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Submitted electronically via http://www.regulations.gov

Mr. Xavier Becerra
Secretary
Department of Health and Human Services
Attention: CMS–4190–P
P.O. Box 8013
Baltimore, MD 21244–8013

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
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RE: Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs (CMS-4192-P)

Dear Secretary Becerra and Administrator Brooks-LaSure:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule titled "Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs" (hereafter referred to as Proposed Rule), as published in the *Federal Register* on January 12, 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 266 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 recommendations on the following topics in the Proposed Rule:

1. Efforts to reduce the effects of social determinants of health on beneficiary access to care, including updates to program regulations for Part D special needs plans (D-SNPs) to improve efficiency and operations, transitions out of the COVID-19 public health emergency (PHE), including the effect of COVID-19 on Star Ratings for 2023 and 2024.
2. Changes to the treatment of pharmacy price concessions related to preferred pharmacy networks.
3. Technical modifications to the contract approval, renewal, and expansion regulations.
4. Modernizations for beneficiary marketing and communications materials.

[1] 87 Fed. Reg. 1842, January 12, 2022.

We close by reminding CMS that it has an important role to play in improving transparency on prescription drug costs and benefits, regarding the full implementation of real-time benefit tools (RTBT) as mandated by Congress for 2023. This topic is not addressed in the Proposed Rule.

Thank you for the opportunity to provide comments. We look forward to working with you on the ongoing efforts to improve Part D.

Sincerely,

Tim Dube

Tim Dube
Vice President, Regulatory Affairs

Enclosure

cc: Jonathan Blum
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I. D-SNP, COVID PHE and Stars Section for 2023 Part D Regulation

A. Dual Eligible Special Needs Plans (D-SNPs)

PCMA supports CMS's goals for the delivery of equitable and consistent, high-quality coordinated care to Medicare Medicaid Dual Eligible beneficiaries who are covered under Dual Eligible Special Needs Plans (D-SNPs). One approach CMS should consider is standardization, which alleviates unnecessary and controllable variances in care. However, equitable care also requires the consideration and analysis of social determinants of health (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. Therefore, PCMA recommends uniformity of requirements for D-SNP plans regardless of state-level differences in contracting regulations and requirements, including marketing and beneficiary communication.

To achieve this uniformity, we ask that the CMS consider:

- The uniformity and integration of contracting and marketing requirements across states will facilitate operational efficiency for all D-SNPs, including large complex multi-state plans. However, uniformity should not be allowed to mask duplication, specifically CMS versus state requirement duplication. Therefore, efficiency of D-SNP plans will be dependent on coordination, efficiency, and inclusivity.

- PCMA recommends that CMS require existing Medicare-Medicaid Plan (MMP) states to identify the end date for their MMP program and proposed transition period. Further, to improve this process, we recommend that CMS include D-SNPs in conversations and planning with the states to ensure aligned messaging and marketing and to promote collaboration.

- Given the on-going, multi-year COVID-19 PHE, D-SNP plan quality and performance should be judged through the categorical adjustments of impact, such as adjustment of Star Ratings and Healthcare Effectiveness Data and Information Set (HEDIS) measures…etc., to account for the fact that D-SNPs disproportionately serve more vulnerable beneficiaries with increased clinical and socioeconomic care needs.

PCMA strongly supports CMS's intent to address health-related social needs by requiring that all Special Needs Plans (SNPs) include one or more SDOH related questions on the topics of housing stability, food security, and access to transportation as part of plan health risk assessments (HRAs). However, rather than require standardized questions, CMS should allow plans flexibility to continue to develop and use their own questions and materials since this proposal could lead to overlapping or

conflicting state requirements for collection of similar information from enrollees. Moreover, PBMs are already addressing SDOH and disparities in their efforts to provide equitable, whole-person focused care.[2]

PCMA supports the intent of this proposal to better capture social risk factors in HRAs that may impact the overall health of enrollees. However, flexibility, innovation, and customization should be allowed for development of HRAs and state-specific assessments for D-SNPs that are tailored to specific beneficiary populations. Lastly, we urge CMS to work with plans to identify a long-term and more comprehensive solution to the impact of beneficiary-level demographics and social risk factors on Star Ratings.

***PCMA recommendation*: CMS should focus regulatory revisions to the D-SNP program on providing nationwide uniformity. This will increase the efficiency and delivery of highly coordinated care to this vulnerable population.**

B. D-SNP Star Ratings Changes

PCMA appreciates the 30-day grace period following the end of a disaster or emergency as a transition phase before the commencement of business as usual. Additionally, PCMA acknowledges the need to address SDOH factors for unique populations, such as D-SNPs, given that the PHE impact is magnified when assessing access issues and addressing disparities related to housing, transportation, and remoteness of location. However, we are concerned that implementing technical methodological changes for one cycle will skew data and may even introduce validity issues related to survey sources and responses.

Specific to contracting and Stars quality measurement, we are concerned about the inclusion of D-SNP contracts in the same realm as MAPD for Star Ratings purposes. The D-SNP contracts are highly specialized and often have low enrollment. Instead, we recommend the following:

- Given CMS's method to establish cut points, it only takes a small number of contracts to create a 5-Star cluster (or change existing patterns) that would then impact the rest of the industry as they fall in line behind. These contracts would also qualify for a higher Categorical Adjustment Index (CAI) adjustment given the LIS and disability population. Since the program requirements are vastly different than the standard MAPD plan, this may create a disparity between D-SNP contracts and the rest of the MAPD industry.

[2] Sara Heath. (February 1, 2022). "CVS Health Invests $6.5M in Housing, Social Determinants of Health." *Patient Engagement HIT*. Accessed February 25, 2022. Available at https://patientengagementhit.com/news/cvs-health-invests-6.5m-in-housing-social-determinants-of-health

- The current MMP program should have a separate rating system that is similar to Stars, instead of lumping the MMP plans in with the rest of the MAPD industry. We recommend that CMS follow that same model for the D-SNP contracts, rather than including them with other MAPD plans. We would also request supporting analysis from CMS on the impact to cut points when D-SNP is carved out of other MAPD plans to assess trends in cut-point performance and contract distribution as a check before implementation.

- We are concerned that there will be insufficient D-SNP data to support whether there will be impact to the Star Ratings program across the industry.

***PCMA recommendation*: CMS should ensure that D-SNP Star Ratings changes are applied in a way that does not indirectly benefit one plan type over another.**

C. Star Ratings Measurement and Flexibilities

PCMA recommends that CMS consider extending previous decisions to pause ongoing data collection surveys used to calculate several Star Ratings measures for 2021 and 2022 into 2023. This approach will allow Part D plans and their PBMs to focus on addressing the needs of beneficiaries during the PHE. In general, we recommend the continued application of CMS's Extreme and Uncontrollable Circumstances (EUC) policy for CY2023.[3] As we transition out of the COVID-19 PHE, we ask that CMS consider several separate issues[4]:

- The effects of the PHE on plan Star Ratings may vary based on geography.

- CMS should consider reweighting these survey-based measures to measure plans equitably based on what was known at the time.

- CMS should acknowledge and account for the effects of the PHE on other Star Ratings measures outside of those collected through these surveys.

- Re-opening these surveys too soon could pose a risk to public health, for example, if some states are still under their own declared emergencies.

Prior to resuming these surveys, CMS should engage with stakeholders to verify whether plans, PBMs, and CMS have the resources available not only to maintain any ongoing pandemic mitigation efforts but also perform their duties during these surveys.

[3] The 2021 Merit-based Incentive Payment System (MIPS) Automatic Extreme and Uncontrollable Circumstances Policy. UPDATED: 11/10/2021
[4] "PCMA comments on Policy and Regulatory Revisions in Response to the Covid-19 Public Health Emergency – CMS-1744-IFC." June 1, 2022. Accessed February 25, 2022. Available at https://www.regulations.gov/comment/CMS-2020-0032-2066.

The pandemic continues to have different effects in each state. We expect that measures of plan performance will be tied to these differences. In future rulemaking for the Part C and D programs, CMS should correct for regional- or state-specific differences in alignment with its EUC policy. As noted in our comments on the 2021-2022 Part D Proposed Rule,[5] we urge CMS to extend this policy to state-declared emergencies that extend beyond the national PHE period.

We commend CMS's efforts to determine whether additional Star Ratings changes are necessary for future contract years.[6] Part D plans invest considerable resources on a long-term basis to increase plan performance and make improvements in their Star Ratings scores. For some plans, the surveys may have been completed prior to the CMS order to stop. In these cases, if the scores show an improvement, then CMS should use the improved score. If survey data was not collected or was incomplete or if the data collected results in lower scores, then CMS should carry over the 2019 scores.

Since the pandemic has now continued beyond 2021 well into plan year 2022, CMS could take this same approach for surveys not undertaken during that year as well. In summary, CMS should use 2020 Star Ratings not impacted by the pandemic for the 2021-2023 Star Ratings, given the data challenges with calculating accurate measure-level ratings. CMS should consider the ongoing COVID-19 PHE an EUC for the 2023 Star Ratings and maintain the weight of patient experience, complaints, and access measures at 2, rather than increasing the weight to 4 in the 2023 Stars Ratings.

CMS should recognize that Star Ratings beyond Consumer Assessment of Healthcare Providers & Systems (CAHPS) and HEDIS will be affected by the PHE. Plan activities in response to emergency situations can have effects years following these events, in terms of audits, Star Ratings, risk corridors, and payment reconciliation, among other considerations. For example, generic dispensing, call center volume, grievances, and turn-around time measures may be affected. These differences may vary state to state, making comparisons (and any subsequent payment differentials) across plans difficult. Plan-level effects will likely persist for a period of time after the PHE, and we request that CMS entertain further rule changes as needed to ensure plans are held harmless against these unintended effects.

***PCMA recommendation*: PCMA supports CMS's recalculation of Star Ratings for 2021, 2022 and 2023 to account for deferred surveys. We recommend that CMS extend this flexibility to other measures for plans in severely affected states. We also recommend that CMS make other conforming changes on the weights associated with carried-over measures, and extend this flexibility through future annual rules as necessary.**

[5] Filed April 6, 2020. Available at https://www.regulations.gov/comment/CMS-2020-0010-0389.
[6] Executive Order on Economic Relief Related to the COVID-19 Pandemic | The White House

II. PCMA Opposes CMS's Proposal to Incorporate All Pharmacy Price Concessions into the Negotiated Price Paid to the Pharmacy

Proposal:

With a goal of reducing beneficiary out-of-pocket (OOP) spending and bring greater reimbursement certainty to network pharmacies, CMS proposes to redefine "negotiated price" for the purpose of cost-sharing calculations to require the inclusion of contingent pharmacy price concessions otherwise collected after the point of sale (POS) by PBMs on behalf of Part D plan sponsors. Due to the statutory construction of the brand-name drug manufacturer Coverage Gap Discount Program (CGDP), the proposal would not require the same reduced cost sharing for prescriptions of applicable drugs dispensed to applicable beneficiaries in this phase of the Part D benefit.

Discussion:

Since 2014, CMS has proposed several related policies that would undercut PBMs' abilities to negotiate for high-performing pharmacy networks on behalf of Part D plan sponsors. All of these proposals have been based on a fundamental misunderstanding of the mechanism through which pharmacy price concessions create a higher-quality and lower-cost prescription drug benefit. PCMA opposes this proposal, for five reasons:

1. The Proposed Rule is contrary to the Medicare statute's protections of contract negotiations between Part D plan sponsors and pharmacies.
2. The Proposed Rule would not have the effect CMS predicts, and thus is arbitrary and capricious.
3. The Proposed Rule disincentivizes value-based care and reduces the quality of pharmacy care provided to Medicare beneficiaries.
4. The Proposed Rule makes Medicare Part D pricing *less* transparent and introduces unnecessary confusion.
5. The Proposed Rule cannot be implemented in 2023 as proposed, and not without considerably higher costs to plans and CMS than described.

We will describe each of these arguments in detail below. In short, we reject all of CMS's premises. If CMS proceeds with a rule change for 2023, drastic upheaval in pharmacy access and plan offerings is likely, absent significant financial safeguards for both pharmacies and plan sponsors. If CMS chooses to move forward with a version of this rule change, it should by no means start before 2024.

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1. **The Proposed Rule is contrary to the Medicare statute's protections of contract negotiations between Part D plan sponsors and pharmacies.**

CMS faces significant legal impediments to the proposed policy. The proposed redefinition of "negotiated price" and "price concession" conflict with Congress's express limits on CMS's authority over the Part D program, including the statutory definition of "negotiated price" and the noninterference clause at § 1860D-11(i) of the Social Security Act. CMS must ensure that any finalized policy complies with the law.

A. The proposed redefinition of "negotiated price" violates the statutory definition of negotiated price

The plain language of the Part D statute requires that negotiated prices "*shall take into account* negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations."[7] This underlying statutory language ("take into account") unambiguously indicates Congress did not intend that Part D sponsors be required to pass through *all* possible pharmacy price concessions at the POS as CMS now proposes. PCMA is concerned that the policy changes discussed in the Proposed Rule directly conflict with the authorizing statute and thus are arbitrary, capricious, an abuse of discretion, and not otherwise in accordance with law.[8]

First, as quoted above, the statutory text makes clear that Part D sponsors are not required to pass through all pharmacy price concessions at the POS.[9] As CMS recognizes in the preamble to the Proposed Rule, CMS has previously interpreted the statute to mean that "some, but not all, price concessions must be applied to the negotiated price."[10] In the Proposed Rule, CMS now changes course, stating that the agency now believes that "a proper reading of the statute supports requiring that all pharmacy price concessions be applied at the point-of-sale."[11] The agency's reversal, however, disregards the plain meaning of the statute. If Congress intended to require all pharmacy price concessions to be reflected in the calculation of negotiated price, "[a] phrase other than "take into account" would have been used…"[12] As CMS has previously acknowledged, "[t]he plain language of [the negotiated price definition] demonstrates Congress' intent to be permissive – that Part D sponsors are permitted to choose how much of their negotiated price concessions to pass through to Part D

[7] 42 U.S.C. § 1395w-102(1)(B) (Emphasis added).
[8] See 5 U.S.C. §706(2)(A) (requiring a reviewing court to hold unlawful and set aside agency actions found to be "arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law").
[9] A court reviewing an agency's construction of a statute which it administers must first ask whether "Congress has directly spoken to the precise question at issue." *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 842 (1984)
[10] 87 Fed. Reg. 1915; *see also* CMS, Medicare Program: Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4244 (Jan. 28, 2005).
[11] Id.
[12] CMS, Medicare Program: Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions, 74 Fed. Reg 1494, 1511 (Jan. 12, 2009)

beneficiaries at the point of sale."[13] While an agency may faithfully interpret statutory language, such an interpretation cannot veer from the plain meaning of such text.[14]

Second, even if the statutory language were ambiguous, CMS's policy changes would be inconsistent with Congress's intent to provide Part D sponsors with flexibility in administering the Part D prescription drug benefit as a private market model.[15]

Congress intended the Medicare prescription drug benefit to be a private market model.[16] For example, Congress gives Part D sponsors significant flexibility in designing their prescription drug plans, as long as they can show it is actuarially equivalent to standard prescription drug coverage.[17] As a result of this flexibility, Part D plans have been drivers of innovation in benefit design. In 2020, for example, not a single individual was enrolled in a defined standard benefit plan and nearly 50% of Part D beneficiaries were enrolled in plans offering enhanced benefits.[18] This private market-led innovation has similarly resulted in Part D premiums remaining stable during the life of the program.

The proposed pharmacy price concession policy breaks with this fundamental trust in private markets instilled in the statute by Congress, due to a clear misreading of the statutory text. In the Proposed Rule, CMS takes a perceived ambiguity regarding the extent to which Part D sponsors are required to pass through negotiated price concessions at the POS, and then hurls forward to the conclusion that the best reading of the statute is one in which Part D sponsors have no flexibility to determine the amounts passed through. Had Congress intended that Part D plans include all price concessions in the calculation of a negotiated price, certainly they would not have directed plans to merely "take into account" such amounts. CMS fails to explain why it no longer believes Congress sought to provide Part D sponsors this flexibility, stating only that its prior interpretation "may have been overly definitive."[19] An agency may not reverse a longstanding and reasoned policy without an adequate and thoughtful explanation for such a decision.[20] Because the Proposed Rule is unaligned with the

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[13] Id.
[14] See *Chevron*, 467 U.S. at 842-43 (courts and agencies "must give effect to the unambiguously expressed intent of Congress").
[15] See *Chevron*, 467 U.S at 843 (if a reviewing court "determines Congress has not directly addressed the precise question at issue…the question for the court is whether the agency's [interpretation] is based on a permissible construction of the statute")
[16] *See* H.R. Rep. No. 108-391, 108th Cong., 1st Sess. at 428 (Nov. 21, 2003) ("[Private] plans will determine premiums through a bid process and compete based on premiums and negotiated prices").
[17] See 42 U.S.C. § 1395w-102(a)(1)(B); see also 42 U.S.C. 1395w-104(b)(3) (providing PDP sponsors wide flexibility to develop formularies within certain parameters). And see 42 C.F.R. § 423.104(e) ("Alternative prescription drug coverage.")
[18] MedPAC, (MedPAC), Report to the Congress: Medicare Payment Policy, March 13, 2020, Chapter 14, Table 14-5, p. 418 at http://medpac.gov/docs/default-source/reports/mar20_medpac_ch14_sec.pdf?sfvrsn=0.
[19] 87 Fed. Reg. 1915.
[20] *See FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 516 (2009) ("a reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy").

intent of Congress, a reviewing court may find such policy changes to be substantively invalid because they would not be based on a permissible construction of the statute.

***PCMA recommendation*: CMS has on multiple previous occasions recognized that the term "negotiated price" grants Part D plans the discretion in to treat pharmacy price concessions. CMS cannot now purport to interpret the statute in a way that requires inclusion of pharmacy price concessions in the negotiated price at the POS, based on the plain language of the law.**

B. The proposed redefinition of "negotiated price" violates the noninterference clause of the Medicare Modernization Act (MMA)

Under the Part D statute's noninterference clause, CMS is explicitly prohibited from "interfer[ing] with the negotiations between drug manufacturers and pharmacies and PDP sponsors."[21] Preventing such interference was very clearly the intent of Congress when it created the Part D program and is well-documented. This provision has long been understood as prohibiting CMS from interfering in payment negotiations between both Part D plan sponsors and pharmacies, and Part D plan sponsors and manufacturers.[22] Indeed, CMS has long taken an appropriate view of the noninterference clause's applicability to negotiations between Part D plan sponsors and pharmacies and manufacturers, reflecting the understanding that the Part D program's success is built upon free market competition.

In the 2005 Part D final rule, for example, CMS interpreted the noninterference clause as prohibiting CMS from "interfering with negotiations between drug manufacturers and pharmacies and PDP sponsors, and requiring a particular formulary or a price structure for the reimbursement of covered Part D drugs."[23] This free market approach (and CMS's past willingness to abide by the statute and not to step in between negotiations) is generally credited for the overwhelming success of the program.[24]

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[21] 42 U.S.C. § 1395w-111(i)(1).
[22] See House Conference Report No. 108-391 at 461 (Nov. 21, 2003), reprinted in 2003 U.S.S.C.A.N. 1808, 1840 ("In order to promote competition, the Secretary is prohibited from interfering with the negotiations between drug manufacturers and pharmacies and Part D plans.") See also *id*. at 748-9 (Nov. 21, 2003), reprinted in 2003 U.S.S.C.A.N. 1808, 2105 ("[t]hese negotiations would be carried out by private plans, eager to capture market share through lower premiums, and manufacturers, willing to negotiate discounts for volume assurance. Such private sector entities are far better suited to achieve maximum discounts and lower premiums for plan participants than a disinterested Administrator.")
[23] 70 Fed. Reg. 4,194, 4,298 (January 28, 2005). See also 69 Fed. Reg. 46,632, 46,681 (August 3, 2004) (where CMS stated that the MMA "envisions that most price negotiation including discounts, rebates, or other direct or indirect subsidies or remunerations would take place between PDP sponsors or MA organizations (or their subcontractors) and pharmacies and pharmaceutical manufacturers" and that "price negotiation would be conducted by the private drug benefit managers and plans that are already familiar with negotiating prices of prescription drugs on a local, regional or national basis.")
[24] "In beginning with the words 'In order to promote competition under this part and in carrying out this part. . .' we believe that the Congress intended that the activities addressed in the rest of the provision should take place through private market competition." 79 Fed. Reg. 29,874 (May 23, 2014).

CMS is now proposing significant limits on the format and application of pharmacy price concessions negotiated by plan sponsors. Post-POS pharmacy price concessions are a critical negotiating tool for plan sponsors to drive lower costs across the Part D program. Under the Proposed Rule, plan sponsors and their PBMs will be limited in their ability to negotiate downside incentives with pharmacies tied to performance or quality targets. By requiring all pharmacy price concessions to be reflected in the negotiated price, Part D plans would lose significant leverage in pharmacy negotiations, resulting in excess costs to the Part D program and ultimately higher premiums for beneficiaries.

CMS attempts to preempt these arguments in the Proposed Rule.[25] However, the agency's reasoning is flawed. It ignores the practical realities of the relationship between Part D sponsors, their PBMs, and network pharmacies. The financial, logistical, and regulatory implications of the proposed change to "lowest possible reimbursement" are so significant that most PBMs will need to negotiate new contractual terms with participating pharmacies and plan sponsors.

The proposed definition of "negotiated price" will impact payments from Part D plans to pharmacies in a manner beyond reporting obligations. Current payment systems lack the functionality to track multiple prices at the POS. In CMS's view, if the Proposed Rule doesn't require that prices paid to pharmacies be changed, then it expects that plan sponsors can administer four separate prices rather than one. There would be two prices for the reimbursement rate to the pharmacy (for claims inside of and outside of the Coverage Gap) and two for the calculation of cost sharing (inside and outside of the Gap). What CMS overlooks is that every single price is the subject of negotiation and a contract, so to administer four prices rather than one, a new contract is required.

The Proposed Rule also impedes certain patient adherence program designs. Many plan sponsors offering preferred pharmacy networks operate multi-tier pharmacy performance structures today. Very few pharmacies are on the bottom tier, which would owe the largest price concessions, and few are on the highest tier, owing the least or earning bonuses. Under CMS's proposal, if contracts did not change, all cost sharing would need to be calculated as if they were dispensed by the lowest performers. In the case of a pharmacy contract that assesses a fixed fee rather than a percentage, for less costly drugs like common generics, the newly calculated negotiated price could be negative. This would generate a $0 cost share for the patient, and full liability for the plan. Because today the fixed fees (in this example) are paid at the end of the performance period, across a wide range of drug prices, any single claim is not viewed as "underwater." This net reimbursement level is a strong incentive to participate in quality performance activities. Under the Proposed Rule, under current contracts, pharmacies may be disincentivized to dispense generic drugs because the lowest

[25] 87 Fed. Reg. 1915.

possible negotiated prices would yield low new reimbursement levels from plans and may not generate any patient OOP payments to pharmacies.

Other preferred pharmacy agreements apply performance incentives through a net effective rate, where the pharmacy agrees to an overall brand and generic discount based on adherence rate performance. Both designs are not operationally or economically workable under the Proposed Rule. By pushing discounts to the POS, the Proposed Rule favors patient adherence programs funded through separate payments from Part D sponsors instead of price concessions from pharmacies. Such a structure impermissibly alters negotiations between Part D sponsors and pharmacies, limits pharmacy cash flow, and discourages Part D sponsors from making significant investments in performance incentives.[26]

We believe that if there's enough time, both plan sponsors and pharmacies will renegotiate contracts to re-base reimbursement to an appropriate minimum level – well above today's lowest possible reimbursement – and re-instate preferred pharmacy networks. This argues for at least a delay in implementation of the rule, to allow for this renegotiation. The lowest performing pharmacies will see an increase in net reimbursement under these agreements. CMS should consider whether higher payments for the lowest-performing pharmacies matches its policy goals.

Thus, to the extent the Proposed Rule mandates that certain kinds of price concessions be applied to the negotiated price at POS, it interferes in Part D plan sponsors' negotiations, by specifying benefit designs. The allocation of such price concessions is appropriately the subject of arm's length business negotiations between Part D sponsors and pharmacies. Under the statute, CMS may not interfere in these negotiations.

***PCMA recommendation*: Simply put, by requiring Part D sponsors to pass through all possible pharmacy price concessions at the POS, CMS is directly interfering with negotiations between pharmacies and Part D sponsors in violation of §1860D-11(i)(1).**

C. The Negotiated Price Proposal Also Impermissibly Institutes a Price Structure (42 U.S.C. §1395w111(i))

The Part D statute also states that CMS may not require "a particular formulary or institute a price structure for the reimbursement of covered part D drugs."[27] Yet, by proposing potential policies that would create a structure around pharmacy prices, CMS

[26] CMS has previously suggested a policy that redefines negotiated price does not run afoul of the noninterference clause because "Part D sponsors will not be required to use a particular pricing approach in their contractual agreements with PBMs." See 74 Fed. Reg. 1494, 1508 (January 12, 2009). The Proposed Rule thus clearly violates CMS' own test for noninterference – it necessitates a change in pricing through contracts.

[27] 42 U.S.C. § 1395w-111(i)(2)

would also be violating the prohibition against instituting a price structure for the reimbursement of covered Part D drugs.[28]

In the past, CMS has carefully balanced the competing goals of pharmacy access and Part D plan flexibility, ensuring neither of these requirements is read out of the statute. While neither Congress nor the agency has formally adopted a definition of "price structure," the meaning of the clause is clear: CMS cannot specify a "standard" (e.g., what is paid or how payments are calculated), nor can it impose any "structure" (e.g., any rules around the elements of that pricing). This meaning is evident both from the plain language of the statute (i.e., the term "structure" is commonly defined as an arrangement or organization of elements or parts[29]), as well as other language in the Part D statute. For example, the significance of the clause is evident when one compares it to how Congress phrased the limitation on CMS activity involving formularies. In particular, section 1860D- 11(i)(2) prohibits CMS from requiring a "particular" formulary. The statute does not use the same modifier "particular" in front of the price structure language.

Thus, CMS's proposal would violate the prohibition on establishment of a price structure. By requiring that all pharmacy price concessions be passed through to beneficiaries at the POS, CMS is effectively instituting a price structure for pharmacy payment whereby plans are no longer afforded discretion in how much of their negotiated price concessions to pass through to Part D beneficiaries.

***PCMA recommendation*: CMS is proposing to create a structure around pharmacy prices, with all possible price concessions required to be passed through to the beneficiary at POS. This structure violates the plain meaning of §1860D-11(i)(2).**

2. The Proposed Rule would not have the effect CMS predicts and thus is arbitrary and capricious.

Private prescription drug plan sponsors provide the outpatient Medicare Part D benefit to enrollees, who chose from among plans available to them at different prices (premiums) depending on beneficiary preference. Plan sponsors create networks of retail and mail-order pharmacies. CMS regulations generally require broad access to pharmacies,[30] meaning that the plan's network has to be constructed to incentivize the plan's desired outcomes. Preferred cost-sharing pharmacy networks and pharmacy price concessions are the mechanism that has emerged, based on CMS's current rules. Today, beneficiaries choose plans based on premiums, cost sharing, and quality. The Proposed Rule would destabilize these important considerations.

[28] See 70 Fed. Reg. 4,194, 4300 (January 28, 2005).
[29] Merriam-Webster Dictionary (online); available at http://www.merriam-webster.com/dictionary/structure.
[30] By this we mean both the retail pharmacy access standard borrowed from the TRICARE program and current Any Willing Pharmacy rules.

A. The growth of pharmacy price concessions is overstated

In the Proposed Rule, CMS writes "pharmacy price concessions … have grown faster than any other category of DIR."[31] The Part D program's net cost and beneficiary premium stability comes from the price concessions PBMs negotiate with manufacturers and pharmacies.[32] CMS's concern that price concessions are detrimental is plainly rejected by both its own Office of the Actuary and the Congressional Budget Office (CBO).[33] CMS's own previous work reaches the same conclusions.[34]

As a threshold event, CMS should acknowledge the origin of preferred cost-sharing pharmacies. This phrase was defined in the original set of Part D rules in 2005.[35] For plans to meet the regulatory obligations, such pharmacies had to offer covered drugs at lower cost sharing and lower total prices. Plans often instituted contracts with retrospective price concessions for these pharmacies, to reduce plan costs, and meet CMS's requirements. The system that CMS considers problematic today emerged from CMS rules and market forces over the past 17 years.

Indeed, a closer look at its own data would have revealed that pharmacy price concessions are plateauing as a total percentage of Part D program spending. First, CMS's own rule changes since 2005 influence what is reported as DIR, which affects the observed growth rate. For example, CMS in 2009 redefined the treatment of pharmacy payment and the treatment of fees and other payments.[36]

Second, since CMS rules support this specific benefit design, it should not surprise the agency that the proportion of PDPs offering preferred networks grew over time. Starting with very few such plans in 2006, by 2013 half of PDPs were offering them. From 2013 to 2018, most of the remaining PDPs began to offer them.[37] (The trend is similar in MAPDs but not to the same extent.) Most of the growth in pharmacy Direct and Indirect Remuneration (DIR) therefore is attributable to more plans building out these contracts, rather than larger price concessions being applied.

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[31] 87 Fed. Reg. at 1910.
[32] CMS, "CMS Releases 2022 Premiums and Cost-Sharing Information for Medicare Advantage and Prescription Drug Plans," September 30, 2021. Available at https://www.cms.gov/newsroom/press-releases/cms-releases-2022-premiums-and-cost-sharing-information-medicare-advantage-and-prescription-drug.
[33] See https://www.cbo.gov/system/files/2022-01/57050-Rx-Spending.pdf (2022)
[34] Medicare Part D – Direct and Indirect Remuneration (DIR), January 19, 2017. Available at https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir.
[35] 71 Fed. Reg. 4194 (January 28, 2005), at 4537.
[36] For example, see 79 Fed. Reg. 29844, May 23, 2014, at 29962 which redefined the types of price concessions and fees that must be reported as DIR, beginning in 2016.
[37] Drug Channels, November 2, 2021. "Consolidation and Preferred Pharmacy Networks in 2022's Medicare Part D Plans: Cigna, CVS Health, Humana, UnitedHealthcare, WellCare, and More." Available at https://www.drugchannels.net/2021/11/consolidation-and-preferred-pharmacy.html.

Fourth, drug prices, Part D enrollment, and utilization all continue to rise. Had CMS taken into account these well-established secular trends, it would have instead concluded that pharmacy DIR growth rates are similar in magnitude to other categories of DIR. Aiming a policy squarely at reducing something whose growth is in line with expectations is solving a problem that doesn't exist.

B. The rule will increase premiums for all but only reduce cost sharing for some

In the Proposed Rule, CMS estimates that, if pharmacy DIR were applied at the POS in all phases except the coverage gap phase, base premiums will increase $11.8 billion (5%, $20.37 per member per year increase) over the ten-year budget window, and beneficiary OOP cost sharing will decrease $33.1 billion (6% or $57.03 per member per year savings) over the same period. Total government costs will increase $40 billion (3%) as costs shift from the coverage gap and reinsurance to direct subsidy payments to plans. Manufacturers will save $14.6 billion due to the same downward shifts in total drug costs. CMS also conducted an "alternative" analysis if instead the price concessions were also applied at the POS for claims in the coverage gap.

PCMA commissioned an independent analysis to gain additional insight into the Proposed Rule's potential impacts.[38] The analysis assumes pharmacy DIR is applied at the POS in all phases including the coverage gap. Its results are generally consistent with the direction and magnitude of CMS's overall findings by stakeholder. The independent analysis assumed no behavior changes among stakeholders, which, if considered, could have a material impact on the estimates.

While *in total*, both reports conclude beneficiaries may save more in cost sharing than they would pay in increased premiums, this conclusion does not hold among individuals. The independent analysis indicates that *at best* 29% of beneficiaries may see cost-sharing savings that exceed their increases in premiums. By contrast, at least 38% of beneficiaries may realize higher net costs, as their premium increases typically outweigh their cost-sharing savings, and 33% (low income enrollees) may see little or no change in OOP costs.[39] Since there is wide variation in how plan sponsors and PBMs contract DIR with pharmacies, there is also a chance that as few as 10% of beneficiaries (those who are non-low income (NLI) and end the year in the coverage gap or catastrophic phases) could recognize cost-sharing savings in excess of increased premiums. In this scenario, 57% of beneficiaries (35% of beneficiaries who are NLI with no claims or end the year in the deductible and 22% of beneficiaries who are NLI and end the year in the initial coverage limit) would see an increase in net costs. See Figure 1.

[38] Milliman Report: Medicare Part D Pharmacy Price Concessions at the Point of Sale. February 18, 2022. Available at https://www.milliman.com/en/insight/medicare-part-d-pharmacy-price-concessions-at-the-point-of-sale. Note that Figure 3 in our letter is Figure 2 in the Milliman report.
[39] We do not hold, however, that LIS enrollees are actually "held harmless" under the Proposed Rule. We argue later that enrollment disruptions and benefit reductions are likely outcomes for LIS enrollees.

Figure 1. *Estimated Share of Individual Market Part D Enrollees in 2023 and How They are Affected by the Proposed Rule.*

BENEFICIARY CATEGORIZATION	PERCENTAGE OF BENEFICIARIES[1]	ESTIMATED FINANCIAL IMPACT OF REFLECTING PHARMACY DIR AT THE POS
Low Income	33%	Small or no effect on premiums and cost sharing
Non-low income, end year with no claims or in deductible phase	35%	Typically experience net increase in costs (potential premium increases typically outweigh potential cost sharing reductions)[2]
Non-low income, end year above deductible phase	32%	Could experience net increase or decrease in costs[3] • If pharmacy DIR is contracted on a per script basis, NLI beneficiaries who end the year in the initial coverage limit (ICL) or coverage gap phases (29%) may typically experience lower overall costs, and NLI beneficiaries who end the year in the catastrophic phase (3%) may typically experience higher overall costs • If pharmacy DIR is contracted as a percentage of allowed cost, NLI beneficiaries who end the year in the coverage gap or catastrophic phases (10%) may typically experience lower overall costs, and NLI beneficiaries who end the year in the ICL phase (22%) may typically experience higher overall costs.

[1] Projected 2023 baseline scenario in which pharmacy DIR is applied after the POS.
[2] The impact to plan premium depends on the current level of pharmacy DIR. Plans with little or no pharmacy DIR may experience premium decreases.
[3] Percentages are of total individual Part D market (i.e., additive to the 32% who are NLI and end the year above the deductible phase)

There are important dynamics that make it difficult to better predict outcomes among NLI beneficiaries. These include the volume and cost composition of a beneficiary's prescriptions over the course of the year, whether they filled their prescriptions at preferred pharmacies or other network pharmacies, and benefit design applied to filled prescriptions, with coinsurance designs yielding greater savings than copay savings.

We acknowledge that all policy changes create winners and losers. However, CMS has not proposed a change that reduces OOP costs for most beneficiaries. This finding alone should be sufficient for CMS to abandon this proposal.

C. CMS is risking a complete destabilization of the Part D program with this rule

CMS ignores the most likely outcome of the rule: the disintegration of preferred cost-sharing pharmacy arrangements for plan year 2023. Under current rules, plans incentivize their enrollees to patronize preferred pharmacies through lower cost sharing on covered drugs. CMS benefits as well, since negotiated prices are also lower at preferred pharmacies. These pharmacies accept these terms in exchange for higher patient volumes, and retain their statuses based on meeting pre-defined performance metrics related to Part D Star Ratings measures. Pharmacies that meet these metrics retain larger amounts of potential price concessions. Pharmacies that underperform pay back the plan sponsor and are at risk of being removed from preferred networks. This

double-whammy effectively preserves preferred pharmacy performance at a minimum threshold, which protects beneficiaries.

In the rule, CMS seems to argue that existing price concession arrangements can continue.[40] However, PCMA believes PBM-pharmacy contracts need to be renegotiated in full. Pharmacies will continue to prefer upside-only arrangements, and due to operational complexities of administering multiple prices, PBMs may yield. We are concerned that without preferred cost-sharing pharmacy network agreements lacking negative price concessions, that pharmacy quality performance will suffer. These arrangements rely on the "loss aversion" theory of incentives which are used throughout Medicare's programs.[41] Pharmacies do not need CMS to step in and "save" them from PBMs.[42] If anything, CMS should step back and allow PBMs to better incentivize generic dispensing among independent pharmacies, for the benefit of Part D enrollees and taxpayers.[43]

D. Beneficiaries will not observe out-of-pocket savings at the time of enrollment or notice them at the POS

While CMS regulations directly touch the defined standard benefit, plans have the flexibility to apply actuarial equivalence testing to design benefits that are more appealing to potential enrollees. These designs include reduced or eliminated deductibles and copays rather than standard 25% coinsurance. The Kaiser Family Foundation estimates that in 2021, copays are the normal cost share applied to generic drugs, and coinsurance is typically limited to non-preferred brands and specialty drugs.[44] The vast majority of prescriptions dispensed in the Part D program are generic drugs.

We acknowledge continued high OOP costs for select groups of beneficiaries.[45] At the same time, OOP costs have been declining at the aggregate level, and at each measured quantile.[46] Part D plans, through tools such as preferred pharmacy networks,

[40] There is disagreement on this point in the Proposed Rule. OACT assumes that pharmacies retain 2 percent of existing price concessions. This could only happen through improved pharmacy leverage at the outset of a new negotiation, rather than the execution of existing contracts.
[41] See for example Medicare ACO Results for 2018: More Downside Risk Adoption, More Savings, and All ACO Types Now Averaging Savings", Health Affairs Blog, October 25, 2019.
[42] Independent pharmacies are not at risk of closing and continue to maintain reasonable operating margins across their lines of business. See https://www.drugchannels.net/2022/02/five-things-to-know-about-state-of.html.
[43] *Ibid*. Fein writes "IQVIA data show that for 2020, the GDR for unbranded generics in the overall market was 88.5%. The NCPA Digest reports that the GDR for independent pharmacies was only 86% for 2020."
[44] See https://www.kff.org/medicare/issue-brief/key-facts-about-medicare-part-d-enrollment-premiums-and-cost-sharing-in-2021/.
[45] ASPE, "Prescription Drug Affordability among Medicare Beneficiaries," January 19, 2022. Available at https://aspe.hhs.gov/sites/default/files/documents/1e2879846aa54939c56efeec9c6f96f0/prescription-drug-affordability.pdf.
[46] Carroll WA, Miller GE, Hill SC. AHRQ STATISTICAL BRIEF #532: Out-of-Pocket Spending for Retail Prescribed Drugs by Age and Type of Prescription Drug Coverage, 2009 to 2018. Available at https://meps.ahrq.gov/data_files/publications/st532/stat532.shtml.

have helped decrease OOP costs for chronic medications by 12% from 2009 to 2019.[47] While we acknowledge that beneficiaries at the upper end of the distribution do pay high amounts OOP, this Proposed Rule does not meaningfully help those patients.

E. With this rule, CMS is piling on premium increases for beneficiaries

In November 2021, CMS announced a historical premium increase for the Part B benefit of 15% for 2022.[48] While some of this increase is statutory, the majority of it is a contingency related to a single, expensive, unproven prescription drug. In a striking case of complete tone-deafness, this Proposed Rule increases premiums for prescription drug coverage while failing to address the underlying issue that caused the Part B premium increase: the prices that drug manufacturers alone set for their drugs. In both cases, the warnings regarding premium increases are being made from within CMS. While the prior administration flagrantly dismissed OACT estimates on several occasions,[49] this administration risks looking uncaring and unsympathetic.

F. In combination, these likely yet unexplored outcomes make CMS's proposal arbitrary and capricious

The proposal to re-define "negotiated price" is based on a series of incorrect assumptions and factual errors. CMS's flawed reasoning renders the Proposed Rule unlawful. An agency's policy choices must be the result of reasoned decision-making.[50] Courts have concluded previously:

> Normally, an agency rule would be arbitrary and capricious if the agency … entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.[51]

Reasoned decision-making requires an agency to "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'"[52] It requires an affirmative showing "that the agency genuinely consider[ed] the salient problems presented in the record.[53] As

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[47] Zhou T, Liu P, Dhruva SS, et al. Assessment of Hypothetical Out-of-Pocket Costs of Guideline-Recommended Medications for the Treatment of Older Adults With Multiple Chronic Conditions, 2009 and 2019. JAMA Intern Med. 2022;182(2):185–195. doi:10.1001/jamainternmed.2021.7457
[48] See https://www.cms.gov/newsroom/press-releases/cms-announces-2022-medicare-part-b-premiums.
[49] Secretary Azar's signing statement for the final rebate rule, most notably.
[50] *See American Mining Cong. v. EPA*, 907 F.2d 1179, 1187 (D.C. Cir. 1990).
[51] *See Motor Vehicle Mfrs Ass'n of the United States, Inc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).
[52] *State Farm*, 463 U.S. at 43 (1983); *see also Bowman Trans., Inc. v. Arkansas-Best Freight Syst., Inc.*, 419 U.S. 281, 288 n.4 (1974) ("[A] party is entitled…to be apprised of the factual material on which the agency relies for decision so that he may rebut it.").
[53] *See Cross-Sound Ferry Servs. v. Interstate Commerce Com.*, 738 F.2d 481, 487 (D.C. Cir. 1984).

such, "*ipse dixit* conclusion[s]…epitomizes arbitrary and capricious decision making."[54] Furthermore, an agency's mere assertion that a factor was taken into consideration cannot serve as a substitute for actually considering it.[55]

Here, the agency has failed to appropriately consider relevant data that dramatically undermines its policy choices, resulting in CMS's reaching implausible conclusions. As described above, CMS has overstated the growth of pharmacy DIR (with the one-sided implication that any growth is nefarious) and miscalculated in concluding that any limited savings in beneficiary cost sharing outweighs the significant increase in premiums, among other failures. CMS must genuinely consider each of these issues in order for the new policy to be permissible under the APA.

***PCMA recommendation*: CMS failed to adequately understand the effects of this proposal on beneficiaries, Part D plan sponsors, and pharmacies. Finalizing it would be arbitrary and capricious.**

3. The Proposed Rule disincentivizes value-based care and reduces the quality of pharmacy care provided to Medicare beneficiaries

A. Pharmacy price concessions are generated by two-sided, value-based contracts, for which CMS otherwise is pushing

Since 2010, the traditional Medicare fee-for-service program has made significant progress in moving from paying for volume to paying for value.[56] CMS's efforts including programs for physicians and hospitals, as fee-for-service providers,[57] and as participants in accountable care organizations (ACOs).[58] For Part C Medicare Advantage (MA) plans, CMS continues to press for value-based payments.[59] Obtusely, CMS in this Proposed Rule is ignoring that the Part D program operates the most value-based Medicare benefit of all: preferred cost-sharing pharmacy networks.

Preferred pharmacy networks are two-sided, value-based contracts between Part D plans and pharmacies. If pharmacies meet pre-defined thresholds, they can retain a larger amount of their reimbursements and possibly earn bonuses. If they fail to meet

[54] *See Illinois Pub. Telecomm. Ass'n v. FCC*, 117 F.3d 555, 564 (D.C. Cir. 1997).
[55] *See Treasury Employees Union, v. Horner*, 854 F.2d 490, 499 (D.C. Cir. 1986).
[56] See https://www.hanys.org/communications/publications/healthcare_intelligence_reports/docs/2020-06_the_next_decade_of_value_based_care.pdf, finding that in 2019 nearly 35% of original Medicare payments were made under value-based arrangements rather than straight fee-for-service.
[57] See 86 Fed. Reg. 63458 (November 16, 2021) and 86 Fed. Reg. 44774 (August 13, 2021).
[58] Medicare ACO Results for 2018: More Downside Risk Adoption, More Savings, and All ACO Types Now Averaging Savings", Health Affairs Blog, October 25, 2019.
[59] Advance Notice of Methodological Changes for Calendar Year (CY) 2023 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies, February 2, 2022. For 2023, CMS is soliciting feedback on new Star Ratings measures that assess whether MA plans engage in value-based care models with providers.

these thresholds, they pay price concessions back to the PBM. Plans through their PBMs similar face both sides of the risk. Unlike value-based models FFS Medicare, where CMS still faces significant financial risk, CMS is wholly protected against these risks in Part D because of the annual bid and payment reconciliation processes. For 2022, 99% of PDP enrollees elected plans with these kinds of networks in place.[60]

To draw this out more directly, the Proposed Rule under consideration would be akin to canceling CMS's physician quality performance program, which today provides meaningful and downside risk. CMS should strongly reconsider any rule change that moves toward volume, and away from value, like this Proposed Rule does.

B. The Proposed Rule contradicts CMMI's strides toward drug-specific models

CMMI was created in 2010 to specifically identify value-based care opportunities. However, in its first decade, only a few models that targeted the Part D program were launched,[61] and only one is still in operation. The Part D Senior Savings Model (SSM) program relies on voluntary drug manufacturer participation to reduce cost sharing for select insulin products to no more than $35 for a 30-day supply. CMMI is considering expanding this model to other therapeutic areas.[62]

Part D plans that participate in SSM are relying on their preferred pharmacy networks to stock and dispense the specific insulin products. Additional contract terms help plans achieve their goals for this population. Pharmacy interactions can increase adherence to prescribed medications and foster therapeutic substitution that can save beneficiaries and plans money in the long run. This Proposed Rule would undercut the relationships formed between PBMs and pharmacies, misaligning their work on behalf of beneficiaries, putting CMMI's objectives at risk.

C. Pharmacy quality has improved since preferred networks began to grow

To track pharmacy quality and administer preferred pharmacy contract terms, PBMs measure pharmacies using third-party endorsed measures,[63] tracked through industry standard portals,[64] that represent a subset of the Part D Star Ratings measures where pharmacies can play a role in improving beneficiary health outcomes. In May 2021,

[60] Drug Channels, "Supermarkets Again Dash Past CVS and Walgreens in 2022's Part D Pharmacy Networks," March 1, 2022. Available at https://www.drugchannels.net/2022/03/supermarkets-again-dash-part-cvs-and.html.
[61] CMS implemented and then retired the Part D Payment Modernization Model from 2019 to 2021. See https://innovation.cms.gov/innovation-models/part-d-payment-modernization-model.
[62] CMMI, "Innovation Center Strategy Refresh," January 2022. Available at https://innovation.cms.gov/strategic-direction-whitepaper.
[63] Respondents identified Medication Adherence for Diabetes Medications, Medication Adherence for Hypertension (RAS antagonists), Medication Adherence for Cholesterol (Statins), and Statin Use in Persons with Diabetes (SUPD).
[64] For example, the EQuIPP tool, available at https://www.equipp.org/professional.aspx.

PCMA conducted a survey of its members regarding the measures used for pharmacy performance management, which were expected to be subject to federal government reporting beginning in 2022. Members reported that measurement focus is on adherence to specific classes of medication therapy that target chronic conditions with widely-available, low-cost generic drugs.

In looking at CMS's historical Part D Star Ratings data for these commonly used measures, we find the average contract level performance has increased each year since 2013 for diabetes, hypertension, and cholesterol medications. It has increased each year also since 2017 (when it was first measured) for statin use in persons with diabetes (SUPD).[65] (See Figures 2 and 3.) If plan sponsors can no longer rely on programs run by their preferred pharmacies to improve patient adherence, CMS is putting all of these gains at risk.

D. Pharmacy performance measures are population-based, which provide broad-based incentives to improve care across SDOH-barriers

Recent research has shown that pharmacy performance measures that address social determinants of health (SDOH) help promote equitable and high-quality care.[66] Recognizing the importance of SDOH, entities as wide-ranging as the Pharmacy Quality Alliance (PQA)[67] and the World Health Organization are concluding that health care outcomes are dependent on factors such as the built environment and economic stability.[68] Ultimately, Medicare beneficiaries are best served when their providers are focused on addressing community-level SDOH barriers. In pharmacy care, a number of programs are funded and incentivized through Part D plan price concessions that CMS would effectively eliminate.

[65] Analysis of Stars Rating Measure Data files for CY2015-CY2022, available online at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.
[66] See https://www.healthaffairs.org/do/10.1377/forefront.20220120.825396 (2022)
[67] See The Importance of SDOH and Pharmacist Intervention (pqaalliance.org)
[68] See ConceptualframeworkforactiononSDH_eng.pdf (who.int)

Figure 2. Trends in Average Contract Level Performance on Stars Adherence Measures, CY2015 to 2022.

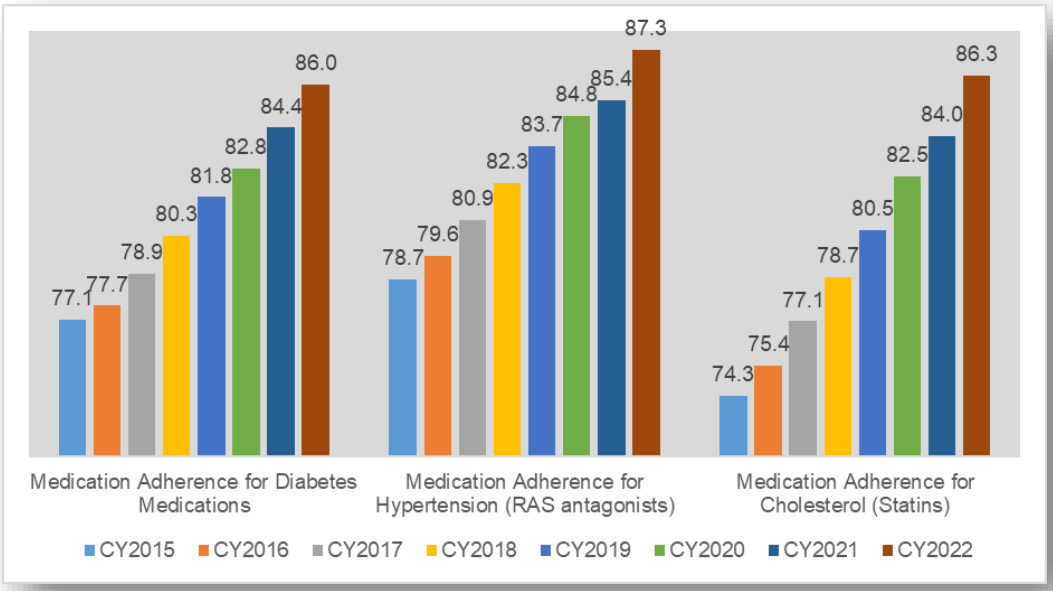
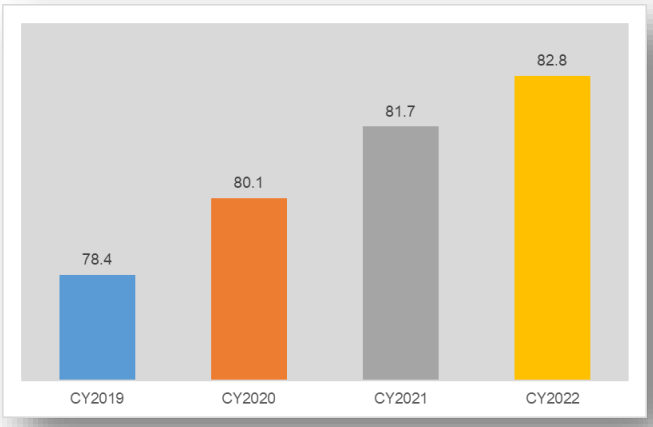


Figure 3. Trends in Average Contract Level Performance on the Stars Statin Use in Persons with Diabetes (SUPD), CY2019 to 2022.[69]



This Proposed Rule is also out of step with CMS's own efforts to link payment to quality. In February 2022 CMS issued a request for quotes for the development of a potential "health equity index" across the Part D Quality Rating System (Star Ratings).[70] De-

[69] This measure was first collected for CY2019 (during calendar year 2017).
[70] Request for Quote: Analysis Related to Medicare Advantage and Part D Contract Star Ratings. February 14, 2022. Available at https://sam.gov/opp/702c556cd8714ca99006b237ea3e3bb2/view.

linking pharmacy payment from performance puts in peril any efforts CMS itself otherwise has underway.

E. CMS is risking its important work with partners toward a standard set of measures to improve pharmacy certainty

The stakeholder community in support of value-based pharmacy care recognizes the importance measuring pharmacy quality with a focus on SDOH. As one example, PQA is investigating the impact of SDOH on pharmacy and medication access by using a community-level multi-stakeholder perspective to analyze current gaps in knowledge and interventions that currently exist in pharmacy settings.[71] PQA is proactively investigating the role of pharmacists and pharmacy services in addressing patients' SDOH, including SDOH screenings and additional services that address barriers to medication access and increase medication adherence.[72] These efforts include community partners and other stakeholders and are focused on gathering and finding solutions regarding existing knowledge gaps about SDOH in the pharmacy settings. CMS should take note of this and similar efforts and work on facilitating the development of SDOH-focused pharmacy quality measures, rather than disincentivize this important work.

A significant change to discourage value-based care in pharmacy would be a major setback for CMS's (and PCMA's) partner organizations. For example, AMCP has updated its principles on pharmacy pay-for-performance[73] and continues to develop regulatory pathways for health plan and pharmacy-level measurement innovations. PQA has just unveiled new pharmacy-level measures that bring much better transparency to individual pharmacies on their performance.[74] If plans and pharmacies have to back away from preferred networks for financial and operational reasons, all of the momentum on these efforts is halted.

F. Generic dispensing is at risk based on changes to incentives for pharmacies

Beyond overall quality improvement in Medicare Part D, the Proposed Rule could misalign the incentives pharmacies have today to substitute generic drugs when available. A PBM's pharmacy contract may target generic substitution or dispensing as a triggering event along with medication adherence scores for price concessions. The uptick in preferred pharmacy contracts is correlated with a consistent upward trend in the overall Part D generic dispensing rate. See Figure 4.

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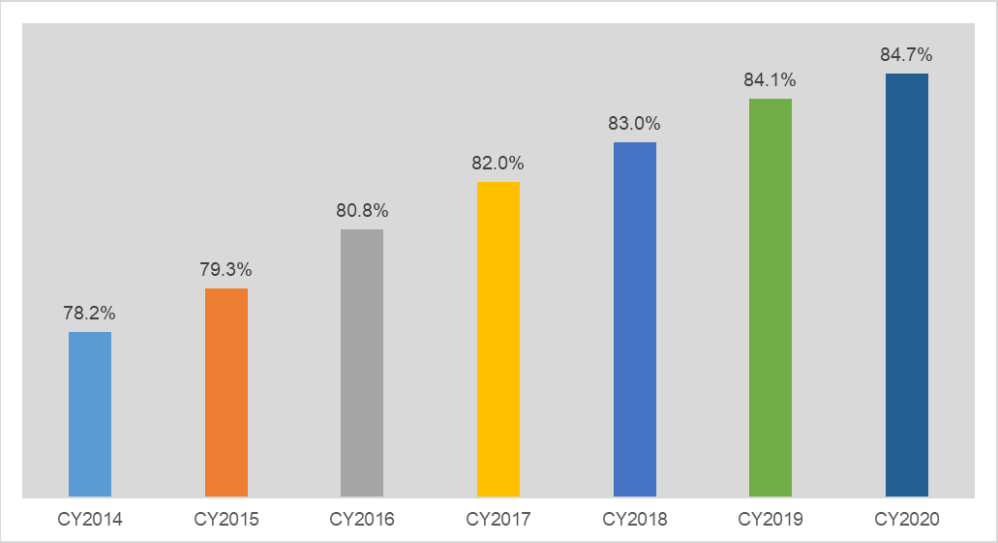
[71] The Importance of SDOH and Pharmacist Intervention (pqaalliance.org)
[72] The Importance of SDOH and Pharmacist Intervention (pqaalliance.org)
[73] Available at https://www.amcp.org/policy-advocacy/policy-resource-center/amcp-pharmacy-pay-performance-principles, last revised December 14, 2021.
[74] Cost M, "Implementing Pharmacy Performance Measures for Value-Based Care." February 10, 2022. Available at https://www.pharmacytimes.com/view/implementing-pharmacy-performance-measures-for-value-based-care.

Figure 4. Trends in Part D Generic Dispensing Rates, 2014 to 2020.[75]



G. Moving away from preferred networks increases costs

Under the Proposed Rule, CMS estimates that cost sharing would be reduced for some beneficiaries. However, a more likely outcome – especially if this rule is implemented for 2023 – is that preferred networks would disappear in the short term. The increase in cost sharing that would occur without preferred networks would overwhelm the savings CMS estimates based on marginally-reduced negotiated prices.[76] CMS's own research in 2014 (when the first pharmacy price concessions policy proposal was offered) demonstrates that cost sharing and negotiated prices are lower in preferred pharmacies.[77] More recent research confirms that preferred networks reduce total costs by about 2%.[78] Because this Proposed Rule will effectively eliminate preferred networks in 2023, it will increase costs for all stakeholders beyond what CMS has estimated.

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[75] Analysis of CMS, "Medicare Part D Utilization," available online at https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-service-type-reports/medicare-part-d

[76] A 2014 analysis found that PDP enrollees would pay $80 to $100 more in out-of-pocket costs if plans no longer offered preferred pharmacy networks. See https://www.pcmanet.org/wp-content/uploads/2016/08/ow-report-part-d-proposed-rules-mar-2014.pdf. This compares to the CMS estimate of $57 per year in cost-sharing savings in Table 16.

[77] The Federal Trade Commission summarizes this research in its 2014 comment letter to CMS entitled "re: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs," March 7, 2014. Specific CMS studies cited include http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/PharmacyNetwork.pdf and https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Negotiated-Pricing-Between-General-Mail-Order-and-Retail-PharmaciesDec92013.pdf

[78] Starc A and Swanson A, "Promoting Preferred Pharmacy Networks." Available at https://onepercentsteps.com/policy-briefs/promoting-preferred-pharmacy-networks/.

H. The Proposed Rule poses serious risks to the LIS population

Another important consideration CMS has overlooked in the rule is the effect this change may have on the competitive dynamics of PDPs and MAPDs and whether there would be a significant change in plan offerings. PDPs are more likely to offer plans with preferred pharmacy networks,[79] since they have fewer non-pharmacy levers at their disposal to constrain costs or gain from non-pharmacy offsets. Thus, the plan types most greatly disadvantaged by this proposal are standalone PDPs. Should sponsors decide to offer fewer PDPs as an outgrowth of this rule change, CMS needs to consider the effects this would have on plan availability and LIS auto-enrollment and re-enrollment.

More strikingly, this Proposed Rule could reduce the supplemental benefits offered to LIS enrollees enrolled in MAPDs, including food and nutrition services, housing renovation, transportation, and vision and dental benefits.[80] These are not benefits under the traditional Medicare program, but can be offered by MA plans using the rebates generated under their bids. Currently, MA plan sponsors use these rebates to create $0 premium Part D prescription drug benefits first, and then take additional rebate dollars to build out robust supplemental benefits like those listed above. Should this rule be finalized, premiums will increase by 5-11% as estimated by CMS and Milliman. MA plan sponsors will need to allocate more bid rebate dollars toward Part D coverage. This reduces the amount of dollars MA plans can put toward these other benefits, which can help to ameliorate many SDOH-based barriers to care. CMS should pause to consider the clear spillover effects that this rule would have on vulnerable populations.

I. CMS should follow its previous path forward before making any changes

Rather than disrupt beneficiary care and the Part D program's record of stellar financial performance, CMS should pursue its previously finalized regulatory path forward. Just as we showed above in terms of CMS drawing the wrong conclusions about the growth of DIR, CMS has not collected or analyzed the quality performance data discussed in this section to conclude that the current rules do not work. Without a full understanding of how PBMs hold pharmacies accountable, CMS is risking tearing down the scaffold on which high-quality benefits are delivered. Instead, CMS should initiate data reporting by PBMs as called for in the January 2021 final rule.[81] Under that rule, CMS should be collecting the specific measures that Part D plan sponsors are using to measure pharmacy quality during 2022. With these data, CMS could assess the claims raised by pharmacies that the measures are unknown or unachievable. However, CMS has not published for public comment even its initial draft data collection forms under the

[79] Drug Channels, November 2, 2021.
[80] Gundhi S and Gebremehdin D. "Expanding Supplemental Benefits In Medicare Advantage: Barriers To Adoption And Opportunities To Accelerate", Health Affairs Blog, February 24, 2021.
[81] 86 Fed. Reg. 5864, January 19, 2021. This provision was first proposed in January 2020 to be implemented for 2021, but not finalized for plan year 2020 due to the COVID-19 pandemic.

Paperwork Reduction Act, so the data collection cannot feasibly begin for several more months – and maybe not even until 2023.

Beyond CMS's own proposals, the Medicare Payment Advisory Commission (MedPAC) was recently granted access to CMS's detailed DIR reporting data by Congress.[82] MedPAC staff are just beginning to sort through the several years of rich data these files contain. CMS should pause any policy proposal development until MedPAC (or CMS itself) analyzed the data to better understand how the industry uses these price concessions to improve the Part D benefit. Even merely updating its own 2014 research[83] would demonstrate the adverse effect of this proposal.

***PCMA recommendation*: The proposal undercuts CMS's own initiatives to improve the value of health care provided to beneficiaries. Rather than finalize this rule, CMS should continue forward on its path toward proposing standardized measures with limits on pharmacy price concessions tied to their usage.**

4. The Proposed Rule makes Medicare Part D pricing *less* transparent and introduces unnecessary confusion

A. Beneficiaries choose plans based on price and quality

During the Annual Enrollment Period (AEP) and when someone is new to Medicare, potential enrollees can view, search, and sort plans on the Medicare Plan Finder (MPF) tool, on a wide variety of dimensions. They can search on premiums, pharmacy network, plan Star Ratings, cost sharing, coverage of their specific drugs, and for MAPDs, specific provider networks, too. Over the course of the Medicare Part D program, enrollees have typically prioritized premium, accounting for plan quality (Stars), above all else. Reconfiguring the program to prioritize cost sharing runs counter to consumer preference.

Star Ratings drive enrollment, and plans use Star Ratings to align pharmacy incentives and to keep premiums competitive, through pharmacy price concessions. The entire selective pharmacy network paradigm is geared toward consumer preference. Diminishing the importance of pharmacy quality performance unwinds years of iterative learnings in designing and offering the plans people most prefer.

[82] Section 112 of Division CC, Title I, Subtitle B provides MedPAC and MACPAC access to otherwise confidential data held by CMS for the Medicare and Medicaid programs.
[83] See http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/PharmacyNetwork.pdf and https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Negotiated-Pricing-Between-General-Mail-Order-and-Retail-PharmaciesDec92013.pdf

If CMS is concerned that enrollees prioritize premiums over OOP costs, CMS could use recent changes to the MPF tool as a "natural experiment" to see how important premiums are in the total calculus of plan choice when OOP estimates are more broadly available. Beginning for the 2019 plan year, the MPF tool allows users to input their drug lists and pharmacy preferences and view which plans might offer them the best value, accounting for both premiums and OOP costs. For 2019, CMS operated both the original and the revised MPF tools, allowing beneficiaries to opt-in to the new tool. For 2020, only the new tool was available, but several quirks led to stakeholder engagement and new round of revisions to make the tools work as designed, for plan year 2022 enrollment.[84] One of these improvements is to specifically flag for potential enrollees which pharmacies are preferred within the plan. Nowhere in this rule does CMS analyze the effect of these changes, which would better draw out what matters to Medicare beneficiaries.

B. The rule reduces transparency to enrollees

We described previously why many contracts between pharmacies and PBMs and PBMs and plan sponsors will need to be renegotiated. As a result, a pharmacy may be reimbursed based upon higher, current negotiated prices, and continue to pay price concessions when warranted. Cost sharing would be based upon the rule's resultant lower negotiated prices. Under the same plan, another pharmacy may instead accept different reimbursement terms, to be paid the negotiated price cost sharing is based upon, and possibly earn performance bonuses rather than pay price concessions. Compounding this confusion, as proposed, the rule would not require that pharmacy price concessions be applied to the POS price for claims filed during the beneficiary's Coverage Gap benefit phase.

Contracts thus may need to account for four pharmacy reimbursement rates and two cost-sharing amounts. CMS's MPF tool will need to be revised to allow plan sponsors to list all of these prices. CMS will need to consider how to address these prices and straddle claim prices in beneficiary model communications like the Explanation of Benefits (EOB). CMS's PDE data reporting and True Out-of-Pocket (TrOOP) accumulator will need to be reprogrammed since the benefit phases are based on a combination of OOP costs incurred by enrollees and also total drug costs paid by the plan. Important questions for the EOB and TrOOP accumulator include how the new negotiated price compared to the plan-paid amount will be reflected for claims in the deductible.[85] These complex external and internal operational changes cannot be completed by October 2022 for open enrollment.

[84] CMS Health Plan Management System, Medicare Plan Finder Enhancements for Contract Year 2022, May 16, 2021.
[85] With two potential negotiated prices, a pharmacy may request reimbursement from the plan sponsor for a claim in the deductible, if cost sharing is based on price net or price concessions, but pharmacy reimbursement is tied to existing negotiated prices. A claim in the deductible then will count in part toward the meeting the Initial Coverage Limit (ICL).

C. CMS should instead focus on implementing real-time benefit tools (RTBT)

Rather than slight differences in beneficiary cost sharing through this Proposed Rule, the most direct path to pricing transparency is through the widespread use of provider and beneficiary-level RTBTs. Specifically, prescriber RTBT allows for real-time decision-making to guide beneficiaries and advise them regarding their options and focus on clinically needed drugs and their respective prices.

Many plans have already implemented RTBT solutions. However, these solutions are proprietary and can lead to highly variant user experiences. In an effort towards standardization, following CMS regulation requiring the availability of at least one RTBT per plan that communicates with at least one widely-used electronic prescribing system,[86] Congress mandated broader adoption of RTBTs for 2023, and mandated provider use of these tools.[87] In response to these events, the National Council for Prescription Drug Programs, (NCPDP) has developed a standard for a real-time prescription benefit request and response for use by providers and asked that CMS name the specific telecommunications standard for use by Part D program participants.[88] Having the NCPDP standard named by CMS could help with provider RTBT adoption. CMS has not yet issued a Proposed Rule naming the NCPDP standard, therefore, compliance by January 2023 is not possible.

Also arguing for RTBT, rather than changing POS pricing, is that it creates a way to get price information into the hands of beneficiaries that don't have smart phones or computers. This population has fewer options once the prescription has been sent to the pharmacy which again leads to rework for the prescriber and pharmacy. While the Medicare population is becoming more comfortable with technology, financial and social barriers to technology remain. Therefore, implementation and mandatory requirement of provider RTBT is necessary for efficient and socially-sensitive social determinants of health focused care delivery.

PCMA recommendation: The proposal would lead to less transparency and more confusion about the Part D benefit. CMS will better improve the Part D program experience for beneficiaries if it focuses on meaningful and actionable transparency, such as that created by RTBTs, integrated into existing EHRs.

5. The rule cannot be implemented in 2023 as proposed, and not without considerably higher costs to plans and CMS than described

[86] 84 Fed. Reg. 23842, May 23, 2019
[87] Sec. 114 of the Division BB, Title I, of the Consolidated Appropriations Act of 2021, also known as the No Surprises Act. Public Law 116-260, December 27, 2020.
[88] Available at https://standards.ncpdp.org/Standards/media/pdf/Correspondence/2021/20210820_To_CMS_RTPBandFandBStandardsAdoptionRequest.pdf.

A. CMS should not make such significant changes to the program when it should instead be working to wind down or officially incorporated policies put in place during the COVID-19 PHE

Pharmacies, pharmacists, and pharmacy techs have stepped up in the face of the COVID-19 pandemic, and CMS should not impose this rule's significant financial burden on them. If the PHE has expired by the time the 2023 plan year begins, then pharmacies and beneficiaries deserve a chance to return to normal – acknowledging that "normal" will mean something different than it did in 2019. CMS waived a number of policies across Part D and the entire Medicare program that made seeking care and getting needed medicines much easier.[89] Some of these changes were mandated by Congress and will revert to pre-PHE stances.[90] However, the practice of telemedicine and telepharmacy increased significantly and should be normalized to an extent.

If instead the COVID-19 PHE continues into plan year 2023, then that would mean that retail pharmacies are still handling diagnostic tests, dispensing, and counseling for anti-virals, and playing the role of the front-line voice of the national public health apparatus. It would be extremely unwise to then at the same time, reduce reimbursements to high-performing pharmacies across the board by regulatory fiat.

B. Current technical standards from NCPDP do not support the hypothesized claims adjudication process

There's an entire ecosystem of stakeholders that will need to make systems and infrastructure upgrades to accommodate this rule change. Beyond those already named in this letter – CMS, PBMs, plan sponsors, and pharmacies – electronic transaction communication standards from NCPDP will need to be assessed, with potentially new codes or values to be developed.[91] Electronic prescribing and electronic health records software may need to be revised, as will mandatory RTBTs. Without a final rule and subsequent rounds of subregulatory guidance and technical workshops, these changes cannot be made for the 2023 plan year.

C. CMS will be unable to finalize any rule in time for 2023 bid preparations

The Proposed Rule presents a significant timing issue because it was published in the *Federal Register* on January 12, 2022, too late to be effectively integrated into the Part D bidding and contracting cycle. At a high level, contracting, operational changes including

[89] For example, see CMS's announcement here: https://www.cms.gov/newsroom/press-releases/cms-issues-guidance-help-medicare-advantage-and-part-d-plans-respond-covid-19.
[90] See CARES Act Section 3714, for example.
[91] NCPDP stood up a working group to address the CY2015 proposed rule. It was disbanded because the final rule did not include the proposed changes.

information technology updates, and formulary and bid development are at risk. Errors that can impact beneficiaries are more likely and managing to these risks both adds unnecessary administrative costs and introduces conservativism in bidding behavior that care reduce the value of the benefit.

Specifically, we are concerned that finalizing the pharmacy DIR rule for CY2023 is unworkable because it would be misaligned with the timelines for many critical aspects of the typical Part D calendar. For context, recent technical rules have taken on average 4.5 months between *Federal Register* publication of the proposal and promulgation of the final. This means we likely would not receive the final pharmacy DIR rule until late May 2022, roughly a week before bids are due to CMS. We list below the key calendar elements that require a final regulation.

i. **Draft Bid Pricing Tool (BPT) has already been released**

CMS already has the BPT for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP) CMS-10142 paperwork reduction act (PRA) process in flight.[92] Historically and in this draft, the BPT does not distinguish between pharmacy DIR and other types of DIR. In other words, the BPT and the BPT guidance have utilized an all-in DIR metric. CMS would have to make modifications to the BPT to implement pharmacy DIR. We note that historically the BPT PRA process, has on average taken about three months.[93] Moreover, the beta testing has also already begun.[94] Comments for the beta testing are due March 7, 2022, the same date we are filing these comments, and well before the expected release of the final rule.

ii. **The Advance Notice of Methodological Changes for Calendar Year (CY) 2023 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies ("AN") already released**

The AN was released on February 2, 2022.[95] There are Part D bidding and payment policies in the AN that would be impacted by these provisions, if finalized, but the proposal is altogether unmentioned in the AN. For example, the risk adjustment model for CY2023 is proposed to be calibrated on 2018 claims and encounter data, plus expenditure data from 2019 PDE records that do not reflect pharmacy DIR being applied at POS.

[92] See PRA package released on January 14, 2022, available online at https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10142
[93] Analysis of BPT Information Collection Review Timelines, available online at https://www.reginfo.gov/public/Forward?SearchTarget=PRA&textfield=bid+pricing+tool&Image61.x=14&Image61.y=7
[94] CMS HPMS memo from Jennifer Lazio, "Contract Year 2023 MA and Part D Bid Pricing Tool Beta Testing," February 11, 2022.
[95] Advance Notice of Methodological Changes for CY2023 for MA Capitation Rates and Part C and Part D Payment Policies, February 2, 2022 (CY2023 Advance Notice).

There is historical precedent for CMS making adjustments to the model in such situations. For example, the RxHCC model was recalibrated to factor in the impact of the new Medicare Part D benefit structure and coverage gap discount program as a result of passage of the ACA.[96] Moreover, CMS applied an actuarial adjustment to the coefficient of the chronic Hepatitis C RxHCC in payment years 2016 and 2017 to account for the medications to treat chronic Hepatitis C that had mostly entered the market after the model calibration years.[97] We note that risk adjustment is not the only issue impacted by pharmacy DIR at POS. The underlying trends used to make the annual adjustments to Medicare Part D benefit parameters would also be impacted. Here as well, CMS makes no mention of the Proposed Rule. The Final Notice will be published not later than April 4, 2022, well before the expected release of the final rule. The Final Notice is the guidance plans need to construct their bids.

iii. **Out-of-Pocket Cost (OOPC) Models are under development**

These models are targeted for release in April 2022, possibly before the publication of a final rule.[98] The values produced from these models are used in CMS's bid review. The baseline was already released on January 21, 2022.[99] Since the average price for each RxCUI in the model could be influenced by pharmacy DIR at POS, CMS would have to decide if adjustments for that would be appropriate.

iv. **Release of the CY2023 Plan Creation Module, Plan Benefit Package (PBP), and Bid Pricing Tool (BPT) software in the Health Plan Management System**

The BPT launch is targeted for April 8, 2022, before the expected promulgation of a final rule.[100] We have already discussed the obvious pharmacy DIR impacts to the BPT. However, it is not clear if CMS would want to address pharmacy DIR at all in the PBP submissions.

v. **Final Beneficiary Materials**

Final beneficiary materials are often released by May of each year.[101] These include the Annual Notice of Change (ANOC), Evidence of Coverage (EOC), and pharmacy directory. They would likely early have to be delayed or re-released later to reflect changes made to the benefit under the rule, as have been described above.

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[96] CY2012 Advance Notice and Call Letter
[97] CY2017 Advance Notice and Call Letter
[98] CY 2023 Medicare Parts C and D Annual Calendar, February 4, 2022
[99] CY 2022 Baseline OOPC Models (01.21.2022) (ZIP), available online at https://www.cms.gov/files/zip/cy-2022-baseline-oopc-models-01212022.zip
[100] CY 2023 Medicare Parts C and D Annual Calendar, February 4, 2022
[101] *Ibid*.

vi. **Health Plan Management System (HPMS) Formulary Submission and Part D Pricing File Submission (PDPFS) Modules**

These modules are expected to be released on May 16, 2022. While the formulary submission module itself may be impacted directly by pharmacy DIR changes, plan sponsor and PBM formulary strategy most certainly will. However, the Part D pricing file module would likely either have to be delayed or re-released to appropriately reflect any final pharmacy DIR impacts.

vii. **Bids and Formularies Due Right After Expected Rule Release**

Based on recent timelines for CMS MA and Part D technical rules, we would expect a final pharmacy DIR rule to be released in late May. Bids and formularies will be due on June 6, 2022. It will not be possible for CMS and plan sponsors to make pharmacy DIR adjustments in that time frame.

D. CMS's cost estimates in the rule are far too low

CMS's proposes to reduce beneficiary cost sharing by basing its calculation on a revised definition of negotiated price. To make all necessary contract and systems changes, CMS expects "a one-time cost to plan sponsors of $0.1 million" to implement the Pharmacy DIR provisions of the Proposed Rule.[102] CMS provides no details on how it derived this exceptionally low figure in the regulatory impact analysis or elsewhere.[103]

At a high level, we expect systems changes to be required for any final pharmacy DIR rule for at least PBM to pharmacy claims adjudication and any backend financial reconciliation processes for upward performance bonuses. We note that the complexity of having pharmacy DIR applied to POS in most cases, but not necessarily in the coverage gap, introduces significant operational complexity, especially for claims that straddle phases. PBM systems will need to be adjusted to support changes to the BPT, MPF submissions, DIR reporting and PDE development and submission.

To get this right, plans and their PBMs will have to invest in information technology (IT) changes. Therefore, it is reasonable to expect that each parent organization and/or their PBM will need to hire at least one additional IT professional to manage these changes. According to the Bureau of Labor Statistics (BLS), average mid-level wage compensation for information technology professionals is $99,640, per annum.[104] This does not include fringe benefits and onboarding costs. ***In other words, just one IT hire in all of industry would equal the CMS cost estimate for IT***. In this context, clearly

[102] 87 Fed. Reg. 1849
[103] 87 Fed. Reg. 1944-1948.
[104] Bureau of Labor Statistics (BLS), "Computer and Information Technology Occupations," available online at https://www.bls.gov/ooh/computer-and-information-technology/home.htm.

the CMS estimate is invalid. Even if these functions were completely outsourced to just PCMA's members we would expect to see around $1.79 million in wages alone for just one IT hire per organization.

As mentioned elsewhere in the letter in detail, plan sponsors and PBMs will not know the details of this final rule, let alone downstream implementation guidance, until around the time bids are due. Thus to mitigate risks, plan sponsors and their PBMs will have to engage in parallel processing where they effectively engage in two bid development processes at once: one under existing rules and another making a good faith guess on what a final pharmacy DIR rule and guidance would look like. In context, CMS has estimated the development and submission of the MA and PDP bid pricing tools to cost approximately $22,477,500 (149,850 hours x $150 per hour) for each contract year.[105] We expect those costs to at least double because of the parallel processing involved in the necessary two bid development strategy.

***PCMA recommendation*: CMS did not adequately account for industry costs, failing the standards set out for regulatory impact analysis. The rule cannot be implemented without significant additional investments and considerably more time allotted. CMS should provide at least a one-year delay, if it moves ahead with the policy.**

In conclusion, PCMA supports value-based approaches to delivering the Part D prescription drug benefit, of which preferred pharmacy networks are a critical aspect. The Proposed Rule would harm beneficiaries and pharmacies and imposes much more significant cost on regulated entities and CMS than outlined. The rule change would not meaningfully reduce beneficiary OOP costs. To improve pharmacy reimbursement certainty, CMS should abandon this proposal and follow-through on its 2021 rulemaking path, under which plan sponsors would report pharmacy performance measures and CMS would assess whether there is uniformity in these before pressing ahead with any other regulatory changes. To improve transparency, CMS should pursue with haste the implementation of national standards for real-time benefit tools, instead.

[105] CMS, "Supporting Statement Part A Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP) CMS-10142, OMB 0938-0944," available online at https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202112-0938-012.

III. Past Performance Methodology (§§ 422.502 and 422.503)

CMS proposes to include Star Ratings, bankruptcy issues, and compliance actions in its review of MA and Part D plan applications going forward and adds specificity to the 2021 rulemaking's policies.[106] In response to CMS's 2021 proposed rule for the Part C and D programs, we wrote that we were concerned that CMS considered a deficit of any one of these factors to be grounds for non-approval. A single year of low Star Ratings seems to be an arbitrary test. Regarding compliance actions, CMS proposes to assign points to each type of compliance action, but again fails to state whether the test is definitive or used in the context of other measures (e.g., not a low Star Rating plan). We repeat: CMS should clarify exactly how it uses these factors to determine whether a contract will be renewed. Beyond this overarching concern, we provide specific comments on various aspects of the past performance methodology below.

1. Persistently low Star Ratings

We continue to believe that a one-year lookback on Star Ratings is insufficient. CMS proposed but did not finalize this proposal in the 2021 rule. As proposed, CMS could deny an application if a plan has fewer than three Stars for 12 consecutive months. CMS should use a three-year lookback instead. This three-year window provides a more accurate and empirically derived portrait of plan performance versus the one-time 12-month application review period. A three-year lookback also aligns with the criterion CMS currently uses to assign the Low Performer Icon on MPF (i.e., summary ratings of less than 3 Stars for three or more years). When at all possible, CMS should seek to align its guardrails so that all actors have better visibility into what is required of them.

We are also specifically concerned that the proposal would have the unintended consequence of limiting the availability of high-quality plans if one small plan under a contract underperforms. This is particularly important as we emerge from the COVID-19 PHE, which has affected populations and regions differently and further exacerbated existing socioeconomic factors that ultimately impact Star Ratings. Should CMS move forward with the proposal, at a minimum, we encourage the agency to look at a parent organization's Stars performance over three years and use the overall Star Rating score or an average Star Rating score across an organization as the basis for its denial, rather than the use of summary ratings, to take a more comprehensive view of an organization's past performance.

2. Past performance reports

As noted in previous comments, PCMA recommends CMS re-establish its Past Performance Outlier reports. These reports provide useful information for plans (particularly

[106] 86 Fed. Reg. 5864 (May 10, 2021).

those identified as poor performers) so they can improve. While plans are monitoring their own performance, it is helpful to review the information that CMS is tracking and utilizing for its various decisions in determining poor performance. It's also helpful to beneficiaries, who may be considering enrollment or re-enrollment in what CMS terms a "low performing" plan for their own reasons. This report gives the potential enrollee more information to make a sound judgment.

3. CMS compliance actions

The previous rule also allows CMS to deny an application if the plan sponsor was subject to an intermediate sanction and/or failed to maintain a fiscally-sound operation during the performance review period. CMS failed to fully define which sanctions it considered in this analysis. The Proposed Rule specifies that going forward, only Notices of Non-Compliance (NONCs), Warning Letters (WLs), and Corrective Action Plans (CAPs) would apply. PCMA believes these are indeed sufficiently problematic sanctions that identify plans putting beneficiaries and taxpayers at heightened continued risk.

4. Exclusions from past performance methodology

PCMA continues to believe that CMS should consider an exclusion from past performance for plans with low enrollment, in low population counties for example. Any plan exempt from a Star Rating, for example, should be exempt from the past performance methodology. Measurement in low enrollment plans in low population counties is exceedingly difficult.

***PCMA recommendation*: We broadly support CMS's efforts at ensuring beneficiaries have access to high quality and continuously operating Part D plans. However, CMS should better formalize how it defines and uses the various measures of past performance when considering contract applications and renewals.**

IV. Marketing and Communications Requirements (§422.2267 and 423.2267, 422.2274 and 423.2274)

1. Multi-language insert

CMS proposes to require a one-page multi-language insert (MLI) in the 15 most common languages spoken by Medicare beneficiaries, along with any language spoken by 5% or more of potential enrollees in a plan's service area, to inform enrollees that translation services are available. They would require plans to include this printed insert in three significant communications: the Summary of Benefits and Coverage (SBC), the Annual Notice of Coverage (ANOC), and the Evidence of Coverage (EOC).

This proposal would re-align the use of the MLI to the requirements in place for plan year 2017 and earlier, preceding the publication of 2016's ACA Non-discrimination final rule. Since that time, the previous administration issued regulations in 2020 to repeal the 2016 rule,[107] and although that rulemaking was not targeted at language access issues, federal judicial processes have negated the entirety of the 2020 rule. The current administration, in compliance with the courts, has declared that plans should revert to previously existing guidance or regulations to ensure appropriate access to translation services.[108] CMS also notes that to the extent the Office of Civil Rights (OCR) proposes and adopts more robust requirements, and plans adopt those requirements, CMS will consider plans compliant with the MLI requirements proposed in this rulemaking, rather than re-issue rules to impose any enhanced requirements.

PCMA appreciates that CMS is pulling back previous requirements to align with the MLI as finalized in the 2016 Medicare Managed Care and Marketing Guidelines (MCMG). PCMA supports the use of the 2016 MLI going forward, but recommends CMS limit its inclusion to just the ANOC. This would align the use of the MLI to the Notice of Privacy Practices (NOPP) document issued annually by covered entities. We also support CMS's proposal to not include the MLI in other documents. We further recommend CMS remove the MLI from the EOC and SBC documents. Rather, for all other enrollee interactions, CMS should reinstate the previously required "Availability of Non-English Translation Disclaimer" for all Medicare Communication materials in non-English languages that meet the five% threshold for language translation.

In addition to limiting delivery to once per year, we believe this is an opportunity to drive toward electronic delivery of the ANOC, MLI, and other documents as well. We disagree with CMS's ongoing opt-in only stance on significant documents. It is beyond time that at least new Medicare enrollees, if not all, should be presented electronic documents first with

[107] 85 Fed. Reg. 37160, June 19, 2020.
[108] See https://www.hhs.gov/about/news/2021/05/10/hhs-announces-prohibition-sex-discrimination-includes-discrimination-basis-sexual-orientation-gender-identity.html, May 10, 2021.

an opt-out. This better aligns with the administration's efforts at reducing greenhouse gases, as well.

Electronic delivery would reduce program costs significantly. CMS's cost estimates in the Proposed Rule for implementing the MLI across the board do not fully take into account programming, production, and print and mailing costs. As PCMA and other industry stakeholders have argued since the adoption of the 2016 final rule,[109] adding up the costs of all the unnecessary mailings related to pharmacy services created as a result of the 2016 final rule, yielded additional costs of nearly $1 billion per year. These costs are passed along to PBMs' customers and are reflected in higher premiums charged to enrollees. PCMA reiterates its analysis from 2017 and appreciates CMS's understanding that these costs are excessive compared to the Proposed Rule's published costs. (More than half of all printed documents are sent to Medicare beneficiaries.)

We would also note that reverting to the 2016 MLI will not meaningfully alter the beneficiary experience. In general, the PBM industry receives very few calls related to language access. It has recorded no meaningful increase in these calls or for translation services since the 2016 final rule was implemented, nor since the 2020 final rule was published or then enjoined.

CMS also proposes that the Medicare regulation, if finalized, would apply even if the Office of Civil Rights issues new rules for other affected entities. This seems like an appropriate stand-in, to avoid two implementation cycles and keep costs to a minimum.

***PCMA recommendation*: We support CMS's proposal to align its regulations to incorporate previous guidance on MLIs, and request that delivery need occur only once per year (with the ANOC). We recommend CMS also take this opportunity to consider electronic delivery of significant documents.**

2. Disclosures to Enrollees Regarding Preferred Pharmacies

CMS proposes that Part D plan sponsors provide a disclaimer to enrollees who select plans with limited access to preferred cost-sharing pharmacies. The proposed regulatory text in this rule aligns to an inadvertent omission in the 2021 final rule.[110]

We present a defense of preferred cost-sharing pharmacy networks in Section 2 of this letter. They present the only longstanding value-based contracting opportunity available in the Medicare Part D program and should not be disadvantaged relative to non-value-based broad pharmacy networks. We acknowledge preferred pharmacy networks can be fairly

[109] See EO 12866 Meeting Materials for RIN: 0945-AA11 (meeting on May 9, 2018). Available at: https://www.reginfo.gov/public/do/viewEO12866Meeting?viewRule=true&rin=0945-AA11&meetingId=3184&acronym=0945-HHS/OCR.
[110] 86 Fed. Reg. 5884, January 19, 2021, at 5998.

limited, but in all cases, the plan sponsor has met the rigorous network adequacy standards imposed by CMS prior to plan approval.

We believe that enrollees of these plans have affirmatively elected them knowing the network is limited. Enrollees using the MPF are inputting their own preferences and selecting plans that include them – whether as preferred pharmacies or other network pharmacies. The additional disclosure is unnecessary and foreboding to new enrollees and should not be finalized.

PCMA recommendation: We oppose CMS's proposal to require additional communication to enrollees electing Part D plans with more limited preferred pharmacy networks.

3. Appointment of Representatives

CMS proposes that plans post instructions about how to appoint a representative on their website and include a link to a downloadable version of the CMS Appointment of Representative (AOR) form.

PCMA supports this modernization effort for AOR forms. AOR forms allow beneficiaries to delegate their ability to file an appeal or grievance to a caregiver or other trusted individual. We would note that the 2023 Medicare Managed Care Marketing Guidelines, published February 9, 2022, already includes the language from the Proposed Rule.[111]

PCMA recommendation: We support CMS's efforts to modernize the Part D beneficiary experience, including allowing for downloadable and online form-fillable AOR forms.

[111] Medicare Communications and Marketing Guidelines (MCMG), February 9, 2022. Available at https://www.cms.gov/files/document/medicare-communications-marketing-guidelines-2-9-2022.pdf.

V. CMS Should Drive Toward Full Implementation of Prescriber RTBTs

Given ongoing concerns over high drug prices, RTBT provides a level of transparency that helps prescribers and beneficiaries make better choices to reduce their actual OOPC. However, facilitation of RTBT is dependent on the NCPDP standards finalization for plans, PBMs, and providers, along with CMS guidance to promote adoption. Optimal adoption of RTBT, requires NCPDP action to precede HHS action, with the final step being CMS action. Moreover, a conservative and thoughtful approach needs to happen as we approach the beneficiary RTBT implementation deadline of January 1, 2023, for plans per prior rulemaking.
Many plans and PBMs have already implemented solutions for use by their members. However, these solutions are proprietary and can lead to different experiences and levels of satisfaction for users.

NCPDP has developed a standard for a real-time prescription benefit request and response for use by providers and in August of 2021 requested that CMS name the standard for use by Part D program participants. Separately, Health Level 7 (HL7), in conjunction with the CARIN Alliance,[112] has developed a standard for use by consumer-facing entities, such as application developers, plans, and PBMs. For standardization purposes, NCPDP has reviewed the HL7 guidance and is sharing feedback for opportunities for alignment between the two standards that focuses on consistent experience for consumers and providers.

Currently, both plans and PBMs are mostly using proprietary solutions. However, a smooth transition is expected to the NCPDP standard without a loss in functionality, given that the standard was developed with industry input.

Plans and PBMs are already supporting and providing RTBT as they approach the regulatory deadline. However, this deadline does not include a corresponding provision for providers and adoption by providers is inconsistent. This inconsistency is having an impact on beneficiaries since their in-office RTBT related interactions with providers will have a greater impact versus beneficiary's use of RTBT by themselves. However, providers are dependent on their HER vendors to integrate the functionality which will allow for the implementation of RTBT through a system upgrade. This system upgrade is what will allow access to provider RTBT. Moreover, given the impact of the COVID PHE on providers over the last few years, RTBT is probably not a priority for them. It is anticipated that a proposed rule will be issued in 2022 that will address the inclusion of RTBT in EHRs.

Additionally, having CMS name the NCPDP standard for RTBT use should help with adoption. However, CMS's role has been constrained with regards to requiring both RTBT use and NCPDP standards for provider transactions. For example, the requirement of electronic prescribing is directly within the purview of CMS versus provider RTBT, since they don't have

[112] Home - CARIN Alliance

the same level of authority over the providers as they do the plans. Moreover, CMS has not issued a proposed federal rule naming the NCPDP standard so compliance by January 2023 is not possible.

***PCMA recommendation*: We recommend that CMS focus on fostering provider RTBT through EHR vendor engagement that includes NCPDP and does not disrupt the Medicare ecosystem through higher premiums and re-contracting requirements.**