa.org/pubs/reports/practitioner/2022-covid-psychologist-workload.pdf

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address this increase in demand for MH/SUD services amid a workforce shortage, Elevance Health has implemented several initiatives to best address the needs of beneficiaries, including utilizing peer support specialists (individuals with lived experience of MH/SUD conditions) and providing expanded telehealth options.

Congress began working to address the shortage of MH/SUD professionals in the Consolidated Appropriations Act, 2023 (CAA; also known as the 2023 Omnibus Appropriation bill) signed into law on December 29, 2022. The bill provides a meaningful expansion of access for Medicare beneficiaries by adding coverage for intensive outpatient mental health programs and care provided by marriage and family therapists and mental health counselors. It also increases reimbursement provided via mobile crisis care units and funds additional graduate medical education training positions, half of which must be reserved for psychiatry specialties.

Despite these efforts, a major challenge for all stakeholders is—foundationally—there are currently not enough MH/SUD providers in the U.S. As an alternative, Elevance Health supports policymaker efforts to increase the supply of MH/SUD providers over time to better meet increasing demand. This includes:

- Allowing peer support specialists to be eligible for Medicare reimbursement;
- Expanding the types of services and providers eligible to receive federal/state funds. For example, payment of asynchronous care, coaching, texting, and wellness services should be evaluated;
- Examining scope of practice/physician oversight/supervision rules to increase access to a broad array of providers and services and to further support opportunities for providers to practice at the top of their level of licensure;
- Increasing funding for graduate medical education programs specifically designated for MH/SUD providers; and,
- Working with CMS and other stakeholders to develop a comprehensive strategy to address the shortfall of MH/SUD providers.

Addition of Specialty Types Subject to Network Adequacy: MOUD

CMS proposes to add three MH/SUD specialty types to network adequacy regulation, clinical psychology, clinical social work, and prescribers of Medications of Opioid Use Disorder (MOUD). As outlined above, Elevance Health supports CMS' efforts to maximize beneficiary access to MH/SUD providers, including prescribers of MOUD. The prescribing of MOUD is an area that is quickly evolving, particularly with the recent enactment of Section 1262 of the 2023

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CAA, which removed the federal requirement for practitioners to submit a Notice of Intent (that is, have a waiver commonly referred to as an "X-Waiver") to prescribe medications, like buprenorphine, for the treatment of opioid use disorder.

Given that all licensed practitioners can now prescribe MOUD, it is incongruous to have a specific network adequacy test for MOUD prescribers. The network adequacy test could essentially be attached to all licensed prescribers.

Recommendation: Elevance Health recommends CMS withdraw the proposal to add prescribers of MOUD as a specialty type to network adequacy requirements, as it is incongruous with the 2023 CAA, and the expansion of MOUD prescribers. CMS should allow the impact of the CAA to take effect before considering additional regulation related to MOUD.

Appointment Wait Time Standards

CMS proposes to codify primary care appointment wait time standards from existing sub-regulatory guidance and to extend those standards to MH/SUD services. While Elevance Health supports CMS' efforts to ensure beneficiaries do not have a significant wait for key services, there are many variables that make it challenging to precisely track and adhere to wait times. CMS does not have a reasonable and efficient framework for assessing appointment availability, and existing audits do not generate objective, consistent outcomes that would generate proof of compliance. This lack of a workable framework—amid the national shortage of MH/SUD providers described above—creates substantial uncertainty for health plans, exacerbating the likelihood that health plans could curtail offerings and consumer choice.

Health plans also need time to collaborate with providers to develop a reporting system that allows health plans to collect appointment wait time data. FHIR is the industry interoperability standard that allows health data, including clinical and administrative data, to be quickly and efficiently exchanged between entities. Currently, appointment scheduling information cannot be included in the FHIR record. Any attempt to implement new appointment wait time standards without a reporting system that is workable for both health plans and providers, including modifications to the FHIR standard so that appointment scheduling information can be included in the FHIR record, would lead to significant provider abrasion, discouraging provider participation in plan networks.

Recommendation: Because of these challenges and negative implications for beneficiaries, we recommend CMS:

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- **Add flexibility to any new MH/SUD network adequacy standards**: We recommend CMS provide flexibility for any additional network adequacy justifications that would account for the fact that these standards would be new and implemented during a MH/SUD provider shortage.
- **Reconsider stringent wait time standards**: Wait times cannot be perfectly measured and are enforced using audits that do not generate perfect, objective results. Given the MH/SUD provider shortage, such audits would generate inconsistent results and needlessly increase administrative costs that would be passed on to beneficiaries. Instead, we encourage CMS to reconsider the wait time standards and work with stakeholders on accurately measuring and implementing such standards with appropriate flexibilities to avoid provider abrasion that could discourage participation with MA plans.
- **Help address the MH/SUD provider shortfall**: We request CMS work collaboratively with stakeholders to develop a comprehensive strategy to address the shortfall of MH/SUD providers.

If CMS is intent on moving forward with new wait time standards, we request CMS delay the implementation of such standards until FHIR standards can be updated to help create a more efficient and effective way of demonstrating compliance.

Provider Contract Termination Notification Requirements (Non-MH/SUD and Primary Care)

For provider terminations that are not MH/SUD or primary care, CMS proposes to split beneficiary notification requirements based on two types of provider terminations. For provider terminations with cause, CMS proposes to maintain its "good faith effort" standard for timely notification to beneficiaries. For provider terminations without cause, CMS proposes to remove its "good faith effort" standard since the timeline for notification should be within health plan control to provide notice.

Elevance Health is aligned with CMS' goal to ensure beneficiaries are notified expeditiously when it is clear that a provider is leaving the network, and we support the general concept of this proposed requirement. However, as it relates to provider terminations without cause, it is common that the provider is the party that is initiating the termination, and we do not always receive sufficient notice from the provider to meet CMS' timeframes for beneficiary notification. If this provision were to go into effect, CMS' auditors would find cases where a health plan does not meet the notification timeframes because of untimely notification from providers—not an action from the health plan itself—resulting in administrative confusion

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and unreasonable increased administrative costs that would be passed on to beneficiaries in the form of higher premiums and/or reduced benefits.

Recommendation: Elevance Health requests CMS modify its proposal such that the "good faith" standard remains in effect if the provider (instead of the health plan) is the party terminating the contract. This would avoid administrative confusion with CMS' auditors that would lead to unreasonable administrative costs that would be passed on to beneficiaries in the form of higher premiums and/or reduced benefits.

Provider Contract Termination (MH/SUD and Primary Care): Extending Notification Irrespective of When a Beneficiary Last Saw the Provider

For MH/SUD and primary care providers, CMS proposes to expand the scope of notification requirements to ALL beneficiaries who have ever been patients of a terminating primary care provider (not just those who are patients seen on a regular basis by the terminating provider, which is the notice applicability for all other specialty types).

Elevance Health supports CMS' objective to ensure beneficiaries receive timely notices of contract terminations for all providers for which beneficiaries have a relatively recent—and therefore potentially ongoing—relationship. It is important that beneficiaries know when a provider with which they have an ongoing relationship is leaving the network so that they can make any adjustments to meet their needs.

Because beneficiaries already receive a significant number of notices from their health plan, it is important to consider whether any new notification requirements are important relative to existing requirements because any additional notifications will dilute the impact of all notices, making the beneficiary less likely to pay attention to important notices. Requiring health plans to notify beneficiaries about providers leaving the network they saw in the past—with an unlimited lookback—would cause abrasion and dilute the impact of important notices. For example, if a beneficiary receives a notice about a provider they have not seen in many years and do not have any plans to see that provider in the future, they will not find value in that notice, and may begin to assume that future notifications do not have value.

Additionally, while CMS asserts in this proposed regulation that MH/SUD and primary care providers are especially critical in terms of relationships with the beneficiary and should be

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treated more intensely from a notification perspective, the same could be asserted for other provider types that are particularly important to each beneficiary.

Recommendation: Elevance Health recommends CMS withdraw this proposal and leave in place existing regulatory requirements that require health plans to notify beneficiaries who are patients seen on a regular basis by the terminating provider. Withdrawing this proposal will avoid beneficiary confusion and abrasion.

Provider Contract Termination (MH/SUD and Primary Care): Requiring Telephonic Notification

CMS also proposes to require both written and telephonic notice for contract terminations that involve a primary care or MH/SUD provider (instead of just written notice). Elevance Health supports CMS' efforts to ensure beneficiaries receive timely notices of contract terminations for all providers for which beneficiaries have a relatively recent—and therefore likely ongoing—relationship. However, we do not believe telephonic outreach would help reach this goal.

Our Medicare MH/SUD case managers who perform telephonic outreach only successfully talk with the beneficiary 36% of the time, largely due to beneficiaries not wanting to receive phone calls.

As stated above, health plans are already required to notify beneficiaries by mail who are patients seen on a regular basis by the terminating provider. We believe this is the appropriate standard and would be the preference of beneficiaries for this specific circumstance.

Recommendation: Elevance Health recommends CMS withdraw this proposal and leave in place existing regulatory requirements that require health plans to notify beneficiaries by mail. Withdrawing this proposal will avoid beneficiary confusion and support clear communication.

Additional Provider Directory Elements for Providers Offering MOUD

CMS proposes to add a new provider directory data element showing certain providers who offer MOUD. Elevance Health supports CMS' efforts to ensure beneficiaries can access—and

Elizabeth P. Hall, Vice President, Public Policy and Issues Management
1001 Pennsylvania Avenue, NW, Suite 710, Washington, DC 20004

easily identify—providers offering MOUD. As stated above, this is an area that is quickly evolving, particularly with the recent enactment of the 2023 CAA, which removed the federal requirement for practitioners to submit a Notice of Intent (that is, have a waiver commonly referred to as an "X-Waiver") to prescribe medications, like buprenorphine, for the treatment of opioid use disorder.

As all licensed practitioners can now prescribe MOUD, there is no longer a need to have a data element in provider directories showing which providers offer MOUD. Such a data element could potentially be attached to all relevant practitioners, removing any value from adding the element.

Given that any provider can now prescribe MOUD, the source of truth for this data is in question, and we do not yet have the ability to validate the accuracy of this data. Therefore, we encourage CMS to withdraw this proposal until data can be appropriately gathered and accurately validated.

Recommendation: Elevance Health recommends CMS withdraw this proposal, as it is no longer necessary due to the enactment of the 2023 CAA.

Requiring Non-Renewal Notices as Standard Communication Material

CMS proposes that the non-renewal notice be a model communications material. Model materials are required content created by CMS as an example of how to convey beneficiary information.

Recommendation: Elevance Health supports this proposed change, but we request CMS clarify how it intends to provide "equal prominence" to all healthcare choices within the Non-Renewal and Service Area Reduction (NR/SAR) notice prior to the model release. The NR/SAR model notices are generally released close to the required in-home date, and we have concerns about the timeline should there be changes to how alternative healthcare options are required to be displayed.

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Opt-Outs for Plan Marketing

CMS proposes to require each MA organization and Part D plan sponsor to provide the opt-out information to all beneficiaries, regardless of plan intention to contact, at least annually in writing.

Recommendation: Elevance Health supports this proposed change, but we urge CMS to allow for the addition of the opt-out information in a standard model material. While CMS suggests that the opt-out can be included in the welcome packet, that packet is not provided to all beneficiaries annually. A separate mailer would need to be provided to beneficiaries unless CMS allows health plans to include the opt-out language as part of its model material. This approach would help limit administrative costs, which would otherwise be passed on to beneficiaries, and environmental waste.

***

We value the partnership that we have developed with CMS and welcome the opportunity to discuss our recommendations. Should you have any questions or wish to discuss our comments further, please contact Danielle Horne at (818) 298-7830 or danielle.horne@elevancehealth.com.

Sincerely,



Elizabeth P. Hall
Vice President, Public Policy and Issues Management, Elevance Health

Elizabeth P. Hall, Vice President, Public Policy and Issues Management
1001 Pennsylvania Avenue, NW, Suite 710, Washington, DC 20004

Appendix I: Part C and D Star Ratings Tukey Outlier Deletion Simulations

Upon reviewing the simulations provided by CMS, we have several observations which raise concerns about the applicability of the Tukey Outlier Deletion to the Star Ratings methodology.

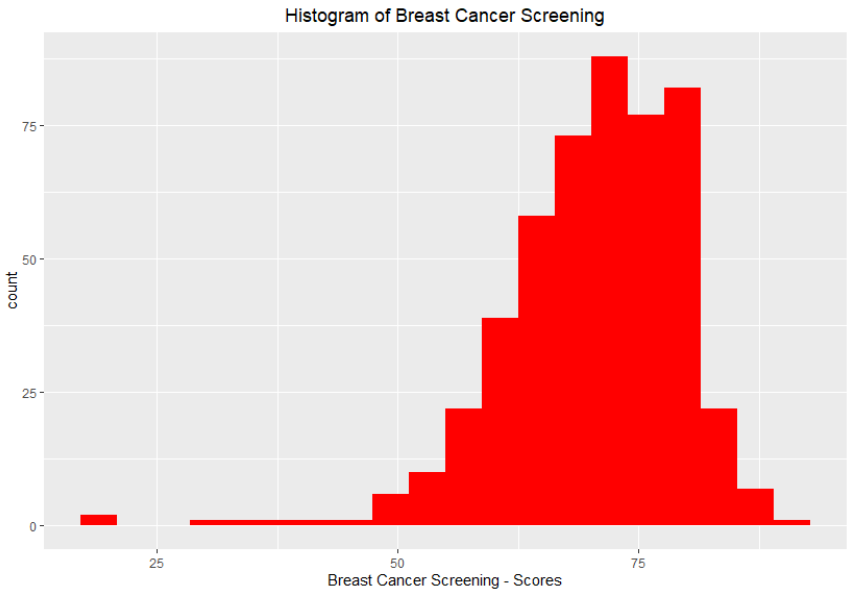
1. There were multiple instances where the lower outlier cutoff is 0 and or the upper outlier cutoff is 100.
   a. As described within the Technical Notes document, "If the calculated outlier cutoff is below the minimum or exceeds the maximum value for the given measure, then the minimum or maximum value is displayed as the cutoff." Interpreting this method with a hypothetical example, in a set of values for a given measure that range from 14 to 92, if the lower outlier cutoff is 10, then the cutoff to be used would be 14, or if the upper cutoff is 95, then the cutoff to use would be 92.
   b. We have revised the 2022 and 2023 Report Card Master Table for actual measure score results, along with Tukey Outlier simulations. An exercise was completed trying to come up with an approximation for the Breast Cancer Screening measure for Star Rating year 2023. Using the statistical description to obtain the quartiles and other parameters, the upper fence that we obtain with the data available is 90, which is the highest value obtained in 2023. However, the Upper Outlier Cutoff defined by CMS for this measure in 2023 is 100. Even if calculation differences were resulting from the mean resampling, there are no values above 90 in the data set that justify the upper cutoff of 100. This is equivalent to determining that there are no outliers, which calls the current methodology into question.

From the summary statistics, we can calculate the median, first quartile (25th percentile), third quartile (75th percentile), upper and lower whiskers also known as inner and outer Tukey fences.

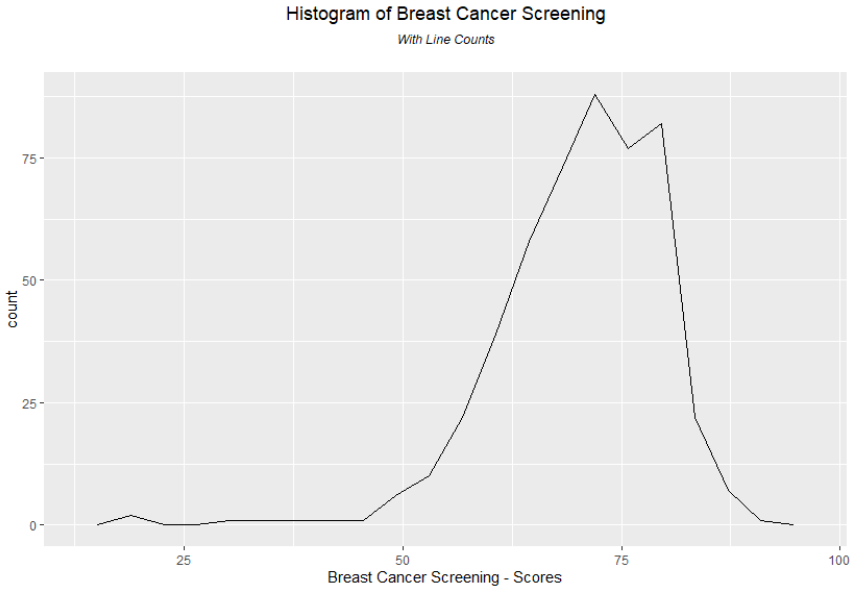
```
> summary (BCS_2023)
Breast Cancer
Min. : 18.00
1st Qu.: 66.00
Median : 72.00
Mean : 70.39
3rd Qu.: 77.00
Max. : 90.00
```

From the output, we see the minimum score is 18%, while the maximum performance execution is 90%. Therefore, the range between max - min is 72. This may suggest variability.

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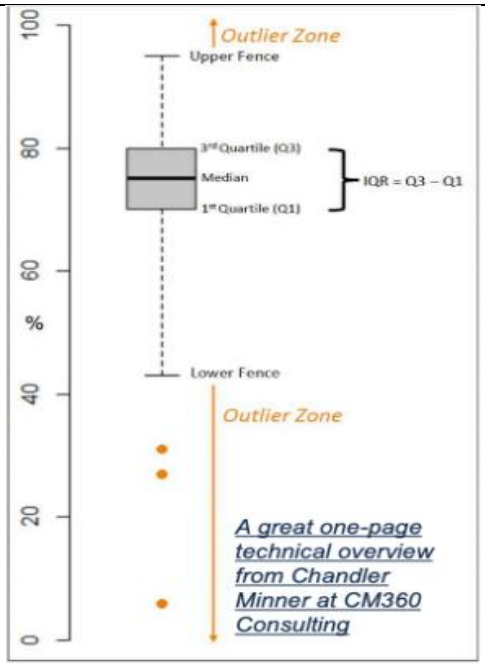


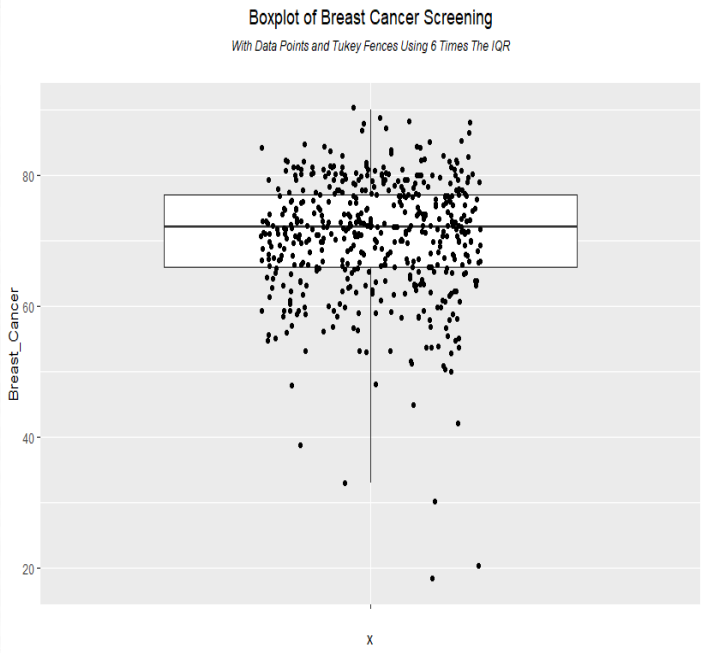
Most of the values are on the right side of the histogram, with fewer values spread along the left tail. In addition, the plot reveals the presence of outliers in the lower left side of the plot.



The breast cancer measure scores are negatively skewed. In a negative skew, the left tail is longer, with observations stretching and spreading along the tail. Similarly, data points are clustered on the right side, proving the asymmetric distribution of the values of the variable. The mean and the median occur at different points, though the difference is small.

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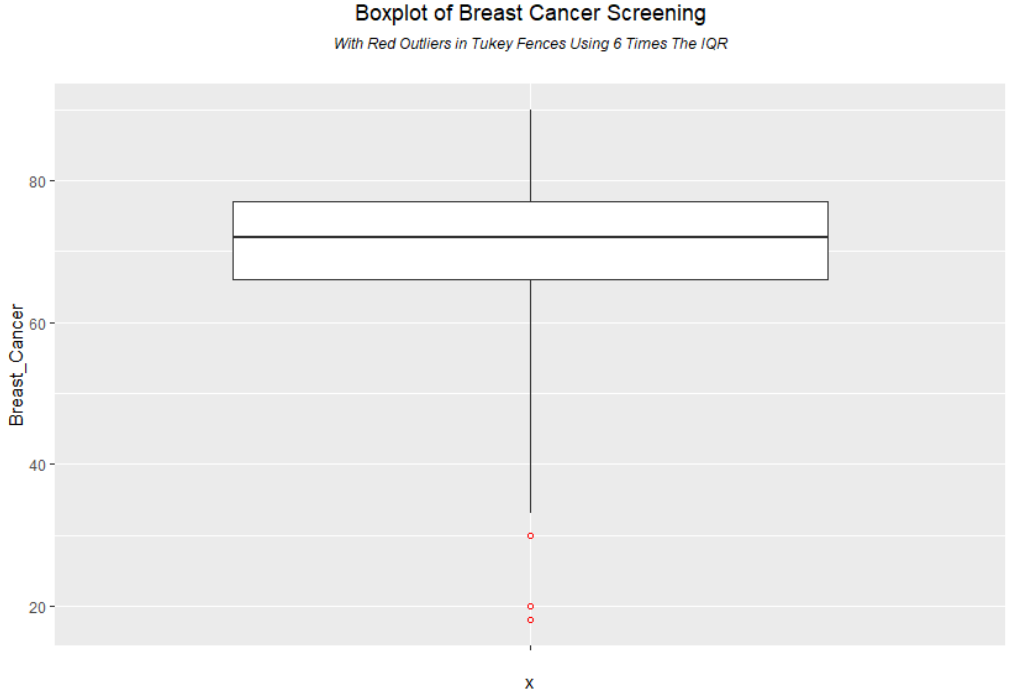


Technical Notes for Star Ratings Tukey Outlier Deletion Simulations:

*"These simulations include identification of Tukey outer fence outliers which are defined as measure scores that are below a certain point (first quartile–**3.0** × (third quartile–first quartile)) or above a certain point (third quartile + **3.0** × (third quartile–first quartile))."*

"If the calculated outlier cutoff is below the minimum or exceeds the maximum value for the given measure, then the minimum or maximum value is displayed as the cutoff."

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CalculatedLowerInnerFence = 66- 3*(77-66) = 33 > minimum score (18) , then cutoff = 33
CalculatedUpperInnerFence = 77+3* (77-66) = 110 > maximum value (90), then cutoff = 90

In the results, the output displays 3 values that are below the lower Tukey fence. These are values below 33%.

c. From the histogram above, we can also conclude that for this measure, there is a negative skew on these scores which results in a distribution far from normal, not indicated for use in the Tukey Outlier Deletion process.

d. One other example to review is the Osteoporosis Management in Women Who Had a Fracture measure, with a range of values for 2023 between 14 and 92, with a cutoff of 0 and 100. There are several instances where the lower outlier cutoff is lower than the minimum value observed, such as Reducing the Risk of Falling, Improving Bladder Control, and Medication Reconciliation Post Discharge.

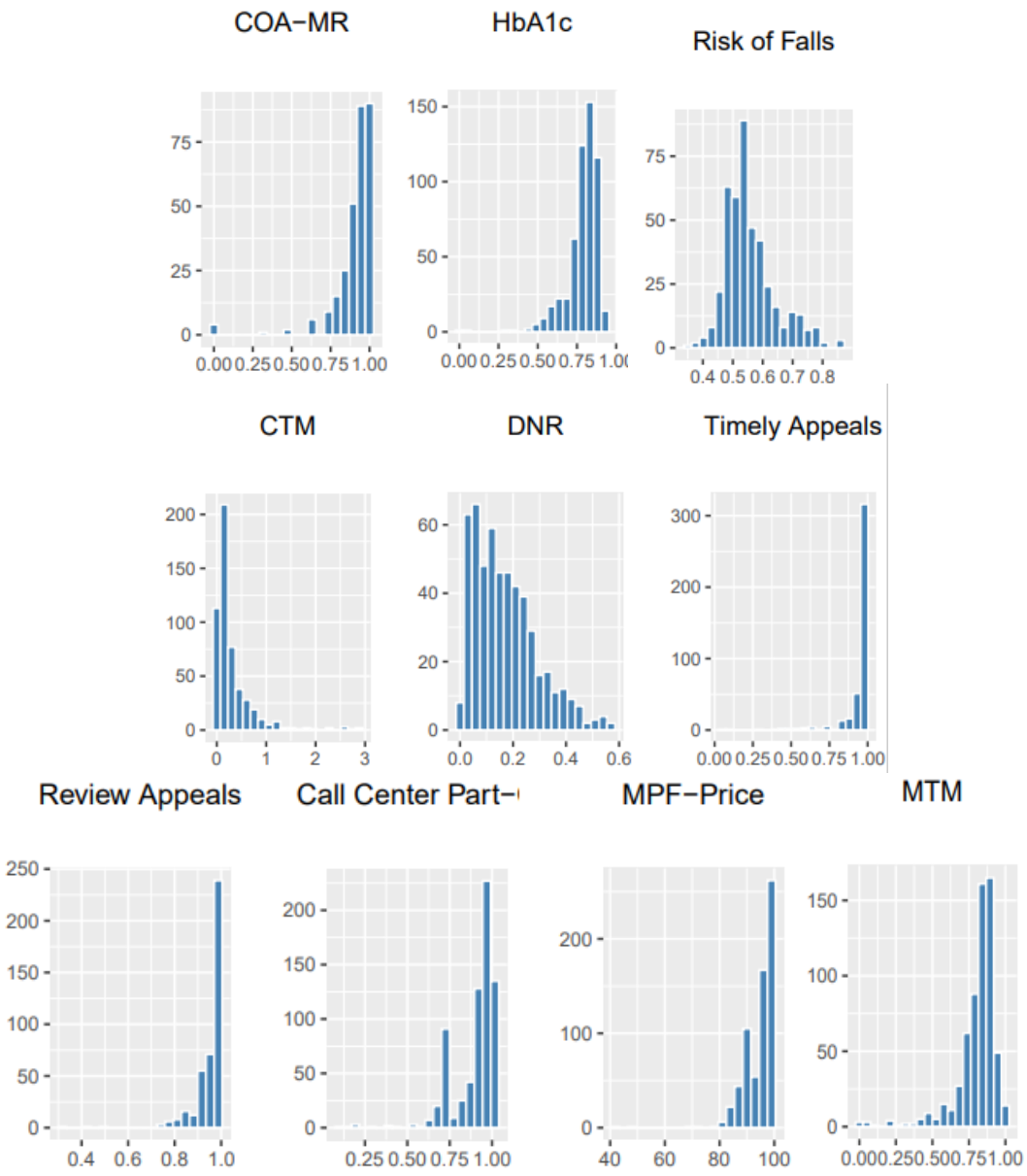
2. We are concerned about significantly different cut points once the Tukey outlier deletion is applied, with several measures experiencing differences greater than 5 percentage points, which from a guardrail perspective was identified as a reasonable difference cap year-over-year. In some circumstances, differences are up to 30 percentage points such as the case of Care for the Older Adult – Medication Review measure. This is an impactful change that would be administered on a single year. We have simulated what would have been the actual distribution of contracts per rating level for Star Ratings Year 2023 had the simulated cut points been utilized; they would depart from the public Part C and Part D performance data showing the scores of each contract at the individual measure level. We have reinterpreted Star Ratings based upon the simulated cut-points resulting in only 5% of enrollees among MA-PD contracts in 5-Star plans as opposed to the reported

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21.87%. A significant shift was also observed in the volume of enrollees in 3.5-Star contracts moving from 18.71% to a simulated 25.4%.

3. HOS measures, however, tend to remain unchanged, and differences for PDP only cut points seem to be stable, likely because of a lower set of scores being evaluated, which calls into question the purpose of the methodology.
4. This is the first-time contracts are given the opportunity to fully explore the impact of this method in the calculation of cut points, and such simulations are based upon measurement years 2020 and 2021, for which Extreme and Uncontrollable circumstances were in place, which have potentially impacted the analysis.
5. Contracts do not have a way to properly review cutoffs or cut points because not all contracts' scores considered are public (that is, rescinded contracts).
6. The methodology does not consider the size of outliers, particularly on the upper cutoff, where smaller contracts may be better positioned to achieve better performance.
7. Many of the measures under the Star Rating methodology do not follow a normal distribution pattern as shown in the histograms below, based on Star Ratings Year 2023 scores:

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COA−MR
HbA1c
Risk of Falls
CTM
DNR
Timely Appeals
Review Appeals
Call Center Part−
MPF−Price
MTM

As of: March 04, 2024
Received: February 13, 2023
Status: Posted
Posted: February 17, 2023
Category: Physician - HC005
Tracking No. le3-by3h-xoqd
Comments Due: February 13, 2023
Submission Type: API

PUBLIC SUBMISSION

Docket: CMS-2022-0191
Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024

Comment On: CMS-2022-0191-0001
Medicare Program: Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, etc.

Document: CMS-2022-0191-0743
Comment on CMS-2022-0191-0001

Submitter Information

Email: lsola@villagemd.com
Organization: VillageMD

General Comment

Please see attached document for comment.

Attachments

VillageMD Part CD Response_20230213_FINAL

VillageMD

February 13, 2023

Chiquita Brooks-LaSure
Administrator
Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: Medicare Advantage RFI
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicare Program; Contract Year 2024 Policy and Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Program for All-Inclusive Care for the Elderly; Health Information Standards and Implementation Specifications

Dear Administrator Brooks-LaSure,

Thank you for the opportunity to assist the Center for Medicare & Medicaid Services in strengthening Medicare Advantage.

About VillageMD
VillageMD was founded with a bold principle: changing primary care in the United States so that our country can be the global leader in health outcomes regardless of background and income. Through its subsidiary Village Medical, VillageMD is a leading provider of value-based primary care services. Village Medical provides primary care for patients at traditional free-standing practices, Village Medical at Walgreens practices, at home and via virtual visits. The VillageMD clinical model spans the spectrum of care, from disease prevention through timely interventions such as immunizations and lifestyle modification, to managing and treating disease conditions. We achieve this by working within the "medical neighborhood," building effective partnerships for all levels of care.

A commitment to health equity underlies VillageMD's organization and clinical model. VillageMD operates in 26 markets with 680 locations. Over the next five to ten years, Village Medical and Walgreens will establish 1,000 Village Medical at Walgreens primary care practices in more than 30 U.S. markets, more than half in which will be in medically underserved communities. These clinics will be deeply embedded in the communities they serve: they will provide care to those living within the community, hire care team members that are reflective of their community, and create healthcare jobs with upward mobility. In addition, locating Village Medical at Walgreens allows for primary care physicians and pharmacists to collaborate to create a more coordinated care approach and integrated patient experience. VillageMD currently contracts across all payer types, including Medicare Advantage, Traditional Medicare, commercial and Medicaid. With that in mind, we offer the following comments in regard to the quality components released in the Medicare Advantage program from Calendar Year 2024.

1. **Medication Reconciliation Post-Discharge:** Following NCQA's retirement of the medication reconciliation post discharge measure, CMS announced that medication reconciliation would roll

into the transitional care management measure. VillageMD applauds the administration for ensuring patients are receiving the care they need across the continuum of care, especially following a discharge from the hospital. However, we were anticipating that the measure would be phased out following the 2022 calendar year, but CMS just announced that it will be continuing through the end of calendar year 2023**.** *VillageMD urges the administration to retire the measure after calendar year 2022 to avoid double-weighing the impact transitional care management will have on quality performance.* This will make the implementation and removal process for the medication reconciliation measures less smooth.

2. **Medication Adherence Measures:** CMS has proposed to implement risk adjustment based on the PQA specifications of SDS characteristics (for age, gender, dual eligibility/LIS, and disability status), which would also be reflected in Star Ratings; further CMS would remove the medication adherence measures from the CAI adjustment. VillageMD appreciates CMS' work to ensure beneficiaries are adhering to their medication to optimize their clinical outcomes. We would appreciate additional clarification around the proposals because it was expected to have a more neutral impact but has been found to have a larger net negative impact than a net positive impact. *VillageMD recommends that CMS explore what is causing this and adjust the measures based on your findings.*
3. **Concurrent Use of Opioids and Benzodiazepines:** CMS has proposed a new measure to prevent drug-drug interactions that could be fatal, specifically the prescribing of both an opioid and benzodiazepine. VillageMD wholeheartedly supports the intention to measure polypharmacy issues, however, we have concerns that this measure would not measure fairly across geographic areas due to the regional variation in opioid usage across the USA. *We urge CMS to incorporate a regional adjustment to account for the well-documented*[1] *regional trends of opioid usage in the USA.*
4. **Cut Points:** CMS has proposed to eliminate the 5% guardrails on the cut point calculation starting in 2024. *VillageMD is supportive of the elimination of the guardrails, however, we recommend that it is phased out over 3 years to minimize the impact it has on STAR ratings during the initial year of guardrail elimination.* In the Tukey Outlier Simulation Output for Contract results shared by CMS in December 2022, we noted several instances of very large cut point adjustments (in excess of 15%), which suggests a three-year guardrail elimination timeline would allow for a more seamless implementation of the Tukey Outlier methodology.
5. **Health Equity Index Reward Program:** VillageMD is deeply supportive of incorporating health equity into the Medicare program as much as possible. We applaud CMS' continual focus on making health equity a reality in the US healthcare system. The Area Deprivation Index is a great start for measuring health disparities, however, there are shortcomings in the indexing that create a misrepresentation of underserved status, specifically in urban areas with higher home values. Due to this issue, VillageMD recommends that CMS continue to monitor different indices that measure socioeconomic status and adopt them if they are found to be a more accurate measure.

Thank you again for your commitment to strengthening our nation's Medicare system, and for thoughtful consideration of the issues and potential solutions we have raised. VillageMD is happy to be

[1] https://collections.nlm.nih.gov/catalog/nlm:nlmuid-101751557-pdf?_gl=1*1306m60*_ga*MTYzMzY0NTA2My4xNjc2MDU2NTU4*_ga_P1FPTH9PL4*MTY3NjA1NjU5MC4xLjEuMTY3NjA1NjYyMi4wLjAuMA..*_ga_7147EPK006*MTY3NjA1NjU5MC4xLjEuMTY3NjA1NjYyMi4wLjAuMA..

a resource for CMS as you further develop the Medicare program. If you have any questions or would like to set up a discussion, please reach out to Lucy Sola at LSola@VillageMD.com.

Sincerely,



Gary Jacobs, Executive Director of VillageMD Center for Government Relations and Public Policy
VillageMD

As of: March 04, 2024
Received: February 13, 2023
Status: Posted
Posted: February 17, 2023
Category: Health Plan or Association
Tracking No. le3-c1r1-fszz
Comments Due: February 13, 2023
Submission Type: API

PUBLIC SUBMISSION

Docket: CMS-2022-0191
Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024

Comment On: CMS-2022-0191-0001
Medicare Program: Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, etc.

Document: CMS-2022-0191-0750
Comment on CMS-2022-0191-0001

Submitter Information

Email: Jennifer.DeAngelis@blueshieldca.com
Organization: Blue Shield of California

General Comment

Attached please find Blue Shield of California's comment letter in response to the CY 2024 Medicare Advantage and Prescription Drug Benefit Program Policy and Technical Changes Proposed Rule (CMS-4201-P). If you have any questions, please contact Jennifer DeAngelis at Jennifer.DeAngelis@blueshieldca.com.

Attachments

Blue Shield of California_2024 MA Part D Policy PR Comment Letter FINAL

blue of california

February 13, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS–4201–P
7500 Security Boulevard
Baltimore, MD 21244

Submitted electronically via http://www.regulations.gov

RE: CMS-4201-P; Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications

Dear Administrator Brooks-LaSure:

Blue Shield of California (Blue Shield) appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services's (CMS) Contract Year (CY) 2024 Policy and Technical Changes Proposed Rule. Blue Shield is a nonprofit health plan that offers health benefits coverage to individuals and groups throughout the State of California. Our mission is to ensure that all Californians have access to high-quality health care at an affordable price. Blue Shield is the parent organization of Blue Shield of California Promise Health Plan, and as such is providing comments on behalf of both organizations.

The CY 2024 Policy and Technical Changes Proposed Rule (CMS-4201-P) includes several proposals that would require extensive plan resources to implement. These proposals would layer on top of significant program changes that were finalized in prior CMS rulemaking and enacted in the Inflation Reduction Act, including the restructuring of the Part D benefit, as well as proposals in the CY 2024 Advance Notice that would revise the Part C risk adjustment model and other rulemaking, like the Advancing Interoperability and Improving Prior Authorization Proposed Rule (CMS-0057-P), that would impact the Medicare Advantage (MA) program.

As CMS assesses stakeholder comments and makes decisions about finalizing proposals in this rule, we strongly encourage CMS to consider the totality of the near-term changes facing MA plans and Part D sponsors and the administrative burden and costs associated with those changes. We request CMS finalize policies in a practical and sustainable manner that provides MA plans sufficient time to plan, garner resources for implementation, and ensure Medicare beneficiaries continue to receive high-quality care.

To that end, we request CMS consider the following priority recommendations:

- **Changes to the Part D Medication Therapy Management (MTM) Program**: We encourage CMS *not* to proceed with the proposed changes to the MTM Program's eligibility criteria due to cost impacts and implementation challenges.

- **Changes to marketing rules:** We request CMS delay the effective date for the proposed changes to marketing rules until 2025 to provide sufficient time for CMS to release – and plans to digest – the sub-regulatory guidance needed to successfully implement these new requirements.

- **Adoption of a Real-Time Prescription Benefit standard**: We urge CMS to specify in the Final Rule that adoption of the NCPDP Real-Time Prescription Benefit standard should not impede conformance to the industry standard of sending 4 drugs or 4 pharmacies for pricing in a single transaction.

- **Use of the Health Equity Index (HEI) Reward for Star Ratings:** We encourage CMS *not* to proceed with the HEI Reward for Star Ratings which would unfairly disadvantage contracts operating in States that are implementing DSNP-only contracts. We also encourage CMS to retain the current Star Ratings Reward Factor.

Additionally, in alignment with America's Health Insurance Plans and the Blue Cross Blue Shield Association, we urge CMS to delay the effective date of any finalized utilization management requirements to 2026. A 2026 effective date would provide plans time to fully assess changes to existing program requirements, reflect these changes in their bids, and modify contracts where necessary. Additionally, this timing would better align with the effective date for the proposed application programming interface requirements related to prior authorization in CMS's Advancing Interoperability and Improving Prior Authorization Proposed Rule.

Our detailed comments follow.

III. Enhancements to Medicare Advantage and Medicare Prescription Drug Benefit Programs

A. Health Equity in Medicare Advantage

Blue Shield supports the intent of the health equity proposals CMS describes at the beginning of the Proposed Rule, but we have concerns with the feasibility of CMS's proposals. On the new data elements for MA provider directories, we are concerned that compliance would be difficult for plans without additional federal or state requirements that create incentives for providers to submit timely and accurate information. If CMS wants to improve the content in provider directories, we encourage the agency to consider new policies aimed toward providers updating their data on a timely basis, and further support CMS pursuing a national provider directory from which plans could pull these data elements.

Blue Shield also has concerns about CMS's proposal to address digital literacy to support beneficiaries' use of telehealth services. It is unclear how plans would be expected to screen for and provide training to members for these needs. To scale this type of educational programming – particularly under a tight compliance deadline – it would have to be offered digitally, which likely is not the most effective mode of outreach for a population that faces challenges using telehealth, often including limited access to the Internet. We think this type of service would be more successful if delivered by community resources such as libraries that can provide in-person support.

Finally, regarding quality improvement activities to address health disparities, Blue Shield has been implementing quality improvement activities that address disparities in health and health care among enrollees for several years. For example, in 2022, we launched a bilingual inbound customer service team that provides in-language support without the use of a translator in 6 non-English languages. While we support the intent of this proposal, we do not feel it is necessary as plans have already widely adopted quality improvement activities that address health disparities.

O. Updating Translation Standards for Required Materials and Content

Blue Shield supports CMS's goal of providing accessible materials to member populations that are non-English language speakers or need auxiliary aids or services, but this proposal would be burdensome, expensive, and operationally challenging to implement, particularly by CY 2024. We expect the increased staff training that would be needed to comply with this proposal would jeopardize the availability and quality of customer service during the Annual Enrollment Period. Given the complexity of the proposal, we strongly encourage CMS to delay the proposed compliance deadline to CY 2025.

We also have concerns about the tight timeliness standards CMS proposes for translation services. We encourage CMS to amend its proposal and provide additional time or flexibility for plans to translate materials that include non-standardized language, such as correspondence for appeals and grievances and utilization management. These types of documents are difficult to translate and sufficient time should be provided to ensure accurate translation services.

P. Medicare Advantage and Part D Marketing

Blue Shield supports CMS's goals of protecting beneficiaries from misleading advertising and marketing practices. However, we are concerned that (1) these proposals would create barriers for beneficiaries getting the information they need to make informed decision about their coverage options; and (2) compliance with the multitude of new requirements that CMS has proposed would be extremely difficult to achieve for CY 2024. In addition to these concerns, we have the clarifying questions detailed below.

- CMS proposes several changes to marketing rules intended to separate educational events from marketing events. We request clarification from CMS on whether or not under these proposals an agent would be permitted to discuss a product or benefit that is different than what is specified by the Scope of Appointment and Business Reply Card if the beneficiary initiates the discussion to learn about a different product or benefit.

- CMS is proposing to prohibit MA organizations and Part D sponsors from marketing "savings" that are based on a comparison of typical expenses borne by uninsured individuals, unpaid costs of dual eligible beneficiaries, or other unrealized costs of a Medicare beneficiary. We request clarification or further guidance from CMS on whether or not marketing premium savings that a beneficiary may realize by switching from a commercial PPO plan at age 65 to a $0-premium MA plan would be allowed under this proposal.

In addition, CMS proposes prohibiting the use of the Medicare name, CMS logo, or official products, including the Medicare card, in a misleading manner. If this proposal is finalized, we would encourage CMS to provide additional guidance – with examples – on what it means to use the image of the Medicare card in a "misleading manner" in marketing materials.

R. Part D Medication Therapy Management (MTM) Program

Blue Shield appreciates CMS's interest in maximizing the benefits of the MTM Program and ensuring Medicare beneficiaries receive a Comprehensive Medication Review (CMR). However, we have significant concerns that the proposed expansion would overwhelm industry resources, significantly increase program costs, and ultimately create an impossible bar for plans to meet.

- Using CMS's estimate that 55 percent of beneficiaries would become eligible for the MTM Program under the proposed criteria, we estimate that Blue Shield's program membership would grow by approximately 400 percent. This would dramatically increase the costs of the MTM program, which are part of MA plans' bid costs, and result in a loss of rebate dollars that would otherwise be used to improve affordability or provide supplemental benefits that support members' well-being.

- Additionally, such a sudden increase in membership would be challenging to absorb given pharmacist shortages across the United States.[1] In recent years, pharmacists' scope of practice has expanded and responsibility for managing patients' care has grown while open positions have gone unfilled due to staff shortages.[2] We believe the dramatic expansion of MTM programs as proposed by CMS would exacerbate this workforce shortage and not be sustainable – there are simply not enough pharmacists in the United States to support MTM programs of the proposed size operating in all plans.

- Blue Shield also has concern that expanding the MTM Program would create duplication with other programs and services that beneficiaries with chronic conditions already access, like case management and annual wellness visits. Overlap between these services and the MTM Program not only would create redundant care management efforts but could result in beneficiary confusion.

- Finally, we oppose the addition of cancer and HIV/AIDS to the MTM Program's core condition list. Beneficiaries with these conditions receive specialty care and use specialty pharmacies, which provide regular CMRs and extensive counseling regarding their medication regimen.

To mitigate these concerns, we urge CMS not to move forward with its proposed changes. However, if CMS chooses to finalize this proposal, we strongly encourage the agency to phase in the eligibility expansion over time and incorporate the following changes to its proposals:

- Rather than requiring Part D sponsors to include *all* Part D maintenance drugs, adjust the maximum number of maintenance drugs from 8 to 6.

- Provide more year-to-year consistency in the cost criteria. For example, we recommend CMS set the cost criteria at $4,000 and reassess that amount based on average drug prices after at least 2 consecutive years with the same cost criteria.

Additionally, we encourage CMS to consider other strategies for growing the pharmacist workforce, expanding the reach of the existing pharmacist workforce by recognizing pharmacists as providers, and providing pharmacists incentives to access to richer data on patient medical histories, such as through health information exchanges.

S. Standards for Electronic Prescribing

Blue Shield supports CMS's proposal to require Part D sponsors to adopt the National Council for Prescription Drug Plans' (NCPDP) Real-Time Prescription Benefit (RTPB) transaction standard. However, the current NCPDP RTPB standard version 12 only supports transactions with one drug or pharmacy at a time while the current industry norm allows electronic health

[1] Tyko, Kelly, "Walmart and CVS cutting pharmacy hours," Axios, Last modified January 27, 2023, https://www.axios.com/2023/01/27/cvs-pharmacy-hours-walmart-hours-shortage.
[2] "Survey: Three Quarters of Community Pharmacies Report Staff Shortages," National Community Pharmacists Association, Published on August 11, 2022, https://ncpa.org/newsroom/news-releases/2022/08/11/survey-three-quarters-community-pharmacies-report-staff-shortages.

record (EHR) systems and payer digital technologies to send up to 4 drugs or 4 pharmacies for pricing in a single transaction.

Given that discrepancy, we urge CMS to further specify that the adopted standard is consistent with the current industry norm that, as noted above, allows EHR systems and payer digital technologies to send up to 4 drugs or 4 pharmacies for pricing in a single transaction. This capability ensures beneficiaries and prescribers have visibility into the most cost-effective drugs and pharmacy alternatives by not exceeding the transaction latency standard of 3 seconds of less for 99 percent of transactions in EHR, web, and mobile platforms. It is critical that the adopted transaction standard supports the current industry norm because:

- Identifying and pricing lower-cost formulary alternatives requires allowing multiple drugs in a single RTPB transaction. Failure to require at least 4 drugs in a single RTPB transaction would necessitate multiple, consecutive transactions to price all appropriate alternatives, which creates more time latency in returning pricing responses for display to beneficiaries and prescribers.

- The primary purpose of RTPB, as noted by CMS, is to identify and support the most cost-effective medication for prescribing. This requires identifying, pricing, and delivering to prescribers lower-cost, therapeutic-equivalent alternatives **at the point of prescribing in 3 seconds or less.** The current NCPDP RTPB standard only supports transactions with one drug or pharmacy at a time. When submitted in sequence to price alternatives rather than allowing 4 in a single transaction, the latency is expected to exceed 3 seconds, surpassing standards for EHRs and resulting in error or reject messages.

- According to the Congressional Budget Office, Medicare enrollees have increased their use of prescriptions to treat co-morbidities to an average of 54 prescriptions per year in 2018, resulting in an increase in enrollee out-of-pocket cost burden.[3] Enrollees benefit from an expanded view of potential cost savings and should not be limited to one prescription at a time to find savings.

- Currently, the vast majority of RTPB transaction responses sent to prescribers only provide pricing for one selected drug and does not include lower cost alternatives.[4] Failure to require up to 4 drugs in a single RTPB transaction will functionally guarantee that lower cost formulary alternatives will not be delivered, undermining CMS's prior rulemaking on RTPB tools (CMS-4180-F and CMS-4190-F).

Again, we encourage CMS to ensure that the adopted standard enables EHR systems and payer digital technologies to send up to 4 drugs or 4 pharmacies for pricing in a single transaction. It is critical that beneficiaries, prescribers, and pharmacists are able to see the intended information delivered through their preferred point-of-care platform.

[3] Tamara Hayford et al. "Prescription Drugs: Spending, Use, and Prices," Congressional Budget Office, Published January 19, 2022, https://www.cbo.gov/publication/57050.
[4] *JAMA Intern Med*. 2022;182(11):1129-1137. doi:10.1001/jamainternmed.2022.3946 Published online September 12, 2022.

V. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System

C. Contract Ratings

We agree with CMS's methodology and proposed clarification for calculating Star Ratings for the Parts C and D improvement measures for the first and second years after contracts consolidate. We believe CMS's process for calculating the improvement measures after a contract consolidation is fair and preserves accuracy by *not* calculating measure-level scores the first year of a consolidated contract.

D. Adding, Updating, and Removing Measures

a. Diabetes Care—Kidney Disease Monitoring (Part C)

Blue Shield of California supports the removal of the Diabetes Care—Kidney Disease Monitoring measure beginning with the 2024 Star Ratings. We had planned for this change in accordance with prior CMS guidance. We recommend that Kidney Health Evaluation for Patients with Diabetes measure be added to the 2024 Star Ratings to ensure that a similar kidney disease measure is monitored in the Star Ratings program.

b. Medication Reconciliation Post-Discharge (Part C)

We request clarification from CMS on the timing of the proposed removal of the Medication Reconciliation Post-Discharge (MRP) measure. It was our understanding from prior CMS guidance that this measure would be retired with 2022 Star Ratings, as the measure would become a component of the Transitions of Care measure effective with 2022 Star Ratings. As CMS indicates in the CY 2024 Advance Notice, keeping MRP as a stand-alone measure alongside the Transitions of Care measure would be duplicative and effectively weight MRP at 1.25 instead of 1 (the standard weight for process measures).

We request that CMS retire the stand-alone MRC measure in 2022 Star Ratings (as Transitions of Care enters the program) or delay the introduction of the Transitions of Care measure until 2024 Star Ratings to coincide with the proposed retirement of the stand-alone MRC measure.

a. Colorectal Cancer Screening (Part C)—Substantive Change

We support CMS's proposal to expand the eligible age range for the Part C Colorectal Cancer Screening measure in alignment with current USPSTF guidance and changes made by the measure steward, NCQA.

b. Care for Older Adults—Functional Status Assessment (Part C) Substantive Change

Blue Shield appreciates CMS's interest in ensuring functional status assessments are conducted to understand and address beneficiaries' activities of daily living (ADLs) and instrumental activities of daily living (IADLs). However, we do not support the return of the Care for Older Adults—Functional Status Assessment (COA—FSA) measure.

The underlying activities captured in COA-FSA are already monitored through existing measures in the Star Ratings program, such as the Special Needs Plan (SNP)—Care Management measure as well as the new Physical Functioning Activities of Daily Living (PFADL) measure.

Specifically, ADLs and IADLs are assessed through standard Health Risk Assessments (HRAs) and HRA completion rates are a component of the SNP-Care Management measure, which applies to the same population as the COA-FSA measure. Moreover, if CMS moves the PFADL measure off the display page and into the Health Outcomes Survey (HOS) measure set, plans would likely complete functional status assessments and address identified needs in screening tools.

c. Medication Adherence for Diabetes Medication, Medication Adherence for Hypertension (RAS Antagonists), Medication Adherence for Cholesterol (Statins) (Part D)—Substantive Change

Blue Shield does not support CMS's proposed changes to the Part D medication adherence measures. First, we oppose applying risk adjustment based on sociodemographic status to the 3 Part D medication adherence measures. Applying risk adjustment at the measure level would make tracking individual measure performance much more complicated for plans and run counter to CMS's expressed interest in simplifying Star Ratings. We strongly encourage CMS to continue adjusting these measures through the Categorical Adjustment Index. Alternatively, if CMS wants to pursue case-mix adjustment for medication adherence measures, we urge the agency to adopt the Pharmacy Quality Alliance's combined medication adherence measure -- Proportion of Days Covered -- and consider applying a case-mix adjustment to that measure.

Blue Shield also opposes CMS's proposal to exclude Inpatient and Skilled Nursing Facility (SNF) days from the calculation of covered days for these medication adherence measures. We are concerned that the proposal to apply a sociodemographic status risk adjustment would not adequately offset the exclusion of Inpatient and SNF days, especially as many of these types of stays are unrelated to social risk factors. For example, a debilitating injury that requires a long stay is not limited to individuals with social risk factors.

In addition, we find that members who experience an Inpatient stay often have extra medication supplies at home as their medications were administered by facility pharmacies during the Inpatient stay. Those unused medical supplies add up the longer and more frequently a member is admitted to the hospital. We also see this with members who are admitted to Long-Term Care facilities. Based on this experience, we recommend that CMS add Long-Term Care days to the list of exclusions.

Ultimately, we do not find the Inpatient and SNF exclusions to be complex or burdensome, and therefore do not believe that eliminating them from the medication adherence measures would simplify the Star Ratings program in a meaningful way.

Finally, we request clarification from CMS on the use of continuous enrollment for the medication adherence measures. Specifically, we request clarification on whether a member

with a gap in enrollment would be excluded for the *entire* measurement period or if their first period of enrollment would be maintained in the measure.

b. Concurrent Use of Opioids and Benzodiazepines (COB), Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH) and Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults (Poly-CNS) (Part D)

Blue Shield does not support the addition of the Concurrent Use of Opioids and Benzodiazepines or either of the Polypharmacy measures to Star Ratings. These medications are already tightly controlled through formulary, benefit, utilization management, and clinical monitoring. Additional monitoring through Star Ratings would be redundant and may restrict access to medically necessary drug regimens, putting patients at risk for clinical decompensation.

If changes to a patient's medication regime – particularly an opioid medication – need to be made, dosage tapering and management of withdrawal symptoms is required. These clinical practices and patient safety efforts are not accounted for in the measure specifications. In addition, some members are stabilized on multiple anticholinergic medications. We are concerned that the addition of these related Star measures could result in abrupt changes to patients' medication regime and put patients at risk of clinical decompensation or other harm.

Finally, given the substantial overlap between the Concurrent Use of Opioids and Benzodiazepine and the Polypharmacy—Central Nervous System measure, we believe use of both measures would be redundant. We request that CMS *not* require both measures.

4. Revising the Rule for Non-Substantive Measure Updates

We support CMS's proposal to simplify the process for making non-substantive measure updates. However, we encourage CMS to continue to communicate these updates with plans through rulemaking like the Advance Notice or the Policy and Technical Changes Proposed Rule.

5. Measure Removal

We support CMS simplifying the process to remove measures alongside measure stewards. However, we encourage CMS to continue to communicate these updates with plans through rulemaking like the Advance Notice or the Policy and Technical Changes Proposed Rule.

E. Measure Weights

1. Patient Experience/Complaints and Access Measures

Blue Shield agrees with CMS's assessment that weighting the Patient Experience/Complaints and Access measures at 4 has created an imbalance in the contribution of different types of measures to plans' Star Rating score. We support CMS's proposal to bring the weight of these measures back down to 2, and strongly encourage CMS to make this change sooner than the

2026 Star Ratings. We think it is a priority to correct the current weighting imbalance as soon as possible.

2. Weight of Measures with Substantive Updates

We support CMS's proposal to codify its current practice of assigning a weight of 1 the first year that measures with substantive updates are added back to the Star Ratings program. Following that first year, as CMS notes, the measure would be assigned the weight associated with its category. We believe this process provides plans sufficient notice to familiarize themselves with a measure's updated specifications, assess potential impacts, and incorporate changes to internal processes if needed.

F. Guardrails

Blue Shield urges CMS to continue to use existing cutpoint guardrails. We believe that the Tukey outlier deletion and mean resampling will help stabilize cutpoints, but we believe the guardrails continue to be an important factor in improving the stability and predictability of cutpoints. We recommend CMS observe the true impact of the Tukey outlier deletion and mean resampling alongside guardrails for several years and then reevaluate the need for the guardrails policy.

G. Health Equity Index Reward

Blue Shield recognizes the importance of health equity and is working toward more equitable health outcomes for our members. We found CMS's Health Equity Summary Score Dashboard, which included stratified, measure-level performance reports, to be helpful in our efforts to identify performance improvements and health disparities. However, we have several significant concerns with CMS's proposal to replace the Reward Factor with a Health Equity Index (HEI) Reward and urge CMS to not finalize this proposal.

Our primary concern stems from the flexibility CMS granted to states in the CY 2023 Medicare Advantage and Part D Policy and Technical Changes Final Rule to require MA organizations to establish one or more DSNP-only contracts. The State of California chose to adopt this flexibility beginning in CY 2024. As such, MA organizations in California will have to apply for a new contract and then crosswalk their DSNP membership to that new contract. This will leave MA organizations' legacy contracts with very few SNP members, which typically account for the majority of a contract's Low-Income Subsidy (LIS), Dual Eligible (DE), and disabled members.

Under the proposed Health Equity Index Reward methodology, it is unlikely that non-DSNP contracts in states like California would be eligible for an HEI adjustment because the percentage of enrollees with social risk factors (SRFs) would be too small to make that contract eligible for an HEI adjustment. Under CMS's proposal, these contracts would not only be unlikely to receive an HEI adjustment but would be further disadvantaged by the proposed removal of the current Reward Factor. This proposal would unfairly disadvantage contracts operating in States that are implementing DSNP-only contracts. In addition to the DSNP-only contract issue, we are

concerned that the eligibility requirements CMS is proposing would make it difficult for plans to receive an HEI adjustment as percentage of members with SRFs falls under the national median for the majority of contracts.

We recommend CMS consider a compromise in which the current Reward Factor and proposed Health Equity Index Reward could operate together: keep but limit the Reward Factor to a maximum reward of 0.2 Stars *and* introduce a Health Equity Index Reward capped at a maximum reward of 0.2 Stars.

H. Improvement Measure Hold Harmless

Blue Shield agrees that plans should always be driving toward continued quality improvement, but we strongly disagree with CMS's proposal to limit the hold harmless rule for improvement measures to plans with a 5-Star rating. We disagree with the rationale that applying the hold harmless to 4-Star and 4.5-Star measures discourages plans from striving for additional improvement. Blue Shield's H0504 contract has been a 4-Star plan for several years. We still set each measure's target rating to not only achieve the 4 or 5-Star cutpoint, but to account for continuous improvement if our prior performance was higher than our projected cutpoint.

We find that the retrospective clustering methodology and mean resampling are natural motivators of continuous improvement. At the same time, we have seen 4- and 5-Star cutpoints become increasingly challenging for many measures. For some measures, the cutpoints are only separated by one or two percentage points. When a plan is operating at mostly the 4- and 5-Star levels, it is extremely difficult to continue to meet the cutpoints and to continuously improve; the margin for improvement is simply much more narrow at the highest Star levels. We believe that the hold harmless rule was sensibly and fairly applied to plans with 4-Stars and above for this reason, and believe these issues continue to exist and necessitate the application of the hold harmless rule.

I. Extreme and Uncontrollable Circumstances

We support CMS's proposed changes to the Extreme and Uncontrollable Circumstances (EUC) policy. We saw how important waiving the 60 percent rule was when the EUC policy was triggered by the COVID-19 Public Health Emergency. We also believe that the Tukey outlier deletion would resolve the issue of outlier plan performance due to an extreme and uncontrollable circumstance. We also support CMS codifying the process for adjusting the HOS measures.

J. Quality Bonus Payment Rules

We support CMS's proposals regarding the Quality Bonus Payment refute process. In our experience, the First and Second Plan Preview processes provide sufficient opportunities to refute suspected errors. We believe, after the Second Plan Preview process, a Quality Bonus Payment refute should only occur in the case of a clerical or similar error that may have occurred between the Plan Preview and the Quality Bonus Payment validation process.

K. Calculation of Star Ratings

While we expected codification of the Tukey outlier deletion methodology for the 2024 Star Ratings, we encourage CMS to delay implementation to give plans more time with the simulation documents they received in December 2022 to understand the methodology and assess impact.

Stars Questions Not Addressed in the CY 2024 Policy and Technical Proposed Rule

Blue Shield requests clarification from CMS on the status of the measures described below. These are measures that CMS proposed taking action on in previous rulemakings but – to our knowledge – has not yet addressed.

Annual Flu Vaccine

CMS proposed moving the Annual Flu Vaccine measure out of the CAHPS survey and into the HEDIS measure set. We agree with this proposal. The administration of a vaccine can easily be captured in claims, PDE, and/or medical records, making it well suited to be a HEDIS measure along with other clinical measures. We think this will be a more reliable approach to collecting information about administration of the flu vaccine than asking a member to recall whether or not they received the vaccine. We request CMS confirm whether or not this proposed change to the Annual Flu Vaccine measure will be implemented in the 2025 Star Ratings (Measurement Year 2023).

Beneficiary Action & Performance Problems

CMS previously proposed adding Beneficiary Action & Performance Problems to the Star Ratings program. We support the addition of this measure to the program, although have concerns about how the measure may discourage plans from self-reporting access and performance problems. We request CMS confirm whether or not this measure will be added to the 2025 Star Ratings (Measurement Year 2023).

Complaints About the Health Plan

CMS had proposed adding "marketing misrepresentations" into the Complaints about the Health Plan measure. We request confirmation from CMS on whether or not this proposed modification will occur in the 2025 Star Ratings (Measurement Year 2023).

Care for Older Adults

CMS previously proposed adding digital indicators for the Care for Older Adults measures and transitioning these measures to electronic clinical data systems (ECDS) reporting methods. We request CMS confirm whether or not this change to reporting the Care for Older Adults measure is effective for the 2025 Star Ratings (Measurement Year 2023).

HEDIS Frailty Exclusions

CMS proposed requiring more than one code for HEDIS frailty exclusions. We request confirmation from CMS on whether or not this change to the HEDIS frailty exclusions would be effective for the 2025 Star Ratings (Measurement Year 2023).

Conclusion

Thank you again for the opportunity to provide comments on these proposed changes. We welcome the opportunity to respond to any follow-up questions you have.

Sincerely,



Andy Chasin
Vice President, Federal Policy and Advocacy
Blue Shield of California

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PUBLIC SUBMISSION

Docket: CMS-2022-0191
Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024

Comment On: CMS-2022-0191-0001
Medicare Program: Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, etc.

Document: CMS-2022-0191-0826
Comment on CMS-2022-0191-0001

Submitter Information

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Organization: The Cigna Group

General Comment

Please see attached.

Attachments

Cigna CY 2024 MA Part D Proposed Rule Comments - 20230213 Final

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February 13, 2023

VIA ELECTRONIC SUBMISSION TO www.regulations.gov

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4201-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Contract Year (CY) 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications

To Whom It May Concern:

Cigna welcomes the opportunity to respond to the *CY 2024 Policy and Technical Changes to the Medicare Advantage Program and Medicare Prescription Drug Benefit Program* proposed rule. Cigna provides commentary, feedback, and recommendations on many of the proposals contained in this proposed rule; taken together, the numerous proposals in this rule across several critical areas of the Medicare Advantage (MA) and Part D programs represent significant change over a short period of time. We urge CMS to consider overlapping impacts, operational complexity, and potential disruption that may result when implementing portions of this rule, especially in light of other large-scale changes taking place outside of its scope.

The Cigna Group is a global health company committed to improving health and vitality. Our subsidiaries are major providers of medical, pharmacy, dental, and related products and services, with over 190 million customer relationships in the more than 30 countries and jurisdictions in which we operate. Within the United States, Cigna provides medical coverage to approximately 14 million Americans in the commercial group health plan market, predominantly in the self-insured segment. We also provide coverage in the individual Affordable Care Act insurance segment in several states, both on- and off-Exchange, to about 235,000 people. Additionally, we serve more than 4.5 million people through our MA, Medicare Prescription Drug Program and Medicare Supplemental products. In all of the segments we serve, Cigna is focused on creating products and services that support a quality, affordable, equitable, and sustainable health care system for all Americans.

This proposed rule would implement extensive changes to the rules and regulations governing some of the most fundamental programs underpinning the MA and Part D programs. We thank CMS for its thoughtful approach in proposing changes that seek to strengthen and sustain these programs for Medicare beneficiaries today and into the future, but we are concerned some of them would have the opposite effect. In this letter, we offer feedback and recommendations on many of these proposals, with particular emphasis on the proposals we believe pose the most risk of undermining the program and the value it

provides to beneficiaries today. While our detailed comments are in the Appendix, below is a summary of our key issues, concerns, and recommendations for CMS' consideration:

Utilization Management and Prior Authorization

Prior authorization and other utilization management tools are critical tools to help protect beneficiaries' health and safety while improving affordability and reducing unnecessary costs. They ensure Medicare benefits are delivered when appropriate and medically necessary, as required by law. The proposed rule would significantly limit MA plans' ability to exercise prior authorization and care coordination, and we have serious concerns about the consequences of these changes for beneficiaries and taxpayers. Moreover, we note the overlapping impacts of this proposed rule with other regulatory proposals related to interoperability, prior authorization, and claims attachments; and we request CMS better align these multiple efforts. Given these considerations, Cigna recommends:

- CMS should not prohibit MA plans from using prior authorization as a tool to determine *when, where,* and *how* Medicare benefits and services are best provided to individuals based on clinical need;
- CMS should maintain the integrity and utility of manuals and instructions, as well as the ability of MA plans to use the evidence-based clinical guidelines widely used today; and
- CMS should align the implementation of any prior authorization policy changes to the timelines of other significant proposed rules regarding interoperability and claims attachments.

Marketing and Education

Effective marketing and education is the most effective way to ensure beneficiaries have the most accurate and reliable information needed to make an informed decision about their coverage options. In this rule, CMS is proposing additional rules and guidelines to improve the quality of information beneficiaries receive and reduce the likelihood of beneficiaries enrolling in the wrong plan based on bad information or misunderstanding. While we support many of the proposals in this section, we ask CMS to consider the timing, ask for additional clarity, and raise concerns that some proposals may actually create barriers to getting the right information to beneficiaries that is necessary for them to make informed coverage decisions. Specifically Cigna recommends:

- CMS delay any implementation of significant changes to marketing rules and regulations until at least the 2025 plan year, to give stakeholders enough time to implement changes in advance of the Annual Election Period (AEP);
- CMS provide additional clarity, including specific examples, of what language, statements, images, and other representations would be permissible under the proposed changes around advertising content, including the use of cost comparisons;
- CMS not finalize proposals to separate marketing and educational events due to concerns that such will create unnecessary burdens to some beneficiaries, especially those with transportation challenges and those who live in rural areas; and
- CMS consider proposals that would reinforce a beneficiary's right to opt out of communications rather than place arbitrary limits on the collection of contact information and timeframes for allowable outreach.

Quality and Star Ratings

The MA and Part D Star Ratings System has been one of the most successful tools to incentivize quality improvement activities and ensuring beneficiary satisfaction and access to care. MA and Part D plans have seen significant improvements across a range of quality

measures and domains, resulting in better care and outcomes for patients. While we offer detailed comments to some of the more technical proposals, we offer the following recommendations on the more significant methodological Stars proposals:

- We strongly urge CMS to finalize its proposal to reduce the weight of patient experience/access measures from 4 to 2;
- CMS finalize its proposal to replace the current Reward Factor with a health equity index (HEI) adjustment beginning with 2027 Star Ratings;
- CMS not finalize its proposal to eliminate the 5% guardrails that were recently implemented to limit measure cut-point movement each year, considering other methodological changes (e.g., Tukey outlier method) already finalized to take effect; and
- CMS not finalize its proposal to limit the improvement hold-harmless provisions to 5-Star plans and should maintain the current policy of application to any contract with a summary rating of 4 Stars or higher.

With these priority recommendations as context, and with our more detailed comments contained in the Appendix, we thank CMS for its consideration of these comments. We look forward to engaging on these proposals, and would welcome the opportunity to discuss these issues with you in more detail at your convenience.

Respectfully,



Kristin Julason Damato

* * *

Appendix: Cigna Detailed Comments

Enhancements to the Medicare Advantage and Medicare Prescription Drug Benefit Programs (Section II)

A. Health Equity in Medicare Advantage (MA) (§§ 422.111, 422.112, and 422.152)

Current regulations require MA organizations to ensure that services are provided in a culturally competent manner and the regulation provides examples of populations that may require consideration specific to their needs. CMS is proposing to amend the list of populations to include people:

- With limited English proficiency or reading skills;
- Of ethnic, cultural, racial, or religious minorities;
- With disabilities;
- Who identify as lesbian, gay, bisexual, or other diverse sexual orientations;
- Who identify as transgender, nonbinary, and other diverse gender identities;
- Who are born intersex;
- Who live in rural areas and other areas with high levels of deprivation; and
- Otherwise adversely affected by persistent poverty or inequality.

Furthermore, CMS provides best practices for organizations to use in developing their provider directories, including incorporating non-English languages spoken by each provider and provider/location accessibility for people with physical disabilities. In this rule, CMS is proposing to require organizations to include providers' cultural and linguistic capabilities (including American Sign Language) in their provider directories.

To address disparities in telehealth access due in part to low digital health literacy, CMS is also proposing to require MA organizations to develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy assistance with accessing any medically necessary covered telehealth benefits.

Finally, CMS is proposing to require MA organizations to incorporate one or more activities that reduce disparities in health and health care among enrollees into overall quality improvement (QI) programs. The agency notes MA organizations' existing QI programs are an optimal vehicle to develop and implement strategies and policies designed to reduce disparities in health and health care, and advance equity in the health and health care of MA enrollee populations, especially those that are underserved.

Cigna Comments:

Cigna supports CMS' goals to advance health equity. We believe health starts in the communities where we live, work, learn, and play. For nearly 15 years, Cigna has promoted the identification of health disparities and influenced the development of solutions that result in improved health outcomes. We do this by leveraging an array of data sources and tools like our proprietary Social Determinants Index (SDI) that allows us to analyze customer populations to understand their potential health disadvantages and build innovative solutions to enhance our clinical program offerings, close disparity gaps, and better serve our customers, our network providers, and the greater community. Through Cigna's enterprise-wide Health Equity Committee we seek to ensure that all people can achieve their full health potential regardless of socioeconomic or environmental circumstances.

We offer the following comments, clarifying questions, and recommendations in response to CMS' proposals relating to health equity:

- **Adding new populations to cultural competency requirements:** Cigna is encouraged by CMS's commitment to addressing the needs of the populations enumerated, but we strongly recommend a phased approach to enable plans to implement form and program changes that best meet the needs of our beneficiaries. Expanding the requirements to this many new population groups will require significant changes to enrollment forms, health risk assessments (HRAs), and an overhaul of multiple workflows. A phased implementation will help to minimize disruption and confusion to beneficiaries.

- **Requiring searchable provider directories:** While Cigna supports overarching efforts to improve the accuracy and utility of provider directories, we recommend that proposed requirements for new directory data elements be aligned with longer-term solutions involving a national directory of healthcare providers and services (NDH). Development of a larger NDH would achieve improved efficiencies for all stakeholders across the health care system. Notwithstanding, if CMS pursues near-term implementation of the new MA directory data elements, we strongly recommend: (1) CMS provide enforcement discretion to allow for proper development, testing, implementation, and refinement of data collection methods within a very short timeframe; and (2) CMS require provider organizations to manage the collection of this information for their individual clinicians and attest to its accuracy.

- **Requiring plans to provide digital health education:** Cigna supports digital health education and appreciates the flexible approach in CMS' proposed changes. Cigna currently supports members through partnerships with organizations such as Findhelp, which can connect members with federal resources and community organizations for free/reduced cost Wi-Fi and other methods of internet connection. These members are identified during interactions with clinical staff. Cigna agrees that further efforts to support digital health education will be important as telehealth grows in use for the Medicare population. Given this is a rapidly evolving area, we also appreciate the proposal's flexibility to give plans the discretion to design a screening tool and develop educational materials for members. This flexibility will allow us to continue to innovate in digital health solutions for beneficiaries.

- **Incorporating one or more health equity-focused activities in QI programs:** Cigna is actively involved in efforts to address social determinants of health (SDOH) to reduce health care disparities among MA enrollees as part of our QI programs. Cigna MA employs bilingual staff and administers social work programs that connect members to a wide range of Cigna benefits. Cigna supports efforts to encourage more health equity-focused quality initiatives, and we appreciate the flexibility embedded within this proposal which will allow plans to tailor initiatives that are best suited for their unique populations.

B. Behavioral Health in Medicare Advantage (MA) (§§ 422.112, 422.113, and 422.116)

CMS proposes the five following changes to strengthen its network adequacy requirements and reaffirm MA organizations' responsibilities to provide behavioral health services:

- Add Clinical Psychology, Licensed Clinical Social Workers, and Prescribers of Medication for Opioid Use Disorder (OUD) as specialty types that will be evaluated as part of the network adequacy reviews, and make these new specialty types eligible

for the 10-percentage point telehealth credit. Currently, MA organizations are only required to demonstrate they meet network adequacy for two behavioral health specialty types: psychiatry and inpatient psychiatric facility services.

- Amend general access to services standards to explicitly include behavioral health services. Specifically, CMS proposes to add behavioral health services to the types of services for which MA organizations must have programs in place to ensure continuity of care and integration of services.

- Codify standards for wait times that apply to both primary care and behavioral health services. CMS is proposing these changes to increase and enhance access to equitable behavioral health care services, similar to how beneficiaries access needed physical health services.

- Clarify that behavioral health services may qualify as emergency services and, therefore, must not be subject to prior authorization. CMS is proposing this change to ensure that emergency medical conditions are easily interpreted as including mental health and thereby guarantee coverage is provided by the MA organization at parity with access to other medical emergency services.

- Extend current requirements for MA organizations to establish programs to coordinate covered services with community and social services to behavioral health services programs to close equity gaps in treatment between physical and behavioral health.

Cigna Comments:

Cigna is committed to ensuring beneficiaries have access to an array of behavioral health professionals and services in the face of a nationwide behavioral health provider shortage. We support CMS' efforts to expand the behavioral health workforce through expanded education programs and other investments to spur growth in the number of providers.

The COVID-19 pandemic accelerated a tectonic shift to virtually-enabled care across the health care spectrum, but especially in behavioral health. In recognition of this, Cigna and Evernorth worked quickly to add virtual care resources to its behavioral health network, and experienced a 60% increase in behavioral health patients using virtual services compared to pre-pandemic levels. We continue to innovate through greater integration of physical and behavioral health care; leveraging virtual solutions, such as MDLIVE, to expand access to those who live in areas with little or no physical behavioral health access.

Cigna appreciates CMS' ongoing commitment to incentivize greater access to behavioral health providers. We firmly believe the root cause of provider supply must continue to be addressed. The root cause of provider supply is far beyond MA plans' control, and we urge CMS to recognize this fact when establishing network and access standards.

With regard to adding new behavioral health provider types to MA network adequacy standards, and to extending requirements to establish behavioral health coordination programs with community-based social services, **Cigna strongly urges CMS to delay these requirements to plan year 2025.** Given the timing of this proposed rule, and the publication of the subsequent final rule and associated guidance, we are concerned plans will not have sufficient time to engage in the level of provider contracting needed to satisfy these requirements for 2024, especially when considering recent CMS rule changes to push back the time when networks must be complete for the following plan year. Additionally, **Cigna requests CMS allow a flexible exceptions process, for at least the first few**

years of these new requirements, to account for systemic provider shortages and other root cause issues beyond plans' control.

Cigna also strongly supports CMS' proposal to allow the 10-percentage point telehealth credit for the new behavioral health specialty types. We urge CMS to allow maximum flexibility to provide virtual BH solutions that would satisfy new network and access standards. Additionally, **we urge CMS not to adopt strict appointment wait time requirements and continue to allow flexibility in meeting existing standards consistent with sub-regulatory guidance.** The above recommendations will provide that we build on and sustain the fostering of innovative solutions for providing and accessing behavioral health and substance use disorder treatment as we work to champion optimal treatment and support in this area.

C. *Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools (§§ 422.101, 422.112, 422.137, and 422.138) (Section II.E.)*

Utilization management tools are critical to ensuring that beneficiaries receive care that is clinically appropriate and consistent with evidence-based medicine principles. Cigna agrees with CMS' view that prior authorization, and utilization management tools more broadly, are important means to help coordinate care, reduce inappropriate utilization, and promote cost-efficient care (87 Fed. Reg. at 79498). For this reason, we have grave concerns that some of the changes CMS proposes in this rule will result in the unintended consequence of fundamentally undermining MA plans' ability to exercise these critical functions. We also agree with CMS that process and operational improvements are needed, and we note the additional efforts across CMS and HHS to implement reforms will ultimately lead to these improvements. **We strongly recommend CMS align the timelines of various efforts and regulatory activities impacting prior authorization, including those contained in the Interoperability and Prior Authorization proposed rule. Specifically, we ask CMS not to implement any significant changes to prior authorization and UM tools before 2026 and to align the implementation timeline with the interoperability proposed rule.**

Cigna offers additional comments on the various proposals in this section driven by a fundamental guiding principle that MA plans should maintain their ability to use UM tools effectively for the benefit of beneficiaries and the health care system.

1. *Coverage Criteria for Basic Benefits (including Medical Necessity Determinations) (Section II.E.2. and II.E.3.)*

CMS proposes to codify standards for coverage criteria to ensure that basic benefits coverage in MA is no more restrictive than traditional Medicare so that benefits are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." In addition, CMS proposes to clarify that MA organizations must comply with general coverage and benefit conditions included in traditional Medicare national coverage determinations (NCDs), local coverage determinations (LCDs), and laws, unless there are specific laws applicable to MA.

When coverage criteria are not fully established in Medicare statute, regulation NCD, or LCD, an MA plan would be able to create internal coverage criteria based on current evidence in widely used treatment guidelines or clinical literature that is publicly available. When making the internal criteria, MA plans would be required to describe a summary and list of the sources of evidence that was considered and an explanation of the rationale.

CMS proposes changes to medical necessity determination requirements, including:

- Requiring that MA organizations consider whether the item or service is reasonable and necessary under Medicare's definition of reasonable and necessary at section 1862(a)(1);
- Codifying that MA organizations must consider the enrollee's medical history, physician recommendations, and clinical notes; and
- Requiring that MA organizations' medical directors be involved in ensuring the clinical accuracy of medical necessity decisions where appropriate. CMS seeks feedback on when this would be appropriate.

CMS also describes in the preamble language that MA plans would be restricted in their ability to limit "when and how" they cover basic Medicare benefits, so that if care can be delivered in more than one way and a provider has ordered or requested items or services for an enrollee, the MA organization may only deny coverage on the basis of the ordered services failing to meet criteria outlined in Medicare coverage rules. If an enrollee in an MA plan is discharged with a physician order for post-acute care, the MA organization would not be able to deny coverage for care in the ordered PAC setting and redirect care toward a different setting.

To clarify appropriate use of prior authorization, CMS proposes to clarify that a coordinated care plan may use prior authorization processes for basic benefits and supplemental benefits only to confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations to ensure that benefits are medically necessary for basic benefits or clinically appropriate for supplemental benefits.

Cigna Comments:

CMS proposes to remove the reference to "original Medicare manuals and instructions," and clarify that MA organizations must comply with "general coverage and benefit conditions include in Traditional Medicare laws" when making coverage decisions, which include Medicare statute, regulation, and both NCDs and LCDs. CMS explains that by removing this reference, they are not diminishing the content and value provided by manuals and instructions and they should be relied upon to interpret and define the scope of Part A and B benefits. **Cigna agrees manuals and instructions are an important resource, and we urge CMS to maintain the integrity and utility of the information contained in these manuals to the extent they provide coverage guidance where Medicare is otherwise silent.** Specifically, CMS should modify its regulatory text to state that Medicare manuals and other CMS-issued guidance may be adopted by MA plans as internal coverage criteria that encapsulate "widely used treatment guidelines," without the requirement to provide summaries of evidence and rationales for the adoption of these CMS manuals and guidance documents.

Cigna supports CMS's efforts to ensure that Medicare beneficiaries receive care that is consistent with the statutory, regulatory specifications for coverage of basic benefits, as well as existing NCDs and LCDs. Cigna MA has long adhered to these requirements and determinations. Moreover, Cigna MA has viewed Medicare manuals and other CMS-issued guidance as key to applying requirements and determinations. Although CMS manuals and guidance do not rise to the level of statute and regulation, these issuances have been used to shape coverage criteria and medical necessity determinations. Because CMS manuals and guidance are government-issued, publicly available information that have gone through government processes, such materials should not be subject to the same type of required explanations. MA organizations should be permitted to cite these CMS issuances as internal coverage criteria that are based on widely used treatment guidelines and clinical literature.

Additionally, CMS should allow MA plans flexibility involving how MA plans' UM tools are applied to the circumstances of when, where and how items and services are delivered to beneficiaries. MA organizations can and should be required to comply with and implement specific statutory, regulatory and NCD/LCD coverage criteria and requirements that specify where, when and how items and services are delivered. However, in the absence of such specified requirements, MA organizations should have flexibility to ensure that beneficiaries receive Medicare-covered benefits in the most clinically appropriate and cost-effective way for that individual, using evidence-based guidelines and approaches. We disagree with the implication that providing the same Medicare-covered service in a different way, in an alternative setting, or with a different clinically appropriate clinician is somehow considered non-coverage of that benefit. **We urge CMS to draw a clearer distinction between Medicare *benefit* policy and Medicare *payment* policy.** MA organizations should continue to be required to provide all Medicare-covered benefits and services, but being able to manage *when, where,* and *how* to best deliver those benefits and services is absolutely critical to driving enhanced value of care management and better coordination to patients.

CMS is proposing to prohibit the ability of MA plans to use step therapy approaches in delivering Medicare-covered benefits (with the exception of Part B drugs). **Cigna opposes this proposal.** In some cases, step therapy may be appropriate, particularly in the context of transitions of care, where it is important to allow MA plans to use their evidence-based tools to appropriately optimize the site and length of service. MA organizations are well positioned to help coordinate and manage care and should be allowed the flexibility to do so.

MA plans should be permitted to deploy UM tools consistent with evidence-based medicine principles so that beneficiaries and the Medicare program receive and deliver truly value-based care. The scientific evidence supporting optimal health care decision making continues to evolve at an ever faster rate, and regulatory wording around how MA plans are permitted to incorporate new and evolving evidence in very dynamic spaces can have unintended consequences if not chosen very carefully. CMS historically recognizes this fact, which underpins the principles in the current criteria hierarchy requirements and allows MA plans the flexibility to fill in guidelines and criteria where the CMS manuals and determinations are not sufficiently specific to accurately assess an individual beneficiary's clinical scenario. Where the available peer-reviewed literature supports the delivery of care in a specific fashion to deliver optimal care for Medicare patients, MA plans should be able to use UM tools to support the same without having to seek specific requirements to this effect in statute, regulation or NCDs/LCDs. MA organizations are and have been partners with the Medicare program for the management of quality care for beneficiaries and the health care system. CMS should allow MA organizations flexibility to apply the latest, highest quality scientific evidence and continue to deliver value for program and patient needs.

2. *Continuity of Care (Section II.E.4.)*

CMS proposes to require that MA prior authorizations be valid for the duration of the entire approved prescribed or ordered course of treatment or service. CMS proposes to define "active course of treatment" as a course of treatment in which a patient is actively seeing a provider and following the prescribed or ordered course of treatment as outlined by the provider for a condition. In addition, CMS proposes to require MA organizations offering coordinated care plans to provide a 90-day transition period for any ongoing course of treatment when an enrollee has enrolled in an MA coordinated care plan after starting a course of treatment, even if it was commenced with an out-of-network provider.

Cigna Comments:

Cigna agrees it is important to guarantee a seamless transition of ongoing care when a beneficiary changes their coverage option under Medicare. We do this today in a number of

circumstances where it is considered most critical and where it is already required by Medicare law. The proposed language requiring approval for the entire ordered course of treatment has the unintended consequence of preventing any ongoing assessment of the treatment's effectiveness, or the opportunity to apply newer treatment options that recent evidence suggests may improve the beneficiary's health. However, Cigna is concerned that a 90-day transition period coverage requirement for *any* ongoing course of treatment is overly broad in scope. Moreover, we urge CMS to consider that Medicare-participating providers are not required to see MA beneficiaries unless the MA plan contracts with such providers. **If CMS finalizes this broad continuity of care policy for a 90-day transition period, we recommend that CMS require out-of-network providers to accept 100% of Medicare payment for such services.** This will minimize disruption and enable beneficiaries to continue care.

In addition, such a broad mandate would need to be facilitated by a manual and time-intensive process until such time as coverage determination information can flow more freely between health care entities, adding complexity, burden, and cost to the health care system. Consistent with the recommendation above, **Cigna recommends that this change not be implemented before January 1, 2026, to align with the Interoperability and Prior Authorization proposed rule timeline, and to allow MA plans to adjust their systems to the continuity of care changes.**

3. *Mandate Annual Review of UM Policies by a UM Committee (§ 422.137) (Subsection 5)*

CMS proposes that MA plans would be prohibited from using any utilization management policies for basic or supplemental benefits on or after January 1, 2024 unless those policies and procedures have been approved by the Utilization Management Committee. CMS proposes to require that MA organizations establish a Utilization Management Committee that is led by the plan's medical director, with specified requirements for the composition of the UM Committee. The Committee must document the reasons for its decisions. CMS would allow the Utilization Management Committee to operate similarly to the plan's Pharmacy and Therapeutics Committee, and to provide some flexibility to define the structure and responsibilities of the Utilization Management Committee.

Cigna Comments:

As a general matter, Cigna supports an administratively streamlined approach to the scope of Utilization Management Committee responsibilities, composition, and operational requirements. Heightened responsibilities and requirements have the potential to increase costs of operation and burden. Cigna emphasizes the importance of flexibility in the composition of the Utilization Management Committee and the manner in which it operates.

Allowing for plan discretion regarding the expertise of Utilization Management Committee members' needed for decisions and the nature of the backgrounds of the committee members will make administration of the committee's functions more streamlined. Furthermore, to the extent that utilization management policies remain consistent with existing statutes, regulations, NCDs and LCDs, and already appropriately established internal coverage criteria, Utilization Management Committees should not need to review and revise such policies annually.

Cigna appreciates CMS's reasonable approach to its proposed Utilization Management Committee composition and functions. As stated above, implementing the changes on a timeline that aligns with the Interoperability and Prior Authorization proposed rule implementation timeline would give MA plans sufficient time to prepare each of their Utilization Management Committees and

processes to comply. We also appreciate CMS' proposal to allow existing Pharmacy and Therapeutics Committees to take on this function, as it would reduce administrative complexity.

4. Additional Areas for Consideration and Comment: Gold Carding

CMS does not propose any change in regulation or guidance associated with gold-carding programs for MA plans. CMS states, however, that they "encourage MA plans to adopt gold-carding programs that would allow providers to be exempt from prior authorization and provide more streamlined medical necessity review processes for providers who have demonstrated compliance with plan requirements."

Cigna Comments:

Cigna seeks to ensure that appropriate care is delivered to patients in a simple, affordable, and predictable manner. Patients should receive clinically appropriate, evidence-based care, and to this end, prior authorization is one tool to align provider practices with clinical guidelines. Gold carding as a practice does not enhance medical care, but rather potentially creates a loophole for providers that results in higher levels of unnecessary care and increased health care system costs without a system of checks and balances to help ensure appropriate care and patient safety. We believe that gold carding practices inhibit improvement of provider performance and assurance that patients are being cared for using the most current evidence-based protocols; creating confusion and administrative burden.

Cigna commends CMS for allowing MA plans to exercise discretion about whether to implement gold carding programs. To the extent a provider organization takes on financial risk, or is delegated risk for prior authorization, from a health plan, gold carding may be appropriate and / or on a case-by-case basis.

D. Review of Medical Necessity Decisions by a Physician or Other Health Care Professional with Expertise in the Field of Medicine Appropriate to the Requested Service and Technical Correction to Effectuation Requirements for Standard Payment Reconsiderations (§§ 422.566, 422.590, and 422.629)

CMS is proposing to modify the existing organizational determination regulations by adding the requirement that the physician or other health care professional who conducts the initial review must have expertise in the field of medicine that is appropriate for the item or service being requested before the MA organization issues an adverse organization determination decision. CMS clarifies that under this proposal, the physician or other appropriate health care professional reviewing the request need not, in all cases, be of the same specialty or subspecialty as the treating physician or other health care provider. CMS seeks to align this proposal with the standards set forth in regulation related to the appropriate expertise applicable to physician review of *reconsiderations*. CMS expects MA organizations to apply the standard of "expertise appropriate for the specific service at issue" at the organization determination level in the same manner as plans have applied this standard at the reconsideration level.

Cigna Comments:

Cigna agrees that health care professionals making coverage decisions should have appropriate expertise in the context of reviews of medical necessity decisions. **We strongly support CMS' decision not to require the case reviewer involved to be of the exact same specialty or sub-specialty as the treating physician.** If a restrictive approach of this nature were required, it would be cost-prohibitive. Cigna strongly supports CMS' intent

to allow flexibility for a plan to determine on a case-by-case basis what constitutes appropriate expertise based on the services being requested and relevant aspects of the enrollee's health condition. **We urge CMS to modify the final regulatory text to make this flexibility and plan discretion clear.**

E. Updating Translation Standards for Required Materials and Content (§§ 422.2267 and 423.2267)

Current regulations require MA organizations and Part D plan sponsors to translate materials into any non-English language that is the primary language of at least five percent of individuals who reside in a plan benefit package service area. Each Fall, CMS posts languages that meet this threshold for every county in the US. CMS is proposing to require plans provide translated materials and auxiliary accessible formats upon request on a standing basis. CMS proposes to also extend this requirement to special needs plans (SNP) enrollee individualized care plans, and to require translation into any languages required by a Medicaid contract in addition to those required under Medicare for certain dual-eligible SNP types.

Cigna Comments:

Cigna supports CMS' goals to ensure to the accessibility of critical plan information and materials for all Medicare beneficiaries, regardless of language or need. We believe reasonable standards for ensuring this access are necessary, but we also express concerns over the significant cost and effort that would be required to meet the expanded nature of this proposal. For example, we believe it will be extremely difficult to turn around materials in some auxiliary aid formats, such as Braille, within the proposed short time frames, given the time required by our external contractors to do so. We anticipate this proposal will also further constrain our contracted vendors who work with multiple plans all subject to these new requirements, and we are concerned about reduced capacity. **We ask CMS to exercise flexibility on stringent turnaround time expectations for certain translation types (e.g., Braille) when plans make a good faith effort to respond to beneficiary requests.**

F. Medicare Advantage (MA) and Part D Marketing (Subpart V of Parts 422 and 423)

CMS is proposing numerous changes to the MA and Part D marketing regulations and guidelines to address concerns around marketing misrepresentation and beneficiary confusion. CMS' proposals generally can be categorized into two groups:

1. **Proposals to clarify permissible language and representations in marketing materials.** CMS is proposing new rules and additional clarity around the type of information and language that may and may not be used in plan materials and new rules around how information must be included and/or displayed in materials.

   Proposals to modify marketing activity and beneficiary interactions. CMS is proposing new rules and restrictions governing agent and broker activities and interaction with prospective enrollees, including required disclosures and limits on when outreach and communication may occur. CMS is also proposing additional rules on marketing by third-party marketing organizations (TPMOs) and plans' responsibilities to oversee that activity.

In general, CMS' proposals would become effective with the 2024 Plan Year (Fall 2023 annual election period [AEP] beginning on October 1, 2023). Further description of specific proposals and our comments follow below.

Cigna Comments:

Cigna agrees with CMS' assertion that beneficiaries should have access to complete, clear, and accurate information about their MA and Part D plan options that allows them to make an informed choice about their Medicare coverage and ensure they have the best plan to meet their needs. We agree beneficiaries must not be subject to misleading marketing or false information, but efforts to ensure complete and accurate information must not inadvertently make it more difficult or burdensome to get the information they need to make an informed choice. This includes access to representatives and licensed professionals who are best positioned to help beneficiaries understand what plan options are available to them and who can guide them through a sometimes complex enrollment process.

If finalized, these proposed rules would become effective for the 2024 Plan Year and AEP, which begins October 1. Depending on the timing of the publication of the final rule and any subsequent guidance, we are concerned that some proposals will not allow sufficient implementation time given the significant lead time required. **Cigna recommends CMS consider postponing the finalization of new sales and marketing regulations for the 2025 Plan Year / 2024 AEP.**

We offer additional feedback and recommendations on specific proposals below:

Proposals to Clarify Permissible Language and Representations in Marketing

- CMS is proposing to clarify when representations and logos of the Medicare name, CMS logo, and other official names and images may be used in MA marketing materials. CMS is proposing these changes to prevent their use in a "misleading" way. **Cigna supports this proposal, but we request additional clarity around permissible use, including examples showing when the use of names or images are acceptable and examples where they are "misleading."**

- CMS is proposing to further restrict the use of superlative statements unless supported by current data, with "current" defined as the current or previous plan year. **Cigna supports this proposal, but we request CMS provide additional clarity around permissible use, including additional examples to those contained in the proposed rule.**

- CMS is proposing to require certain disclaimers used in third-party marketing materials, including a list of all plans available by the seller and adding state health insurance programs (SHIPs) to the existing disclaimer. **Cigna supports CMS' proposal to provide clarity about what information to include and not include in marketing materials; however, as we state above, we ask CMS to consider implementing some changes for the 2025 Plan Year.** Given the timing of this proposed rule, and subsequent final rule and guidance, we are concerned there will be insufficient time for plans to update materials and obtain the necessary reviews and approvals by CMS in time for October 1 AEP.

- CMS is proposing to prohibit MA and Part D plans from including information about potential cost savings available to beneficiaries that are based on a comparison of typical expenses borne by uninsured individuals, unpaid costs of dually eligible beneficiaries, or other unrealized costs of a Medicare beneficiary. CMS is proposing this restriction to limit beneficiaries from being "enticed" about cost savings claims that may not be true. However, there is an often an objective, tangible cost benefit to individuals when comparing plan options or when comparing an MA plan to original Medicare. **While Cigna supports CMS' proposal to limit misleading statements**

that seek to entice beneficiaries, we request CMS confirm that certain cost comparisons remain permissible. We also suggest CMS consider specific required disclaimers or qualifiers when such comparisons are made.

Proposals to Modify Marketing Activities and Beneficiary Interactions

- CMS is proposing to prohibit marketing events from taking place within 12 hours of educational events in the same location. CMS explains this proposal is needed to give beneficiaries the option of leaving and not feeling pressured to attend the marketing event. While Cigna understands CMS' rationale for this proposal, we are concerned this restriction will create unnecessary barriers for beneficiaries, particularly those with transportation challenges or who live in rural communities. We also believe there are current guardrails in place to hold plans accountable to ensuring no beneficiary is pressured or misled into enrolling in a plan after an educational event (e.g., secret shopper programs, beneficiary complaints). **Cigna recommends CMS consider alternatives to this proposal. For example, CMS could require at least 30 minutes between events to give beneficiaries sufficient time to leave if they would like. CMS could also require a specific statement be made following educational events to clearly distinguish the two events, and to indicate that attendees may leave if they are not interested in the marketing event. Cigna opposes arbitrary restrictions that would create unnecessary barriers for certain beneficiaries and prevent them from engaging in appropriate marketing and enrollment events on the same day, in the same location.**

- CMS is proposing to reinstate the prohibition on accepting scope of appointment (SOA) cards and beneficiary contact information at educational events. CMS explains the purpose of this proposal is to address recent beneficiary complaints that *may* be partially a result of collecting this information at educational events. Cigna supports efforts to ensure the clarity and accuracy of information shared with beneficiaries about plan options. However, we believe a broad prohibition on collecting beneficiary contact information and SOAs at educational events is unnecessary and will inconvenience the beneficiary and add unnecessary complexity to the process of comparing Medicare coverage options. **Cigna recommends CMS not finalize this proposal.**

- CMS is proposing a new rule specifying that a beneficiary may only be contacted for six months after providing their contact information to a plan. Cigna believes this proposal will add unnecessary burden to beneficiaries by repeatedly being asked to opt into outreach. We also believe beneficiaries should be permitted to determine when and how they are contacted. **To that end, Cigna opposes this proposal and recommends CMS consider an alternative, such as requiring a statement or disclaimer reaffirming opt-out rights.**

- CMS is proposing to modify the pre-enrollment check list (PECL) to require a discussion of "effect on current coverage." CMS' rationale for this proposal is to address instances in which a beneficiary does not understand if enrolling in a specific plan will have an impact on their current coverage. Cigna agrees with CMS that beneficiaries should understand the impacts enrolling in a plan will have on their current coverage. However, we are concerned this proposal will require plan agents to have detailed knowledge of an individual's coverage that they may not have access to. **Cigna requests that CMS provide detailed guidance around specific scenarios that must be explained to meet this requirement, including the information about coverage implications in different scenarios.**

G. *Part D Medication Therapy Management (MTM) Program (§ 423.153(d))*

CMS is proposing to expand the eligibility criteria for receiving MTM services. Under current regulations, Part D plans are required to target beneficiaries for MTM programs if they have multiple chronic conditions, if they take multiple Part D-covered medications, and if they are expected to hit a certain level in Part D prescription drug costs in a given year. Plans currently have some discretion as to which chronic diseases to target. CMS' rationale for expanding the targeting criteria is to increase MTM program uptake rates, which it believes are too low.

CMS' specific proposals to expand MTM eligibility criteria are as follows:

- CMS is proposing to require plans to include *all* defined chronic conditions in their targeting criteria, rather than having the flexibility to target certain conditions. Current guidance defines nine specified core chronic conditions, and proposes to codify these nine in regulation, and to add HIV/AIDS to the list, for a new total of ten conditions. Plans would remain free to target beneficiaries beyond the core list or to include all diseases in their targeting criteria.
- CMS is proposing to lower the maximum number of covered Part D drugs beneficiaries be prescribed to be eligible from eight to five drugs. The changes make explicit that the definition of Part D drug for purposes of MTM eligibility includes all Part D maintenance drugs (as identified in "widely accepted, commercially or publicly available drug information databases" such as Medi-Span or First Databank). Plans would no longer be allowed to target only specific Part D drug classes.
- CMS is proposing to lower the cost threshold ($4,935 in 2023), which would now be based on the average annual cost of five generic prescriptions ($1,004 in 2020).

In total, CMS' proposals would significantly expand the population of beneficiaries that would be targeted by MTM programs.

Cigna Comments:

Cigna agrees with CMS that MTM is a critical tool in Part D to help manage the care of beneficiaries who are on complex and costly medication regimens. We believe MTM is of highest value when it is person-centered: provided at the right time, with the right level of intervention, to the right patient. While we appreciate CMS' efforts to expand these programs, we have significant concerns about the burdens and challenges plans and beneficiaries will face with this degree of expansion in a short time. We detail these concerns and additional comments below.

- **The proposal would de-value the benefit of MTM programs and introduce excess operational complexity too quickly.** First, the proposal would significantly increase the number of enrollees eligible for MTM. This would dilute plans' ability to target these interventions to those who would most benefit, and would siphon those resources to activities that provide less value and additional burden to beneficiaries. We believe this is in direct opposition to CMS' intent. Second, it would be difficult, if not impossible, to add the appropriate professional staff that would be needed to meet the new expansion requirements. And finally, the increased outreach and communication could frustrate beneficiaries who do not need or want MTM, and duplicate the efforts of MTM activities that are part of other care management programs an individual may be in. Increased abrasion with beneficiaries would likely lead to increased complaints.

- **Standalone Part D plans would face unique challenges.** As part of its proposal to expand the eligibility criteria to more conditions, CMS requests feedback on adding cancer to the list of targeted chronic conditions. Cancer treatment regimens, care

goals, and care patterns are extremely variable and complex. Part D plans do not have access to the level of medical data that would be needed to effectively target MTM programs; Part D (and even Part B) drug claims would be wholly insufficient to guide this process.

- **The proposal would negatively impact Stars.** In addition to operational considerations, the expansion in eligibility for MTM would negatively impact Star Ratings through performance on the MTM measure, and such an impact would likely apply industry wide. We have serious concerns about the overall impact to the MTM Stars measure and how it would interact with other Stars-related proposals in this rule (discussed later in these comments). Specifically, when combined with CMS' proposals to remove the cut point guardrails and eliminate the improvement standard, industry performance on the MTM measure will likely decline, resulting in even fewer resources available to meet the mandates of this expansion.

Because of these concerns, **Cigna strongly recommends CMS not finalize its proposal to expand MTM eligibility criteria in Part D at this time.** At a minimum, we urge CMS to delay any expansion until at least the 2025 plan year, phase in the expansion over several years, and consider moving the MTM measure to display only until the effects of expansion are understood.

Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (42 CFR 422.162, 422.164, 422.166, 422.260, 423.182, 423.184, and 423.186) (Section V)

CMS is proposing several updates and modifications to the MA and Part D Star Ratings system, including: adding, updating, or removing various measures; proposing several methodological changes; proposing a health equity index award factor; and proposing several technical changes to the policies around administration of the Star Ratings program. Cigna offers comments and recommendations on individual proposals contained throughout this section of the proposed rule below.

Cigna Comments:

Proposals to Modify Overall Star Ratings Methodology

- CMS proposes to reduce the weight of patient experience/complaints and access measures to further align the Part C and Part D Quality Rating System with other CMS programs. CMS previously increased the weight of these measures from 2x to 4x in a final rule published in June 2020. CMS explains that since then, it has received extensive stakeholder feedback and concerns with the decision to increase the weight of these measures, including a concern that it would disincentivize greater focus on measures related to patient outcomes, screenings, and preventive care. **Cigna strongly agrees with CMS' concerns and rationale.**

  Cigna strongly supports CMS' goal of reducing the weight of Access & Experience Star measures from 4 to 2 beginning with the 2026 Star Rating. Cigna values the voice of beneficiaries when evaluating the quality of care provided and places an emphasis on putting measures in place to improve customer experience. By increasing the value of data-driven evidence-based clinical measures and health outcomes in the total Star Rating, plans will be encouraged to prioritize and increase efforts to drive clinically appropriate care and promote health and safety. We believe this change will improve health outcomes long-term for Medicare beneficiaries as well as provide more stability in Star Rating outcomes.

- CMS proposes to limit the improvement hold harmless provision to 5 Star plans beginning with the 2026 Star Rating period. Under current regulations, 4.0- and 4.5-Star plans are also held harmless from the improvement measures, meaning that if a contract would have earned at least 4 Stars without the improvement measures, the overall contract Star Rating calculation would not include the improvement measures in the event that they would degrade the overall rating. This current policy aligns with CMS' quality standard for Quality Bonus Payments, which is also set at a minimum of 4 Stars as this broadly represents high performance. Cigna believes that if a contract genuinely performs at 4+ Stars (the CMS definition of high performance), even while facing a significant decline in measure performance from the prior year, it should not induce any penalties, especially penalties that could negatively impact plans' ability to offer robust benefits.

  Cigna also believes that limiting the improvement measure hold harmless provision to only 5-Star plans will further drive health equity disparities. Plan sponsors that manage a larger portion of customers with challenging health issues or issues related to SDOH may have a more difficult time achieving significant improvement when currently performing at a 4 or 4.5 Star level. Also, since the majority of measures that are included in the Part C and Part D improvement calculations are not case-mix adjusted (and Categorical Adjustment Index (CAI) is only applied at the summary rating level and the Health Equity Index (HEI) is also proposed to apply at the summary level), plan sponsors that grow within or expand into areas of need can find it particularly challenging to achieve significant improvements. Simply maintaining high performance while managing a high-risk population can result in little or no significant improvement for individual measures in the improvement calculation and can lead to earning a rating of 3 Stars on both 5-times weighted improvement measures, which then arbitrarily reduces the overall plan rating. Due to these reasons, **Cigna strongly believes that CMS should maintain the current improvement measure hold harmless provision which applies to contracts naturally earning a summary rating of 4 Stars or higher.**

- CMS proposes replacing the current Reward Factor with an HEI beginning with the 2027 Star Rating. The HEI would reward plans in instances where measure performance for beneficiaries with specific social risk factors, such as being a dual eligible or low-income subsidy (LIS), is similar to measure performance for beneficiaries without the social risk factors. Cigna commends CMS for its efforts to drive health equity across the diverse Medicare populations whom we jointly serve. Cigna offers the following recommendations regarding the HEI and Reward Factor Proposals:

  - **Cigna supports the continued research CMS is conducting on the impact of social risk factors on health outcomes and appreciates the further efforts to report data to plan sponsors stratified by important beneficiary subgroups.** CMS has developed the HEI and HEI Reward Factor as methodological enhancement to incentivize plan sponsors to focus quality improvements on socially at-risk beneficiaries. Cigna supports the development of the HEI and HEI Reward Factor as they align with our goals of improving health care quality for underserved and at-risk populations.

  - **We also support the retirement of the Reward Factor in favor of the more meaningful HEI Reward. However, we request that CMS publicly share the specific measures to be assessed as part of the HEI, such that plan sponsors are able to replicate CMS's calculations and conduct their own testing.** Currently, the proposed rule only provides examples of which measures would be included or excluded along with the general measure exclusion criteria. We request that additional details on methodology and results of the simulations performed using prior year Star data be provided to allow plans to better prepare for the proposed

change to the system.

- **Additionally, we request that CMS apply a phased-in approach for the new methodology whereas CMS would calculate both the Reward Factor and the HEI and apply a "better of" logic between the two for a period of two years before fully switching over to the HEI.**

- CMS proposes to eliminate 5% guardrails that were recently implemented to limit cut-point movement each year beginning with the 2026 Star Rating. Other cut-point adjustments including mean resampling and outlier removal using the Tukey Outer Fence model will remain in place. Cigna is concerned about the timing of making this change given the implementation of Tukey outlier deletion and mean resampling. We do not believe CMS or plans have sufficient experience or data to understand any unintended consequences of removing the guardrails, nor what impact that might have to predictability or stability in cut-points. **We encourage CMS to not finalize this change and consider reevaluating its proposal after we have more experience with Tukey and mean resampling.**

Proposals to Modify the Administration of the Star Ratings Program

- CMS proposes to codify that HEDIS[1], CAHPS[2], HOS[3], Part C & D Reporting Requirements, PDE[4], Medicare Plan Finder pricing files, data from the Medicare Beneficiary Suite of Systems, MARx[5] system, and other Federal Data Sources may not be used as the basis for a QBP[6] Reconsideration Administrative Review. Cigna is concerned this proposal will materially limit plan appeal rights, particularly the right for an administrative review, and will further limit CMS' discretion in reevaluating decisions made during the Plan Preview process. Cigna has experienced situations where some of these data sources were used as the basis for QBP Reconsideration Administrative Reviews. This has enabled CMS to reevaluate and appropriately overturn decisions the Agency made during the Stars Plan Preview. We are concerned this proposal will limit both plans and CMS in ensuring published Star Ratings are complete and accurate.

  Furthermore, we are concerned that "other Federal Data Sources" is a very broad term and may essentially negate the entire QBP Reconsideration Administrative Review process. **We encourage CMS not to finalize this proposal.**

- CMS proposes to revise a rule for non-substantive measure updates to add collection of survey data through another mode of survey administration to a list of non-substantive measure updates that can be made without rulemaking. **Cigna opposes CMS' proposal to add collection of survey data through another mode of survey administration to a list of non-substantive measure updates.** We are concerned that web-based respondents could create a source of bias in the data due to differences in socioeconomic factors, plan type, or geography and result in a material impact to contract performance. We recommend if a web-based mode of survey administration is added to mail and telephone, the change is considered substantive and performed through rulemaking. Additionally, we recommend this modality undergo consideration for inclusion in the case mix adjustment methodology for CAHPS and HOS administration based on observed differences. CMS proposes to expand the age range of the Colorectal Cancer Screening measure from 50-75 to 45-75, based on updated clinical recommendations and the National

[1] Healthcare Effectiveness Data and Information Set
[2] Consumer Assessment of Healthcare Providers and Systems
[3] Health Outcomes Survey
[4] Prescription Drug Event
[5] Medicare Advantage & Prescription Drug
[6] Quality Bonus Payment

Committee on Quality Assurance (NCQA) measure changes, for the 2026 Star year. The Colorectal Cancer Screening measure with its current age range will remain as a Star measure until then. **Cigna supports this proposal.**

Proposals to Add, Update, or Change Specific Measures

- CMS proposes to return Care for Older Adults – Functional Status Assessment as a Star for the 2026 Star year. The measure had been moved to display due to substantive specification changes. **Cigna supports this proposal.**

- CMS proposes to include risk adjustment based on sociodemographic status to the Medication Adherence measures (as recommended by the Pharmacy Quality Alliance [PQA]) for the 2028 Star year. Along with this change, CMS intends to remove these measures from CAI adjustment, align to the PQA continuous enrollment methodology, and remove adjustments for inpatient and skilled nursing facility (SNF) stays. CMS states that the addition of risk adjustment did not have a material impact to simulations they conducted using prior year Stars data, however removal from the CAI did have a marginal adverse impact to performance.

  Cigna generally agrees with CMS and PQA on the need to risk adjust medication adherence measures, at a minimum accounting for age, gender, dual eligibility/low-income subsidy status, and disability status. We also agree with the alignment to the PQA measure specifications for continuous enrollment during the treatment period instead of the current member-year methodology utilized by CMS. **However, Cigna strongly opposes the elimination of adjustments to the proportion of days covered (PDC) calculation, which accounts for days that a Medicare beneficiary is hospitalized or in a SNF stay.** Plan sponsors do not have the ability to impact medication adherence during an inpatient or SNF stay, and prescription claims for medications used during these stays are not included in the PDC calculation. Risk adjustment for socio-demographic factors does not directly account for inpatient or SNF stays and cannot serve as a substitute for this necessary adjustment. Exclusion of this adjustment to the PDC calculation may partially counteract what CMS is attempting to accomplish in measure equity through risk adjustment as it will have a larger impact to plans that manage medically higher-risk patients which often, but not always, have higher sociodemographic risks.

  Cigna also requests that CMS release additional details on the methodology for medication adherence risk adjustment beyond the framework provided by the PQA. For example, CMS should provide clear guidance on details such as whether the adjustments would be based on a current-year or prior-year risk model, and whether the risk model would be constructed using the beneficiary or the contract as the unit of analysis. We also strongly believe that CMS should create a risk adjustment process that is replicable by Part D sponsors such that it could be applied to internal claims data for real-time reporting.

  Cigna disagrees with CMS's proposal to apply the medication adherence risk adjustments only to the final set of Patient Safety Reports which are issued at the end of July after the measurement year has been completed. **We respectfully request that CMS instead provide monthly risk-adjusted beneficiary-level detail and contract summary data in the patient safety reports in order to provide ongoing transparency into the official risk-adjusted performance on the adherence measures. Finally, we request that CMS publicly release the results of the testing and simulations performed which are referred to in the proposed rule.**

- CMS proposes to add a single weighted Kidney Health Evaluation for Patients with Diabetes measure for the 2026 Star Rating year. The measure will replace the current Diabetes Care

– Kidney Disease Monitoring measure and will 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 Ration (UACR) during the measurement year. Cigna appreciates CMS adding the KED metric to the Stars program in the future. **We support following clinical guidelines and adding newly developed measures that are clinically relevant to replace old measures such as Comprehensive Diabetes Care: Attention to Nephropathy.** We also appreciate CMS's approach to put this measure on display as plans gain experience and learn more about the performance of this measure.

- CMS is proposing to include three new Part D measures in the 2026 Star Ratings:
  - Concurrent Use of Opioids and Benzodiazepines (COB) (Part D) - analyzes the percentage of Medicare Part D beneficiaries 18 years and older with concurrent use of prescription opioids and benzodiazepines.
  - Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (PolyACH) (Part D) - analyzes the percentage of Medicare Part D beneficiaries, 65 years or older, with concurrent use of two or more unique ACH medications during the measurement period.
  - Polypharmacy Use of Multiple Central Nervous System-Active Medications in Older Adults (Poly-CNS) (Part D) - analyzes the percentage of Medicare Part D beneficiaries, 65 years or older, with concurrent use of three or more unique CNS-active medications during the measurement period.

While these new measures are well-intended to help Part D plans better manage safety issues and potential abuse, we continue to have concerns about these measures, particularly the measures that include opioid medications in their specifications, being adopted in the Star Ratings program. We believe that including the two new measures which include opioid medications (COB and POLY-CNS) in the Star Rating program will have negative impacts on the perceived quality of care provided by plans solely based on them operating in geographic areas that are more heavily impacted by opioid abuse. This is especially significant where other SDOH, such as lower income and lower educational status, may also be present and creates an unbalanced playing field for plans operating in these areas. Additionally, this generates unnecessary headwinds for plans to earn quality bonus payments, keeping critical dollars away from plans that need funding for additional beneficiary services to help treat opioid-related issues. While CMS is planning to add the HEI to reward plans for managing beneficiaries with issues related to SDOH, we do not believe that it will adequately adjust to overcome the differences related to opioid use.

Cigna is also concerned about duplication and redundancy in these measures. Review of the 2023 CMS Display Measure specifications and medication lists shows that 97% of the medications included in the COB measure overlap with the medications also included in the POLY-CNS measure. Furthermore, analysis of the 2023 public Star Ratings Display data for the COB and POLY-CNS measures shows a statistical correlation between the two measures with approximately 44 percent of the contract-level observations being correlated. This demonstrates that plan sponsors may be penalized twice for the same set of opioid-using beneficiaries across these two measures. **For these reasons, we strongly believe the COB and POLY-CNS measures should not be included in the Star Ratings program.**

* * *

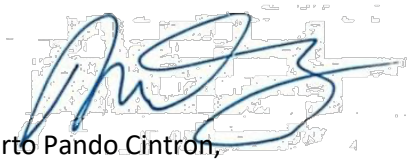
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improvement measure hold harmless policy is necessary for 4 star and 4.5 star contracts in Puerto Rico that have less room to improve.

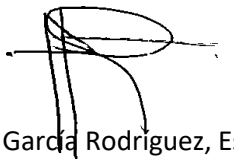
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Sincerely,

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Hypertension (RAS Antagonists), and Medication Adherence for Cholesterol (Statins) measures. We are also finalizing a rule for the removal of certain types of Star Ratings measures in the future; removal of the 60 percent rule that is part of the adjustment for extreme and uncontrollable circumstances (also called the disaster adjustment); and technical clarifications and changes related to the disaster adjustment, treatment of ratings for contracts after consolidation, and the correction of an error related to codification of the use of Tukey outlier deletion. Generally, these changes will apply (that is, data will be collected and performance measured) for the 2024 measurement period and the 2026 Star Ratings, except for the removal of the Part C Diabetes Care—Kidney Disease Monitoring measure, which will apply beginning with the 2024 Star Ratings; the HEI reward, which will apply beginning with the 2024 and 2025 measurement periods and the 2027 Star Ratings; the risk adjustment based on sociodemographic status characteristics to the three adherence measures, which will be implemented beginning with the 2026 measurement period and the 2028 Star Ratings; and addressing the codification error related to the use of Tukey outlier deletion which will be applicable upon the effective date of this final rule and apply beginning with the 2024 Star Ratings.

The remaining Star Ratings provisions of the proposed rule are not being finalized in this rule and instead will be addressed in a later final rule. Those provisions include removing the stand-alone Medication Reconciliation Post-Discharge measure; adding the updated Colorectal Cancer Screening and Care for Older Adults—Functional Status Assessment measures; adding the Part D Concurrent Use of Opioids and Benzodiazepines, Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults, and Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults measures; removing guardrails (that is, bi-directional caps that restrict upward and downward movement of a measure's cut points for the current year's measure-level Star Ratings compared to the prior year's measure-threshold specific cut points) when determining measure-specific-thresholds for non-Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures; modifying the Improvement Measure hold harmless policy; and adding technical clarifications related to Quality Bonus Payment (QBP) appeals and weighting of measures after a substantive specification change.

2. Health Equity in Medicare Advantage (MA) (§§ 422.111 and 422.112)

CMS is working to achieve policy goals that advance health equity across its programs and pursue a comprehensive approach to advancing health equity for all, including those who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality.[1] To that end, in addition to the health equity index, we are finalizing the following regulatory updates.

First, current regulations require MA organizations to ensure that services are provided in a culturally competent manner. The regulation provides examples of populations that may require consideration specific to their needs. In this final rule, we further clarify the broad application of our policy. Specifically, we are amending the list of populations to include people: (1) with limited English proficiency or reading skills; (2) of ethnic, cultural, racial, or religious minorities; (3) with disabilities; (4) who identify as lesbian, gay, bisexual, or other diverse sexual orientations; (5) who identify as transgender, nonbinary, and other diverse gender identities, or people who were born intersex; (6) who live in rural areas and other areas with high levels of deprivation; and (7) otherwise adversely affected by persistent poverty or inequality.

Next, CMS currently provides best practices for organizations to use in developing their provider directories, including incorporating non-English languages spoken by each provider and provider/location accessibility for people with physical disabilities. In this rule, we are codifying these best practices by requiring organizations to include providers' cultural and linguistic capabilities (including American Sign Language, ASL) in their provider directories. This change will improve the quality and usability of provider directories, particularly for non-English speakers, limited English proficient individuals, and enrollees who use ASL.

In addition, as the use of telehealth becomes more prevalent, there is evidence of disparities in telehealth access due in part to low digital health literacy, especially among populations who already experience health disparities. Low digital health literacy is one of the most significant obstacles in achieving telehealth equity, and many older adults with low digital health literacy experience gaps in access to the health care they need. This is concerning for the MA program because its enrollee population includes older adults who are age 65 or older, which is why we are finalizing policies to address the issue by requiring MA organizations to develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy to assist with accessing any medically necessary covered telehealth benefits. We solicited comments from stakeholders on various aspects of our proposal, which informed the types of MA plans we are subjecting to the finalized regulatory requirements, and how we will collect information related to compliance with these requirements.

Finally, MA organizations' existing quality improvement (QI) programs are an optimal vehicle to develop and implement strategies and policies designed to reduce disparities in health and health care, and advance equity in the health and health care of MA enrollee populations, especially those that are underserved. To support these efforts, we will require MA organizations to incorporate one or more activities into their overall QI program that reduce disparities in health and health care among their enrollees. MA organizations may implement activities such as improving communication, developing and using linguistically and culturally appropriate materials (to distribute to enrollees or use in communicating with enrollees), hiring bilingual staff, community outreach, or similar activities. We believe adopting this proposed requirement for MA organizations as part of their required QI programs will align with health equity efforts across CMS policies and programs.

3. Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools (§§ 422.101, 422.112, 422.137, 422.138, and 422.202)

In recent years, CMS has received numerous inquiries regarding MA organizations' use of prior authorization and its effect on beneficiary access to care. We are finalizing several regulatory changes to address these concerns regarding prior authorization. First, we are finalizing that prior authorization policies for coordinated care plans may only be used to confirm

[1] *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.*

We solicited comments on this proposal.

Comment: All commenters supported our proposal to clarify the timing for HOS disaster adjustments.

Response: CMS appreciates the support for clarifying the timing of the HOS measure adjustments for extreme and uncontrollable circumstances at § 422.166(i)(3)(iv).

Comment: A commenter suggested that CMS provide additional clarification on the recall period for HOS measures and the ''hold harmless'' timing for the adjustment for extreme and uncontrollable circumstances.

Response: The measurement period or ''recall period'' is defined by the measure steward. NCQA is the measure steward for the three HEDIS–HOS measures derived from the HOS. As noted by the title of NCQA's technical manual for the 2021 HOS data collection, *HEDIS MY 2020 Volume 6: Specifications for the Medicare Health Outcomes Survey,* the measurement period is one year prior to data collection. Since 2020, HOS survey administration occurs in late summer through fall. HOS is currently fielded from late July through early November.

For Part C measures derived from HOS, the disaster adjustment is three years after the extreme and uncontrollable circumstance. That is, contracts affected by an extreme and uncontrollable circumstance in the year prior to data collection are essentially ''held harmless'' and receive the higher of the previous or current year's Star Rating for each HOS and HEDIS–HOS measure (and corresponding measure score) for the Star Ratings 3 years after the eligible extreme and uncontrollable circumstance. For example, contracts affected by an extreme and uncontrollable circumstance in 2021 will receive the higher of their 2023 or 2024 measure-level Star Rating (and corresponding measure score) for each HOS and HEDIS–HOS measure in the 2024 Star Ratings as described at § 422.166(i)(3)(iv).

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the clarification at § 422.166(i)(3)(iv) as proposed without modification.

H. Calculation of Star Ratings (§§ 422.166(a)(2)(i) and 423.186(a)(2)(i))

In the June 2020 final rule, we finalized use of Tukey outlier deletion effective for the Star Ratings issued in October 2023 and subsequent years. (85 FR 33833–36). In the rulemakings since that time, we have not proposed to eliminate the Tukey outlier deletion aspect of the Star Ratings methodology. In a final rule that appeared in the **Federal Register** on January 19, 2021, we noted how the Tukey outlier deletion provision had been adopted for the Part C and Part D Quality Star Ratings. (86 FR 5917). As we stated in May 2022 final rule (87 FR 27766), we will implement Tukey outlier deletion beginning with the 2024 Star Ratings to help improve stability of cut points and prevent cut points from being influenced by outliers. We further stated that with Tukey outlier deletion, extreme outliers will be removed from measure scores prior to clustering to prevent outliers from impacting cut points for all contracts. However, it appears that the sentence in §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) (''Effective for the Star Ratings issued in October 2023 and subsequent years, prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed.'') was inadvertently removed from the codified regulation text. At no point did CMS propose removal of the Tukey outlier provision and CMS has, since its adoption in the June 2020 final rule, discussed implementation and application of the Tukey outlier provision when applicable. We proposed a technical amendment to fix this codification error from the May 2022 final rule. In addition, although the provision regarding application of the Tukey outlier deletion policy was originally at the end of paragraph (a)(2)(i) in each regulation, we also proposed a non-substantive technical change to move the sentence about removal of Tukey outer fence outliers earlier in §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) since Tukey outlier deletion is applied prior to the other steps. We believe that this makes the regulation text clearer.

We solicited comments on this proposal.

Comment: Some commenters were concerned that Tukey outlier deletion would result in disproportionate losses of QBPs among D–SNPs. They cite an analysis performed by ZAHealth that found that the outlier policy would result in 14 percent of D–SNP contracts losing their QBPs compared to 7 percent of non-D–SNPs, and 27 percent of D–SNPs losing rebate dollars compared to 20 percent of non-D–SNPs.

Response: We are unable to replicate the findings of ZAHealth. Based on our simulations, we do not believe that contracts with D–SNPs will be disproportionately impacted by Tukey outlier deletion. Using the 2023 Star Ratings data, we examined the impact of introducing Tukey outlier deletion assuming no guardrails. In the simulation, approximately 8.2 percent of contracts with D–SNPs and 9.5 percent of contracts without D–SNPs would lose a QBP by their overall rating decreasing from 4 to 3.5 stars overall with Tukey outlier deletion compared to without Tukey outlier deletion. The percentage of contracts losing a QBP is slightly higher for non-D–SNP contracts. In the simulation, 13.6 percent of contracts with D–SNPs would have a decrease in rebates or lose rebates compared to 10.5 percent of contracts without D–SNPs, a very small difference.

Comment: A commenter stated that CMS should withdraw its proposed Tukey outlier deletion for the 2024 Star Ratings as it will create new hurdles for plans that are trying to improve their ratings. Another commenter supported Tukey outlier deletion but raised challenges in the industry implementing multiple changes in the Star Ratings over the next few years, while another commenter suggested CMS delay implementation.

Response: Tukey outlier deletion is the only methodological enhancement to the 2024 Star Ratings. The only other changes for the 2024 Star Ratings are the addition of two new measures, Transitions of Care and Follow-up after Emergency Department Visit for Patients with Multiple Chronic Conditions measures, to the Part C Star Ratings that have been on the display page since the 2020 Star Ratings (2018 measurement year) finalized in the January 2021 final rule (86 FR 5921–26) and the return of the updated Plan All-Cause Readmissions measure finalized in the April 2019 final rule,[169] a measure that has been included in the Star Ratings program since the 2012 Star Ratings. CMS finalized the application of Tukey outlier deletion for non-CAHPS measures beginning with the 2024 Star Ratings in the CY 2021 final rule published in June 2020 so this is not a new enhancement and contracts have been on notice of this upcoming change. For the 2025 Star Ratings, there are no additional measures or methodological enhancements. The primary goal of setting cut points is to disaggregate the distribution of scores into discrete categories such that each grouping accurately reflects true performance. (85 FR 15752). Tukey outlier deletion supports this goal by helping stabilize

[169] See the Announcement of Calendar Year (CY) 2022 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies, page 97, which delayed the return of the Plan All-Cause Readmissions measure to the Star Ratings for an additional year due to the disruption to data collection posed by the COVID–19 pandemic.

(1) To confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations for the specific item or service; or

(2) For basic benefits, to ensure an item or service is medically necessary based on standards specified in § 422.101(c)(1), or

(3) For supplemental benefits, to ensure that the furnishing of a service or benefit is clinically appropriate.

(c) *Effect of prior authorization or pre-service approval.* If the MA organization approved the furnishing of a covered item or service through a prior authorization or pre-service determination of coverage or payment, it may not deny coverage later on the basis of lack of medical necessity and may not reopen such a decision for any reason except for good cause (as provided at § 405.986 of this chapter) or if there is reliable evidence of fraud or similar fault per the reopening provisions at § 422.616. The definitions of the terms ''reliable evidence'' and ''similar fault'' in § 405.902 of this chapter apply to this provision.

■ 14. Section 422.152 is amended by adding paragraph (a)(5) to read as follows:

§ 422.152 Quality Improvement Program.

(a) * * *

(5) Incorporate one or more activities that reduce disparities in health and health care. These activities must be broadly accessible irrespective of race, ethnicity, national origin, religion, sex, or gender. These activities may be based upon health status and health needs, geography, or factors not listed in the previous sentence only as appropriate to address the relevant disparities in health and health care.

* * * * *

■ 15. Section 422.162 is amended by—

■ a. In paragraph (a) adding in alphabetical order a definition for ''health equity index'' and a revision to the definition of ''highly-rated contract''; and

■ b. Revising paragraphs (b)(1) and (b)(3)(iv)(A)(*1*).

The addition and revisions read as follows:

§ 422.162 Medicare Advantage Quality Rating System.

(a) * * *

Health equity index means an index that summarizes contract performance among those with specified social risk factors (SRFs) across multiple measures into a single score.

* * * * *

Highly-rated contract means a contract that has 4 or more stars for its highest rating when calculated without the improvement measures and with all applicable adjustments in § 422.166(f).

* * * * *

(b) * * * (1) *General.* CMS calculates an overall Star Rating, Part C summary rating, and Part D summary rating for each MA–PD contract, and a Part C summary rating for each MA-only contract using the 5-star rating system described in this subpart. Measures are assigned stars at the contract level and weighted in accordance with § 422.166(a). Domain ratings are the unweighted mean of the individual measure ratings under the topic area in accordance with § 422.166(b). Summary ratings are the weighted mean of the individual measure ratings for Part C or Part D in accordance with § 422.166(c), with the applicable adjustments provided in paragraph (f) of this section. Overall Star Ratings are calculated by using the weighted mean of the individual measure ratings in accordance with § 422.166(d), with the applicable adjustments provided in paragraph (f) of this section. CMS includes the Star Ratings measures in the overall and summary ratings that are associated with the contract type for the Star Ratings year.

* * * * *

(3) * * *

(iv) * * *

(A)(*1*) For the first year after consolidation, CMS uses enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts for all measures, except survey-based measures, call center measures, and improvement measures. The survey-based measures will use enrollment of the surviving and consumed contracts at the time the sample is pulled for the rating year. The call center measures will use average enrollment during the study period. The Part C and D improvement measures are not calculated for first year consolidations.

* * * * *

■ 16. Section 422.164 is amended by adding paragraph (e)(1)(iii) to read as follows:

§ 422.164 Adding, updating, and removing measures.

* * * * *

(e) * * *

(1) * * *

(iii) The measure steward other than CMS retires a measure.

* * * * *

■ 17. Section 422.166 is amended by—

■ a. Revising paragraphs (a)(2)(i), (c)(1), (d)(1), (e)(1)(iii) and (iv), (f)(1) introductory text, and (f)(2)(i) introductory text;

■ b. Adding paragraph (f)(3); and

■ c. Revising paragraphs (g)(1), (i)(3)(iv), (i)(9)(i), and (i)(10)(i).

The revisions and addition read as follows:

§ 422.166 Calculation of Star Ratings.

(a) * * *

(2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data. Effective for the Star Ratings issued in October 2023 and subsequent years, prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed. Effective for the Star Ratings issued in October 2022 and subsequent years, CMS will add a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from 1 year to the next. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for 3 years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years in the program.

* * * * *

(c) * * *

(1) CMS will calculate the Part C summary ratings using the weighted mean of the measure-level Star Ratings for Part C, weighted in accordance with paragraph (e) of this section and with the applicable adjustments provided in paragraph (f) of this section.

* * * * *

(d) * * *

(1) The overall rating for a MA–PD contract will be calculated using a weighted mean of the Part C and Part D measure-level Star Ratings, weighted in accordance with paragraph (e) of this section and with the applicable adjustments provided in paragraph (f) of this section.

* * * * *

(e) * * *

(1) * * *

(iii) Through the 2025 Star Ratings, patient experience and complaint measures receive a weight of 4. Starting with the 2026 Star Ratings and subsequent Star Ratings years, patient experience and complaint measures receive a weight of 2.

DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTER FOR MEDICARE

DATE: December 19, 2022

TO: All Part C and D Plan Sponsors

FROM: Amy Larrick Chavez-Valdez
Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: Part C and D Star Ratings Tukey Outlier Deletion Simulations

In the final rule "Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program" (CMS-4190-F), published in the Federal Register on June 2, 2020 (the CY 2021 Final Rule)[1], CMS finalized the addition of Tukey outer fence outlier deletion to the clustering methodology beginning with the 2024 Part C and D Star Ratings. We finalized applying Tukey outlier deletion prior to mean resampling and hierarchical clustering for non- Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS®) measures and measures that have been in the Star Ratings program for more than three years (85 FR 33832–33836).

We are now providing simulations of Tukey outlier deletion with mean resampling and guardrails for the 2022 and 2023 Star Ratings. As we stated in the CY 2021 Final Rule, for the first year that Tukey outlier deletion is implemented (2024 Star Ratings), we will rerun the prior year's thresholds using mean resampling and Tukey outlier deletion so that guardrails will be applied consistently between years. Therefore, in the simulations, the 2022 Star Ratings thresholds were recalculated applying mean resampling and Tukey outlier deletion.

The Tukey outlier deletion simulations and Technical Notes are available to view on the CMS.gov website on this page: http://go.cms.gov/partcanddstarratings. Please email any questions on the Part C and D Star Ratings Tukey outlier deletion simulations to PartCandDStarRatings@cms.hhs.gov.

Thank you for your continued commitment to ensure the success of the Medicare Advantage and Prescription Drug programs.

[1] https://www.govinfo.gov/content/pkg/FR-2020-06-02/pdf/2020-11342.pdf

Technical Notes for Star Ratings Tukey Outlier Deletion Simulations

There are four tabs in the Tukey Outlier Deletion Simulations Excel file. The data on each tab are explained below. These simulations include identification of Tukey outer fence outliers which are defined as measure scores that are below a certain point (first quartile−3.0 × (third quartile−first quartile)) or above a certain point (third quartile + 3.0 × (third quartile−first quartile)).

Part C Outlier Cutoffs: This tab shows the simulated upper and lower Tukey outer fence outlier cutoffs for the 2022 and 2023 Star Ratings for each applicable Part C Star Ratings measure. If the calculated outlier cutoff is below the minimum or exceeds the maximum value for the given measure, then the minimum or maximum value is displayed as the cutoff.

Part D Outlier Cutoffs: This tab shows the simulated upper and lower Tukey outer fence outlier cutoffs for the 2022 and 2023 Star Ratings for each applicable Part D Star Ratings measure for each type of contract (MA-PD and PDP). If the calculated outlier cutoff is below the minimum or exceeds the maximum value for the given measure, then the minimum or maximum value is displayed as the cutoff.

2022 Star Ratings Cut Points: This tab shows two sets of cut points for the 2022 Star Ratings: (1) the actual cut points as calculated for the 2022 Star Ratings, and (2) simulated cut points for the 2022 Star Ratings calculated including Tukey outlier deletion. Neither set of cut points includes guardrails. The actual cut points are identified by 'Actual' in the 'Actual/Simulated Cut Points' column and blue highlighting, and the simulated cut points are identified by 'Simulated' in the 'Actual/Simulated Cut Points' column.

2023 Star Ratings Cut Points: This tab shows two sets of cut points for the 2023 Star Ratings: (1) the actual cut points as calculated for the 2023 Star Ratings including guardrails based on the actual 2022 Star Ratings cut points, (2) simulated cut points for the 2023 Star Ratings calculated including Tukey outlier deletion and guardrails based on the simulated 2022 Star Ratings cut points that included Tukey outlier deletion. The actual cut points are identified by 'Actual' in the 'Actual/Simulated Cut Points' column and blue highlighting, and the simulated cut points are identified by 'Simulated' in the 'Actual/Simulated Cut Points' column.

On both the 2022 Star Ratings Cut Points and 2023 Star Ratings Cut Points tabs, the four cut point thresholds are listed for each measure. These thresholds may be interpreted as shown in the following example for the actual 2023 Star Rating cut points for Breast Cancer Screening (C01).

- The 'Cut Point for 1 to 2 Stars' is 43. This means scores less than 43% correspond to 1 star.
- The 'Cut Point for 2 to 3 Stars' is 62. This means scores greater than or equal to 43% and less than 62% correspond to 2 stars.
- The 'Cut Point for 3 to 4 Stars' is 70. This means scores greater than or equal to 62% and less than 70% correspond to 3 stars.
- The 'Cut Point for 4 to 5 Stars' is 77. This means scores greater than or equal to 70% and less than 77% correspond to 4 stars, and scores greater than or equal to 77% correspond to 5 stars.

Star Ratings Year	2022 Star Ratings Measure ID	2023 Star Ratings Measure ID	Measure Name	Lower Outlier Cutoff	Upper Outlier Cutoff
2022	C01	C01	Breast Cancer Screening	34	100
2023	C01	C01	Breast Cancer Screening	29	100
2022	C02	C02	Colorectal Cancer Screening	35	100
2023	C02	C02	Colorectal Cancer Screening	31	100
2022	C04	C04	Monitoring Physical Activity	25	74
2023	C04	C04	Monitoring Physical Activity	25	74
2022	C05	C05	Special Needs Plan (SNP) Care Management	0	100
2023	C05	C05	Special Needs Plan (SNP) Care Management	0	100
2022	C06	C06	Care for Older Adults – Medication Review	51	100
2023	C06	C06	Care for Older Adults – Medication Review	58	100
2022	C07	C07	Care for Older Adults – Pain Assessment	61	100
2023	C07	C07	Care for Older Adults – Pain Assessment	57	100
2022	C08	C08	Osteoporosis Management in Women who had a Fracture	0	100
2023	C08	C08	Osteoporosis Management in Women who had a Fracture	0	100
2022	C09	C09	Diabetes Care – Eye Exam	26.5	100
2023	C09	C09	Diabetes Care – Eye Exam	27	100
2022	C10	C10	Diabetes Care – Kidney Disease Monitoring	84	100
2023	C10	C10	Diabetes Care – Kidney Disease Monitoring	85	100
2022	C11	C11	Diabetes Care – Blood Sugar Controlled	35	100
2023	C11	C11	Diabetes Care – Blood Sugar Controlled	49	100
2022	DMC	C12	Controlling Blood Pressure		
2023	DMC	C12	Controlling Blood Pressure	37	100
2022	C13	C13	Reducing the Risk of Falling	19	89
2023	C13	C13	Reducing the Risk of Falling	19	89
2022	C14	C14	Improving Bladder Control	24.5	66.5
2023	C14	C14	Improving Bladder Control	21	70
2022	C15	C15	Medication Reconciliation Post-Discharge	0	100
2023	C15	C15	Medication Reconciliation Post-Discharge	0	100
2022	C16	C16	Statin Therapy for Patients with Cardiovascular Disease	66	100
2023	C16	C16	Statin Therapy for Patients with Cardiovascular Disease	67	100
2022	C23	C23	Complaints about the Health Plan	0	0.79

Star Ratings Year	2022 Star Ratings Measure ID	2023 Star Ratings Measure ID	Measure Name	Lower Outlier Cutoff	Upper Outlier Cutoff
2023	C23	C23	Complaints about the Health Plan	0	1.12
2022	C24	C24	Members Choosing to Leave the Plan	0	62
2023	C24	C24	Members Choosing to Leave the Plan	0	71
2022	C26	C26	Plan Makes Timely Decisions about Appeals	80	100
2023	C26	C26	Plan Makes Timely Decisions about Appeals	84	100
2022	C27	C27	Reviewing Appeals Decisions	74	100
2023	C27	C27	Reviewing Appeals Decisions	77	100
2022	C28	C28	Call Center – Foreign Language Interpreter and TTY Availability	71	100
2023	C28	C28	Call Center – Foreign Language Interpreter and TTY Availability	50	100

Type of Contract	Star Ratings Year	2022 Star Ratings Measure ID	2023 Star Ratings Measure ID	Measure Name	Lower Outlier Cutoff	Upper Outlier Cutoff
MAPD	2022	D01	D01	Call Center – Foreign Language Interpreter and TTY Availability	74	100
MAPD	2023	D01	D01	Call Center – Foreign Language Interpreter and TTY Availability	42	100
MAPD	2022	D02	D02	Complaints about the Drug Plan	0	0.79
MAPD	2023	D02	D02	Complaints about the Drug Plan	0	1.12
MAPD	2022	D03	D03	Members Choosing to Leave the Plan	0	62
MAPD	2023	D03	D03	Members Choosing to Leave the Plan	0	71
MAPD	2022	D07	D07	MPF Price Accuracy	72	100
MAPD	2023	D07	D07	MPF Price Accuracy	67	100
MAPD	2022	D08	D08	Medication Adherence for Diabetes Medications	72	100
MAPD	2023	D08	D08	Medication Adherence for Diabetes Medications	72	100
MAPD	2022	D09	D09	Medication Adherence for Hypertension (RAS antagonists)	70	100
MAPD	2023	D09	D09	Medication Adherence for Hypertension (RAS antagonists)	74	100
MAPD	2022	D10	D10	Medication Adherence for Cholesterol (Statins)	69	100
MAPD	2023	D10	D10	Medication Adherence for Cholesterol (Statins)	69	100
MAPD	2022	D11	D11	MTM Program Completion Rate for CMR	46	100
MAPD	2023	D11	D11	MTM Program Completion Rate for CMR	49	100
MAPD	2022	D12	D12	Statin Use in Persons with Diabetes (SUPD)	69	97
MAPD	2023	D12	D12	Statin Use in Persons with Diabetes (SUPD)	67	100
PDP	2022	D01	D01	Call Center – Foreign Language Interpreter and TTY Availability	50	100
PDP	2023	D01	D01	Call Center – Foreign Language Interpreter and TTY Availability	74	100
PDP	2022	D02	D02	Complaints about the Drug Plan	0	0.25
PDP	2023	D02	D02	Complaints about the Drug Plan	0	0.34
PDP	2022	D03	D03	Members Choosing to Leave the Plan	0	45
PDP	2023	D03	D03	Members Choosing to Leave the Plan	0	30
PDP	2022	D07	D07	MPF Price Accuracy	68	100

Type of Contract	Star Ratings Year	2022 Star Ratings Measure ID	2023 Star Ratings Measure ID	Measure Name	Lower Outlier Cutoff	Upper Outlier Cutoff
PDP	2023	D07	D07	MPF Price Accuracy	70	100
PDP	2022	D08	D08	Medication Adherence for Diabetes Medications	76	97
PDP	2023	D08	D08	Medication Adherence for Diabetes Medications	76	97
PDP	2022	D09	D09	Medication Adherence for Hypertension (RAS antagonists)	78	99
PDP	2023	D09	D09	Medication Adherence for Hypertension (RAS antagonists)	82	96
PDP	2022	D10	D10	Medication Adherence for Cholesterol (Statins)	77	98
PDP	2023	D10	D10	Medication Adherence for Cholesterol (Statins)	77	98
PDP	2022	D11	D11	MTM Program Completion Rate for CMR	0	100
PDP	2023	D11	D11	MTM Program Completion Rate for CMR	0	100
PDP	2022	D12	D12	Statin Use in Persons with Diabetes (SUPD)	70	91
PDP	2023	D12	D12	Statin Use in Persons with Diabetes (SUPD)	72	93

Type of Contract	Actual/Simulated Cut Points	Tukey Outlier Deletion	2022 Star Ratings Measure ID	Measure Name	Cut Point for 1 to 2 Stars	Cut Point for 2 to 3 Stars	Cut Point for 3 to 4 Stars	Cut Point for 4 to 5 Stars
MA	Simulated	Yes	C01	Breast Cancer Screening	58	67	73	78
MA	Actual	No	C01	Breast Cancer Screening	38	61	69	76
MA	Simulated	Yes	C02	Colorectal Cancer Screening	55	66	73	80
MA	Actual	No	C02	Colorectal Cancer Screening	48	62	71	80
MA	Simulated	Yes	C04	Monitoring Physical Activity	42	47	52	57
MA	Actual	No	C04	Monitoring Physical Activity	42	47	52	57
MA	Simulated	Yes	C05	Special Needs Plan (SNP) Care Management	45	59	73	87
MA	Actual	No	C05	Special Needs Plan (SNP) Care Management	45	59	73	87
MA	Simulated	Yes	C06	Care for Older Adults – Medication Review	68	80	88	96
MA	Actual	No	C06	Care for Older Adults – Medication Review	48	71	84	95
MA	Simulated	Yes	C07	Care for Older Adults – Pain Assessment	77	87	92	96
MA	Actual	No	C07	Care for Older Adults – Pain Assessment	55	76	87	96
MA	Simulated	Yes	C08	Osteoporosis Management in Women who had a Fracture	27	40	50	68
MA	Actual	No	C08	Osteoporosis Management in Women who had a Fracture	27	40	50	68
MA	Simulated	Yes	C09	Diabetes Care – Eye Exam	53	63	72	79
MA	Actual	No	C09	Diabetes Care – Eye Exam	52	62	71	79
MA	Simulated	Yes	C10	Diabetes Care – Kidney Disease Monitoring	92	94	96	97
MA	Actual	No	C10	Diabetes Care – Kidney Disease Monitoring	75	88	94	97
MA	Simulated	Yes	C11	Diabetes Care – Blood Sugar Controlled	58	69	77	84
MA	Actual	No	C11	Diabetes Care – Blood Sugar Controlled	40	60	72	81
MA	Simulated	Yes	C13	Reducing the Risk of Falling	48	54	61	70
MA	Actual	No	C13	Reducing the Risk of Falling	48	55	64	72
MA	Simulated	Yes	C14	Improving Bladder Control	42	45	49	53
MA	Actual	No	C14	Improving Bladder Control	42	45	49	53
MA	Simulated	Yes	C15	Medication Reconciliation Post-Discharge	39	56	69	82
MA	Actual	No	C15	Medication Reconciliation Post-Discharge	39	56	69	82
MA	Simulated	Yes	C16	Statin Therapy for Patients with Cardiovascular Disease	76	81	84	89
MA	Actual	No	C16	Statin Therapy for Patients with Cardiovascular Disease	76	81	84	89
MA	Simulated	Yes	C23	Complaints about the Health Plan	0.46	0.31	0.17	0.08
MA	Actual	No	C23	Complaints about the Health Plan	1.39	0.81	0.37	0.17
MA	Simulated	Yes	C24	Members Choosing to Leave the Plan	37	26	16	8

Type of Contract	Actual/Simulated Cut Points	Tukey Outlier Deletion	2022 Star Ratings Measure ID	Measure Name	Cut Point for 1 to 2 Stars	Cut Point for 2 to 3 Stars	Cut Point for 3 to 4 Stars	Cut Point for 4 to 5 Stars
MA	Actual	No	C24	Members Choosing to Leave the Plan	44	29	16	9
MA	Simulated	Yes	C26	Plan Makes Timely Decisions about Appeals	86	91	96	98
MA	Actual	No	C26	Plan Makes Timely Decisions about Appeals	64	80	90	97
MA	Simulated	Yes	C27	Reviewing Appeals Decisions	83	90	95	98
MA	Actual	No	C27	Reviewing Appeals Decisions	65	84	91	96
MA	Simulated	Yes	C28	Call Center – Foreign Language Interpreter and TTY Availability	81	87	94	100
MA	Actual	No	C28	Call Center – Foreign Language Interpreter and TTY Availability	31	54	78	94
MAPD	Simulated	Yes	D01	Call Center – Foreign Language Interpreter and TTY Availability	84	89	94	97
MAPD	Actual	No	D01	Call Center – Foreign Language Interpreter and TTY Availability	25	59	84	94
MAPD	Simulated	Yes	D02	Complaints about the Drug Plan	0.46	0.31	0.17	0.08
MAPD	Actual	No	D02	Complaints about the Drug Plan	1.39	0.81	0.37	0.17
MAPD	Simulated	Yes	D03	Members Choosing to Leave the Plan	37	26	16	8
MAPD	Actual	No	D03	Members Choosing to Leave the Plan	44	29	16	9
MAPD	Simulated	Yes	D07	MPF Price Accuracy	78	87	91	96
MAPD	Actual	No	D07	MPF Price Accuracy	73	83	91	96
MAPD	Simulated	Yes	D08	Medication Adherence for Diabetes Medications	81	85	88	92
MAPD	Actual	No	D08	Medication Adherence for Diabetes Medications	80	85	87	91
MAPD	Simulated	Yes	D09	Medication Adherence for Hypertension (RAS antagonists)	81	85	88	90
MAPD	Actual	No	D09	Medication Adherence for Hypertension (RAS antagonists)	73	82	87	90
MAPD	Simulated	Yes	D10	Medication Adherence for Cholesterol (Statins)	80	84	88	92
MAPD	Actual	No	D10	Medication Adherence for Cholesterol (Statins)	78	83	87	91
MAPD	Simulated	Yes	D11	MTM Program Completion Rate for CMR	66	76	83	89
MAPD	Actual	No	D11	MTM Program Completion Rate for CMR	52	72	82	89
MAPD	Simulated	Yes	D12	Statin Use in Persons with Diabetes (SUPD)	76	81	84	88
MAPD	Actual	No	D12	Statin Use in Persons with Diabetes (SUPD)	76	80	84	88
PDP	Simulated	Yes	D01	Call Center – Foreign Language Interpreter and TTY Availability	80	89	94	100
PDP	Actual	No	D01	Call Center – Foreign Language Interpreter and TTY Availability	55	78	88	97

Type of Contract	Actual/Simulated Cut Points	Tukey Outlier Deletion	2022 Star Ratings Measure ID	Measure Name	Cut Point for 1 to 2 Stars	Cut Point for 2 to 3 Stars	Cut Point for 3 to 4 Stars	Cut Point for 4 to 5 Stars
PDP	Simulated	Yes	D02	Complaints about the Drug Plan	0.14	0.08	0.04	0.01
PDP	Actual	No	D02	Complaints about the Drug Plan	0.31	0.19	0.1	0.03
PDP	Simulated	Yes	D03	Members Choosing to Leave the Plan	21	14	9	6
PDP	Actual	No	D03	Members Choosing to Leave the Plan	21	14	9	6
PDP	Simulated	Yes	D07	MPF Price Accuracy	84	88	94	97
PDP	Actual	No	D07	MPF Price Accuracy	84	88	94	97
PDP	Simulated	Yes	D08	Medication Adherence for Diabetes Medications	84	86	88	90
PDP	Actual	No	D08	Medication Adherence for Diabetes Medications	84	86	88	90
PDP	Simulated	Yes	D09	Medication Adherence for Hypertension (RAS antagonists)	85	88	89	91
PDP	Actual	No	D09	Medication Adherence for Hypertension (RAS antagonists)	85	88	89	91
PDP	Simulated	Yes	D10	Medication Adherence for Cholesterol (Statins)	84	87	88	90
PDP	Actual	No	D10	Medication Adherence for Cholesterol (Statins)	82	86	88	90
PDP	Simulated	Yes	D11	MTM Program Completion Rate for CMR	31	46	61	73
PDP	Actual	No	D11	MTM Program Completion Rate for CMR	31	46	61	73
PDP	Simulated	Yes	D12	Statin Use in Persons with Diabetes (SUPD)	77	79	82	84
PDP	Actual	No	D12	Statin Use in Persons with Diabetes (SUPD)	77	79	82	84

Type of Contract	Actual/Simulated Cut Points	Tukey Outlier Deletion	Guardrails	2022 Star Ratings Measure ID	2023 Star Ratings Measure ID	Measure Name	Cut Point for 1 to 2 Stars	Cut Point for 2 to 3 Stars	Cut Point for 3 to 4 Stars	Cut Point for 4 to 5 Stars
MA	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	C01	C01	Breast Cancer Screening	53	63	71	76
MA	Actual	No	Based on 2022 Star Ratings cutpoints	C01	C01	Breast Cancer Screening	43	62	70	77
MA	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	C02	C02	Colorectal Cancer Screening	55	66	74	81
MA	Actual	No	Based on 2022 Star Ratings cutpoints	C02	C02	Colorectal Cancer Screening	43	60	71	79
MA	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	C04	C04	Monitoring Physical Activity	44	49	53	57
MA	Actual	No	Based on 2022 Star Ratings cutpoints	C04	C04	Monitoring Physical Activity	44	49	53	57
MA	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	C05	C05	Special Needs Plan (SNP) Care Management	46	62	75	85
MA	Actual	No	Based on 2022 Star Ratings cutpoints	C05	C05	Special Needs Plan (SNP) Care Management	46	62	75	85
MA	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	C06	C06	Care for Older Adults – Medication Review	73	82	91	96
MA	Actual	No	Based on 2022 Star Ratings cutpoints	C06	C06	Care for Older Adults – Medication Review	43	70	82	93
MA	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	C07	C07	Care for Older Adults – Pain Assessment	73	83	89	95
MA	Actual	No	Based on 2022 Star Ratings cutpoints	C07	C07	Care for Older Adults – Pain Assessment	50	71	85	94
MA	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	C08	C08	Osteoporosis Management in Women who had a Fracture	32	45	55	73
MA	Actual	No	Based on 2022 Star Ratings cutpoints	C08	C08	Osteoporosis Management in Women who had a Fracture	32	45	55	73
MA	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	C09	C09	Diabetes Care – Eye Exam	48	61	71	79
MA	Actual	No	Based on 2022 Star Ratings cutpoints	C09	C09	Diabetes Care – Eye Exam	47	61	71	79
MA	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	C10	C10	Diabetes Care – Kidney Disease Monitoring	92	95	97	99
MA	Actual	No	Based on 2022 Star Ratings cutpoints	C10	C10	Diabetes Care – Kidney Disease Monitoring	80	93	95	97
MA	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	C11	C11	Diabetes Care – Blood Sugar Controlled	63	72	80	86
MA	Actual	No	Based on 2022 Star Ratings cutpoints	C11	C11	Diabetes Care – Blood Sugar Controlled	39	62	75	83
MA	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	DMC	C12	Controlling Blood Pressure	61	69	75	82
MA	Actual	No	Based on 2022 Star Ratings cutpoints	DMC	C12	Controlling Blood Pressure	48	63	73	80
MA	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	C13	C13	Reducing the Risk of Falling	46	53	60	69
MA	Actual	No	Based on 2022 Star Ratings cutpoints	C13	C13	Reducing the Risk of Falling	46	53	60	69
MA	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	C14	C14	Improving Bladder Control	39	43	48	53
MA	Actual	No	Based on 2022 Star Ratings cutpoints	C14	C14	Improving Bladder Control	39	43	48	53
MA	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	C15	C15	Medication Reconciliation Post-Discharge	43	57	69	82
MA	Actual	No	Based on 2022 Star Ratings cutpoints	C15	C15	Medication Reconciliation Post-Discharge	43	57	69	82
MA	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	C16	C16	Statin Therapy for Patients with Cardiovascular Disease	79	84	86	89
MA	Actual	No	Based on 2022 Star Ratings cutpoints	C16	C16	Statin Therapy for Patients with Cardiovascular Disease	75	81	85	89
MA	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	C23	C23	Complaints about the Health Plan	0.6	0.43	0.25	0.12
MA	Actual	No	Based on 2022 Star Ratings cutpoints	C23	C23	Complaints about the Health Plan	1.53	0.89	0.5	0.19
MA	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	C24	C24	Members Choosing to Leave the Plan	37	24	15	7
MA	Actual	No	Based on 2022 Star Ratings cutpoints	C24	C24	Members Choosing to Leave the Plan	39	24	15	7
MA	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	C26	C26	Plan Makes Timely Decisions about Appeals	89	93	97	100
MA	Actual	No	Based on 2022 Star Ratings cutpoints	C26	C26	Plan Makes Timely Decisions about Appeals	59	75	85	97
MA	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	C27	C27	Reviewing Appeals Decisions	84	90	95	98
MA	Actual	No	Based on 2022 Star Ratings cutpoints	C27	C27	Reviewing Appeals Decisions	68	83	91	97
MA	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	C28	C28	Call Center – Foreign Language Interpreter and TTY Availability	76	82	89	95
MA	Actual	No	Based on 2022 Star Ratings cutpoints	C28	C28	Call Center – Foreign Language Interpreter and TTY Availability	36	59	83	94
MAPD	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	D01	D01	Call Center – Foreign Language Interpreter and TTY Availability	68	81	91	97
MAPD	Actual	No	Based on 2022 Star Ratings cutpoints	D01	D01	Call Center – Foreign Language Interpreter and TTY Availability	30	64	80	91
MAPD	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	D02	D02	Complaints about the Drug Plan	0.68	0.43	0.25	0.12

Type of Contract	Actual/Simulated Cut Points	Tukey Outlier Deletion	Guardrails	2022 Star Ratings Measure ID	2023 Star Ratings Measure ID	Measure Name	Cut Point for 1 to 2 Stars	Cut Point for 2 to 3 Stars	Cut Point for 3 to 4 Stars	Cut Point for 4 to 5 Stars
MAPD	Actual	No	Based on 2022 Star Ratings cutpoints	D02	D02	Complaints about the Drug Plan	1.53	0.89	0.5	0.19
MAPD	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	D03	D03	Members Choosing to Leave the Plan	37	24	15	7
MAPD	Actual	No	Based on 2022 Star Ratings cutpoints	D03	D03	Members Choosing to Leave the Plan	39	24	15	7
MAPD	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	D07	D07	MPF Price Accuracy	87	91	95	99
MAPD	Actual	No	Based on 2022 Star Ratings cutpoints	D07	D07	MPF Price Accuracy	72	86	93	97
MAPD	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	D08	D08	Medication Adherence for Diabetes Medications	81	85	88	92
MAPD	Actual	No	Based on 2022 Star Ratings cutpoints	D08	D08	Medication Adherence for Diabetes Medications	79	85	88	92
MAPD	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	D09	D09	Medication Adherence for Hypertension (RAS antagonists)	83	86	89	91
MAPD	Actual	No	Based on 2022 Star Ratings cutpoints	D09	D09	Medication Adherence for Hypertension (RAS antagonists)	78	86	89	91
MAPD	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	D10	D10	Medication Adherence for Cholesterol (Statins)	81	85	88	92
MAPD	Actual	No	Based on 2022 Star Ratings cutpoints	D10	D10	Medication Adherence for Cholesterol (Statins)	81	85	88	92
MAPD	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	D11	D11	MTM Program Completion Rate for CMR	68	78	84	91
MAPD	Actual	No	Based on 2022 Star Ratings cutpoints	D11	D11	MTM Program Completion Rate for CMR	47	67	82	89
MAPD	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	D12	D12	Statin Use in Persons with Diabetes (SUPD)	80	84	86	90
MAPD	Actual	No	Based on 2022 Star Ratings cutpoints	D12	D12	Statin Use in Persons with Diabetes (SUPD)	80	84	86	90
PDP	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	D01	D01	Call Center – Foreign Language Interpreter and TTY Availability	86	92	97	100
PDP	Actual	No	Based on 2022 Star Ratings cutpoints	D01	D01	Call Center – Foreign Language Interpreter and TTY Availability	60	75	91	97
PDP	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	D02	D02	Complaints about the Drug Plan	0.15	0.1	0.07	0.03
PDP	Actual	No	Based on 2022 Star Ratings cutpoints	D02	D02	Complaints about the Drug Plan	0.34	0.22	0.13	0.06
PDP	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	D03	D03	Members Choosing to Leave the Plan	18	13	9	5
PDP	Actual	No	Based on 2022 Star Ratings cutpoints	D03	D03	Members Choosing to Leave the Plan	23	16	11	7
PDP	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	D07	D07	MPF Price Accuracy	90	94	96	99
PDP	Actual	No	Based on 2022 Star Ratings cutpoints	D07	D07	MPF Price Accuracy	90	94	96	99
PDP	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	D08	D08	Medication Adherence for Diabetes Medications	84	86	88	90
PDP	Actual	No	Based on 2022 Star Ratings cutpoints	D08	D08	Medication Adherence for Diabetes Medications	84	86	88	90
PDP	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	D09	D09	Medication Adherence for Hypertension (RAS antagonists)	86	88	89	91
PDP	Actual	No	Based on 2022 Star Ratings cutpoints	D09	D09	Medication Adherence for Hypertension (RAS antagonists)	86	89	91	96
PDP	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	D10	D10	Medication Adherence for Cholesterol (Statins)	86	87	88	90
PDP	Actual	No	Based on 2022 Star Ratings cutpoints	D10	D10	Medication Adherence for Cholesterol (Statins)	84	87	88	90
PDP	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	D11	D11	MTM Program Completion Rate for CMR	34	49	62	78
PDP	Actual	No	Based on 2022 Star Ratings cutpoints	D11	D11	MTM Program Completion Rate for CMR	34	49	62	78
PDP	Simulated	Yes	Based on simulated 2022 Star Ratings cutpoints with Tukey outlier deletion	D12	D12	Statin Use in Persons with Diabetes (SUPD)	80	82	84	86
PDP	Actual	No	Based on 2022 Star Ratings cutpoints	D12	D12	Statin Use in Persons with Diabetes (SUPD)	80	82	84	86