MEMORANDUM

To: Erica Zamborsky, Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB)
Jennifer Shapiro and Amy Larrick, Center for Medicare (CM), Centers for Medicare & Medicaid Services (CMS)

From: Tim Dube, PCMA

Date: November 1, 2022

Subject: PCMA Recommendations to CMS for the 2024 Part C & D Proposed Rule (CMS-4201-P; RIN 0938-AU96)

PCMA appreciates the opportunity to present to OMB and CMS our recommendations for CMS's upcoming rulemaking for plans offering coverage under Medicare Parts C and D in 2024. The agency must implement provisions already in effect for plan year 2023 as enacted by the Congress in the Inflation Reduction Act (IRA), along with new provisions for 2024, and planning for provisions in effect for 2025 and beyond. We acknowledge that CMS must also propose and then finalize other changes under prior statutory direction and its own initiatives, such as programs created under the SUPPORT Act of 2018, Consolidated Appropriations Act of 2021, and pharmacy DIR, among others. PCMA will comment on other proposals relevant to the PBM industry upon the proposed rule's publication. We limit this memo to the IRA provisions affecting the Medicare Part D program. Please feel free to share this memorandum with the teams working on this rulemaking.

Through the IRA, Part D enrollees will see cost-sharing relief beginning in plan year 2023, by limiting cost-sharing for covered insulins and ACIP-recommended vaccines. In 2024, eligibility for the Low-Income Subsidy (LIS) program is increased and non-LIS enrollees will no longer face coinsurance during the catastrophic benefit phase. The Coverage Gap Discount Program (CGDP) is replaced by a new Manufacturer Discount Program (MDP) starting in 2025, and beneficiaries can opt to "smooth" large pharmacy cost-sharing by paying over several months. In 2026, select drugs will have new Maximum Fair Prices (MFP), negotiated directly by CMS.

The benefit design changes are financed in part by shifting the liability of these costs onto pharmaceutical manufacturers, Part D plan sponsors, and taxpayers. To mitigate some of the cost increase on plans, Congress included a temporary retroactive subsidy payable to Part D plan sponsors since these changes for insulins and vaccines were not included in the Final Rate Notice and bids for plan year 2023. Beginning in 2024, CMS will adjust direct subsidy amounts paid to Part D plans to limit any increases in beneficiary base premiums to no more than six percent (the "premium stabilization program" or PSP). Importantly, PSP is designed to minimize premium impact on the aggregate.

The recommendations below would help ensure that there are fewer outliers, which could otherwise cause significant beneficiary disruption despite the PSP. We expect that the 2024 plan year proposed rule will address all or many of these changes.[1] We look forward to engaging with the agency on these and other complicated and important changes.

In short, PCMA recommends that CMS:

- **Narrow the risk corridors.** CMS should propose narrowing the risk corridors starting in 2024 for a few years, to reduce uncertainty for plans regarding pharmacy DIR implementation, premium stabilization, 0% coinsurance in 2024, a lower OOP maximum for 2025, a shift in manufacturer mandatory discounts, and a shift in reinsurance toward plans.

- **Update the risk adjustment model.** CMS should propose to update its risk adjustment model to account for induced utilization at 0% vaccine cost-sharing, 0% catastrophic cost-sharing, and include drug use indicators for insulins. The update should be inclusive of the effects of the 2025 statutory changes, too.

- **Reduce LIS enrollee disruption.** CMS should propose broadening the LIS *de minimis* amount to reduce LIS auto-reassignment and allow a 4th PDP that is LIS only given the expected increase in LIS enrollment with the income eligibility change for 2025. Having the 4th plan in place for 2024 would be helpful in advance of the statutory eligibility change in terms of reducing churn.

- **Focus on the right drugs and simplified processes for direct negotiation.** For direct negotiation, CMS should propose to only negotiate for drugs with limited formulary competitors. rather than only drugs without generics. CMS should also propose that PBMs handle the payment differential for pharmacies. (Meaning, ensuring pharmacies receive the difference between their acquisition cost and the Maximum Fair Price as "negotiated price" for negotiated drugs). We believe the new manufacturer discount program could be the conduit for doing so.

Finally, ***we recommend that CMS issue this proposed rule as soon as possible.*** It is in all parties' interests for the agency to have as long as possible to evaluate the comments it receives, and for plans to have as much time as possible to implement any changes prior to the bid submission deadline (June 5, 2023 for plan year 2024). Ideally, CMS would publish a proposed rule with sufficient time to evaluate comments and publish its final rule in advance of, or at worst, concurrent with, both parts of the Final Rate Notice guidance 60 days prior to the bid deadline. Further details on our substantive recommendations follow.

[1] We acknowledge that some of the topics listed below could be addressed in Part I of the CY 2024 Part C and D Program Advance Notice. Should CMS be able to move some of these topics through the guidance pathway rather than rulemaking, we respectfully request that CMS and OMB consider the points we raise in this memo for that process. That document is typically also submitted to OMB for review.

1. CMS should propose narrowing the risk corridors to reduce uncertainty for plans.

Risk corridors in Part D are designed to protect plans if their enrollees' prescription drug costs are much higher than expected and provide savings to CMS if plans instead overbid for providing these benefits. By narrowing the risk corridors – currently set at 5% above or below the expected cost – to something more like 2.5% above or below, plans will be able to bid with more certainty, having less to "lose" if they underbid.

New provisions for 2023, and those planned for 2024, 2025, and 2026, present significant challenges in modeling expected costs. By the time bids are due for the 2024 plan year, the 2023 provisions will be merely five months old, and plans will not have enough usable actuarial experience to fully understand their effect. Namely, given the likelihood that insulin users may switch plans in the first few months of the year due to the recently-announced Special Enrollment Period (SEP), their cost data will be lost to their original plan. Further, it is likely that now that ACIP-recommended adult vaccines are covered without cost-sharing that first, public education campaigns will induce demand over time from beneficiaries, and second, that ACIP will begin recommending more vaccines for this population. The first five months of 2023 will be insufficient for plans to understand long term cost exposures for these provisions.

On top of these two provisions, 2024 and 2025 bring additional uncertainty in terms of cost projections. The first is that coinsurance for covered Part D drugs during the catastrophic phase will decrease to 0% in 2024, followed by a reduction of the maximum out-of-pocket limit (MOOP) to just $2,000 in 2025 under the full redesign. As CMS is aware, when cost-sharing is reduced, beneficiaries use more of the specific services that cost them less. Though this an intended consequence of the law change, more utilization means more cost to plans, which needs to be reflected in plan bids. Since there are very few $0 or 0% covered services in Part D now, plans will not have enough claims experience to fully capture expected cost increases. Compounding this estimation exercise, without the price pressure faced by beneficiaries through cost-sharing, there is a chance that drug manufacturers may raise their prices more often or set them higher to start. Plans often have a sense of what may be approved by FDA in the coming months, but rarely know much about the prices until after drugs are launched.

Second, 2025 brings a revamped manufacturer discount program, shifting discounts from the coverage gap (which is being removed) to the earlier coverage phase of the benefit and the catastrophic phase upon a beneficiary reaching the maximum out-of-pocket limit (MOOP). This effectively reduces the price to beneficiaries earlier in the benefit, again inducing demand. In catastrophic, since patients face no cost, the greater risk is that manufacturers of expensive drugs will raise prices or set them higher to start. Risk corridors alone cannot wholly protect plans against excessively high drug costs, but they act as an protection when manufacturers can behave in extortionary ways.

2. CMS should propose to update its risk adjustment model to account for induced utilization.

In contrast to risk corridors, which protect plans from significant losses at the end of the year, risk adjustment is a prospective CMS program that helps reduce risk based on the plan's actual enrollment, over the course of the year, paid through the Direct Subsidy. Plans are protected against having an unusually unhealthy population and CMS is protected against plans ending up with unexpectedly healthy enrollees.

As described above, the combined effect of 2023, 2024, and 2025 provisions is significant induced demand, even among healthy populations. In terms of risk adjustment, even lower risk scores will carry higher expected cost. These costs won't be fully captured by the time 2024 bids are due to CMS. We recommend CMS consider previous vaccination claim indicators, previous insulin use indicators, and consider strongly whether conditions with high expected costs are using the most updated prescription drug pricing data.

PCMA has commented on risk adjustment updates previously, and we hold to those prior recommendations here. Adding markers for specific drugs or classes will increase the predictive power of the model. Based on the experiences from the HHS-HCC risk adjustment model. Analysis from RTI and CMS has indicated adding 10 prescription drug classes, called RXCs, to the HHS-HCC model, both improved predictive accuracy, while also minimizing plan incentives to use formulary and benefit design to select against higher-risk individuals.[2]

Both risk corridors and risk adjustment are important programs that keep plans participating in the Part D program. For every reason that these programs are needed, there is a chance that premiums may rise to account for higher costs, as well. We recognize that Congress is having CMS create a premium stabilization program beginning in 2024. However, having narrower risk corridors and more finely-tuned risk adjustment may mitigate the need for such a program. Given that there are significant questions about funding for the premium stabilization program, any methods CMS can use under current law to reduce risk should be explored.

3. CMS should propose policies to minimize disruption to current and future LIS enrollees

Beginning in 2024, enrollment into the Low Income Subsidy (LIS) program will be simplified and more Medicare beneficiaries will quality. Some estimate that as many as 400,000 beneficiaries will move from partial LIS status to full LIS status,[3] and more may join now that enrollment is simplified.

LIS enrollees today make up 35 to 40% of Part D enrollees. Many Part D plan sponsors construct their Part D bids to remain at or near the LIS benchmark that CMS publishes annually, in order to reduce the amount of enrollment "churn" that can happen among individuals who do not select their own plans. (Individuals are automatically assigned a plan if they do not choose one, and are reassigned by CMS if they do not choose a plan the next year but their current plan no longer meets the benchmark.) To minimize such churn, especially going into a year when more people will have full LIS status and the difficulty of assigning and reassigning will increase, we recommend that CMS broaden the LIS *de minimis* amount. Currently, the amount is $2 per month. Given the likely increase in the base bid amount due to the changes described earlier in this letter, CMS should consider instead a percentage (10-15%) or up to a $5 *de minimis* instead.

Based on initial analyses by our member companies, we anticipate that plans with higher proportions of LIS beneficiaries will see an oversized premium impact in the shift to the

[2] Pope, Gregory C., et al. "Incorporating prescription drugs into Affordable Care Act risk adjustment." *Medical Care* 58.6 (2020): 504-510.
[3] See https://www.aarp.org/politics-society/advocacy/info-2022/medicare-part-d-extra-help.html.

new benefit structure. This will could create churn and a disproportionate impact to LIS beneficiaries if there are not steps taken to moderate it.

To further reduce enrollment churn, CMS should also allow a 4th PDP that is designated for the LIS population. Their needs often differ significantly from the non-LIS population, and one way CMS could reduce overall costs is to allow plans to create benefit designs that specifically engage this population's needs. Having a 4th plan in place will also reduce enrollment churn year to year during assignment and reassignment periods.

4. CMS should lay the groundwork for PBMs to administer the price differentials between Maximum Fair Price and Part D negotiated price

Beyond the 2023-2025 benefit changes, CMS is also responsible for rolling out the Maximum Fair Price (MFP) program for selected drugs, beginning for the 2026 plan year. For 2026 and 2027, selected drugs are limited to those covered by Part D plans. We believe CMS should begin to lay the groundwork in the 2024 rule that its existing partners in providing Part D coverage can address the new operational roles needed.

First, CMS is tasked with determining based on a wide range of factors which drugs to select for negotiation, and then what the prices for those drugs should be. There is a statutory ceiling price, should the manufacturer engage but not give additional price concessions. PBMs are highly adept at negotiating drugs, including knowing which ones face direct and indirect therapeutic class competition (not just generic drug competition), and which levers to press with manufacturers regarding additional price concessions. While PBMs aren't forbidden from negotiating further discounts beyond the MFP, they are required to cover the selected drugs on their formularies.

Having this coverage mandate ties Part D plans' hands to some degree, so CMS is best positioned from a long-term cost-savings perspective limiting selected drugs to those that PBMs have little leverage with as it is. Otherwise, the MFP may be leaving some savings "on the table." For instance, a drug with a competitor covered by Medicare Part B rather than Part D may seem like a candidate for negotiation, but PBMs can today negotiate formulary status for this drug requiring step therapy for the Part B drug. If CMS selects this drug, it provides automatic coverage for the Part D drug at the Part B drug's expense, and at likely higher total cost to the Part D Program. We would be happy to work with CMS as it designs its parameters for selecting Part D drugs eligible for negotiation for plan year 2026.

PBMs can also solve a major operational challenge created by MFP: how will pharmacies be held harmless? They are still purchasing drugs through wholesale channels at whole prices, not at the MFP. CMS can and should leverage the new Manufacturer Discount Program here. As described earlier, a new Manufacturer Discount Program will replace the Coverage Gap Discount Program. In theory, the mechanisms under which the new program operates can be nearly identical to the CGDP. The pharmacy is paid the full negotiated price by the Part D plan, who through the PDE flags the amount owed by the manufacturer to a third-party administrator (TPA). The TPA then bills the manufacturer for all CGDP payments and distributes those funds back to the relevant Part D plans. As we see it, the gap between the current negotiated price (reimbursement for which is intended to cover the pharmacy's acquisition cost) and the CMS-determined MFP should be handled similarly, and possibly even through the

same TPA and on the same manufacturer invoices. Only Part D plan sponsors have the data needed to validate whether the claim was paid under Part D.

Conclusion

PCMA stands ready to help CMS implement these critical components of the Inflation Reduction Act. PBMs can play an important role in minimizing enrollee disruption, and in return CMS should consider proposals such as those above to maintain high levels of Part D plan participation among sponsors. If you have any questions on the above recommendations, please reach out to Tim Dube at tdube@pcmanet.org or (202) 756-5738.