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.

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

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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

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[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).

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).

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.

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.**

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.

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.

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

<u>PCMA recommendation</u>: 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.