March 7, 2022

Chiquita Brooks-LaSure
CMS Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention CMS-4192-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-4192-P

Submitted via www.regulations.gov

Dear Administrator Brooks-LaSure:

Prime Therapeutics (Prime) appreciates the opportunity to comment on the Proposed Rule, "Medicare Program: Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Program, as published in the *Federal Register* on January 12, 2022.

Prime makes health care work better by helping people get the medicine they need to feel better and live well by managing pharmacy benefits for health insurers, employers, and government programs, including Medicare and Medicaid. Our company manages drug benefits for over 34 million people nationally and offers clinical services for people with complex medical conditions. We are a unique pharmacy benefit manager (PBM) as we are collectively owned by 19 not-for-profit Blue Cross or Blue Shield plans. In cooperation with these plans and other clients, we provide the pharmacy benefit management services for Part D and Medicare Advantage Prescription Drug (MA-PD) plans and the beneficiaries they serve.

Prime works with our clients to keep Medicare Part D premiums affordable and contain cost-sharing amounts for all beneficiaries. We also help lower drug spending by negotiating price concessions from pharmacies, wholesalers, and drug manufacturers. Every day, Prime employs strategies, clinical programs and tools aimed at improving health outcomes and medication adherence.

Prime is deeply concerned that the changes CMS proposes are short-sighted and will lead to higher premiums and lower pharmacy reimbursement that may hamper beneficiary access. The current pharmacy DIR program and regulatory definition of "negotiated price" contributes to the stability of Part D premiums and helps to improve the quality and safety of pharmacy care. Therefore, **Prime opposes the agency's proposal to change the definition of "negotiated price" and require Part D plans to apply all of the price concessions they receive from network pharmacies at the point of sale.** We believe the changes CMS proposes will increase premiums for seniors and raise costs for taxpayers, while decreasing quality of pharmacy care for beneficiaries.

Prime's comments will focus on the proposed rule's provisions on "Pharmacy Price Concessions to Drug Prices at the Point of Sale (§ 423.100)." On other provisions, we wish to offer our support for the comments submitted separately on this proposed rule by the Pharmaceutical Care Management Association (PCMA).

Introduction

CMS proposes to redefine the definition of "negotiated price" at § 423.100 to eliminate the current exception for amounts that "cannot reasonably be determine at the point-of-sale (POS) and to instead create a new definition of "negotiated price" which would be defined as the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D plan sponsor or the sponsor's intermediary."[1] CMS proposes to make these changes take effect as of January 1, 2023.

CMS's proffered rationale is that beneficiaries should have more predictability and should enjoy lower cost-sharing at point-of-sale even if premiums and taxpayer costs increase. CMS also asserts that redefining negotiated price and requiring all pharmacy price concessions (PPCs) to be included at point-of-sale (POS) will create a more even playing field between competing Part D plan sponsors so that all PPCs are used the same way (i.e., to lower cost-sharing rather than some of it being used to lower premiums and some being used to reduce beneficiary cost-sharing.)

KEY POINTS

- By redefining "negotiated price" and requiring it to be set at the lowest possible reimbursement and thus disallowing negative adjustments, CMS is endangering a key pharmacy quality tool that has shown to improve adherence. This change is out of synch with Medicare's other quality programs which are two-sided (bonus and penalties.)
- CMS and plans and their PBMs have already made important strides in improving predictability for pharmacies. If CMS remains concerned, CMS should consider adapting Prime's model of adjusting pharmacy payment based on metrics *at the time of payment of the pharmacy.*
- CMS proposed changes will force pharmacies to be paid at the lowest possible reimbursement, a level which few are reimbursed at currently. These reimbursement cuts will jeopardize pharmacy access.
- CMS is downplaying the importance of Part D premiums and exaggerating the impact this proposal will have on beneficiary cost-sharing. This proposal would increase costs for two-thirds of Part D beneficiaries and may decrease Part D enrollment.
- CMS is overstating the growth of DIR by failing to consider the overall growth in the Part D program.
- CMS should not finalize the rule as proposed, but should it choose to do so, the proposed implementation date of January 1, 2023 is entirely unrealistic given the lack of implementation guidance and the need for PBMs and plans to renegotiate pharmacy contracts. CMS should not implement the rule before January 1, 2024 *at the earliest*.

[1] Page 1845 of the proposed rule

DETAILED COMMENTS

Changes to DIR Will Hurt Quality and Could Jeopardize Pharmacy Access

This rule, if finalized, will force Prime, other PBMs and payors to use only bonus-based value-based contracting, which we have found has less of an effect on pharmacies' willingness to engage with us to improve the quality of care. Our experience is backed by at least one prominent study on incentives vs penalties in value-based care.[2] Separate from DIR, we will continue to use a bonus-based pharmacy incentive structure, but the upside incentives offered will need to be reduced as the plan funding structure for these programs would be removed. Many of our clients use these pharmacy DIR amounts to support a bonus–based pharmacy incentive model. These bonus-based incentives are already reported as negative DIR to CMS. Instead, the proposed rule would require the lowest possible reimbursement at POS, thereby necessitating that Prime's clients accrue funds to reimburse pharmacies the difference from the CMS required reimbursement and the amount the pharmacies should have paid post POS. This change eliminates the incentive for pharmacies to improve their quality performance as they will now be focused on the increased discounts taken at point of sale.

By changing the definition of "negotiated price," the agency is eliminating an important tool to improve quality and could therefore affect adherence rates and generic dispensing rates. Adherence measures for pharmacies translate into stars measures that allow increasing cut-points as the table below from Prime data demonstrate the ability of the current program rules to improve quality. Changing the program rules to disallow pharmacy DIR in its current form may negatively impact adherence and quality scores and decrease generic utilization rates thereby hurting beneficiaries.

	2018-21 Average Measure Improvement	2018-21 % increase in members that are adherent for Diabetes Measure	2018-21 % increase in members that are adherent for Hypertension Measure	2018-21 % increase in members that are adherent for Statin Measure	2018-21 % increase in Statin use in Persons with Diabetes Measure
Pharmacy Performance Improvement*	6.06%	7.95%	4.95%	7.08%	4.26%

**Values represent the increase in total improvement (i.e., the 7.95% in diabetes improvement may represent a change from a total of 85% of members are adherent in 2018 to 92.95% of members are adherent in 2021)*

Throughout the rest of Medicare, CMS is pushing hard to move faster to value-based care. Pharmacy DIR is an example of value-based contracting. Indeed, this proposal is incompatible with CMS' efforts to catalyze greater adaption of value-based care. CMS officials state in a recent *Health Affairs* article that they are "working across CMS to enhance the movement towards value-based, high-quality care and to ensure that we are rowing in the same direction so that 100% of people with Original Medicare will be in a care relationship with accountability for quality and total cost of care by 2030."[3]

[2] See for example T, Doran, K Maurer and A. Ryan, "Impact of Provider Incentives on Quality and Value of Health Care," *Ann. Rev. Public Health* 2017.28-449-465, downloaded from https://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-032315-021457

[3] https://www.cms.gov/blog/building-cms-strategic-vision-working-together-stronger-medicare

Further, CMS's value-based programs for physicians –the Merit-based Incentive Payment Based System (MIPS) makes providers eligible for *both* upside and downside risk. Medicare's Hospital Inpatient and Outpatient Quality Reporting (HIQR and HOOR) allow *only* down-side risk. Healthcare entities and providers participating in the CMS Accountable Care Organization (ACO) programs are also moving towards two-sided risk. We question why pharmacies should be treated any differently than these other providers in CMS's effort to catalyze the health care system towards a higher rate of adaption of value-based care. The agency should not undermine a key kind of value-based contracting, particularly when it can be used to improve care across the entire population including those that have been historically underserved.

Prime believes that concerns about measure predictability are already being addressed. First, CMS has already implemented as of this year requirements for standardized measures. Prime supports this move as it adds predictability to the program, and this uniformity helps to improve quality. CMS should let these new requirements be implemented without upsetting the program's stability by radically changing the payment model. Additionally, Prime, other PBMs and Part D plans have adapted EQuiPP[4], a widely uses benchmarking program that pharmacies can use to track their progress. This standardized platform also increases predictability for both payors and pharmacies.

Prime uses both a five-tier and three-tier quality network for our plans for pharmacy DIR currently. Only a small minority of pharmacies are in the lowest tier. CMS' requirement to apply the lowest possible reimbursement means *all* pharmacies will be placed in the lowest tier, which will force some pharmacies to take significant losses. Assuming the lowest tier of performance will cost most pharmacies significant reimbursement, but given network adequacy requirements, plans will be limited in how much they can reduce payments to pharmacies. Pharmacies will demand renegotiation and plans will need to increase premiums, thus harming beneficiaries in order to reimburse pharmacies the difference from the lowest possible reimbursement and the pharmacy's actual performance tier at year end reconciliations.

Pharmacies are now concerned about the discounts they must sustain at POS and the impact on their cash flows. Pharmacies are already refusing to enter into agreements for contract year 2023 due to the uncertainty of the DIR provisions of the CMS proposal. Access may become a problem if pharmacies refuse to participate in Medicare networks due to uncertainty of their reimbursement. Members may then face significant disruption and inadequate access to medications.

<u>CMS Misstates the Significance of the Growth of DIR</u>

CMS asserts that PPCs have grown faster than any other category of DIR and implies that this growth alone is something that needs to be remedied. Much of the growth in the beginning of pharmacy DIR was due to plans building out preferred pharmacy contracts, rather than larger price concessions being applied.

CMS has also made a number of rule changes since 2005 that have reclassified other pharmacy contract terms (such as pass-through vs. lock-in pricing) and the treatment of fees. Simultaneously, the number of drug plans offering preferred pharmacy networks has also grown. Therefore, the development and growth of preferred pharmacy networks accounts for much of the early growth of DIR rather than more

[4] https://www.equipp.org/default.aspx

price concessions being applied. Lastly, since both total drug spending and Part D enrollment continues to increase, pharmacy DIR would naturally be expected to increase due to these factors alone. Importantly, the growth of DIR has helped to stabilize premium growth.

Cost-Sharing vs. Premium Increases

CMS states in the proposed rule that too much attention has been paid to premiums at the expense of cost-sharing. Not all evidence indicates cost-sharing is even a problem in Medicare Part D. For instance, a recent *Journal of the American Medical Association* found that the out-of-pocket costs fell 12% over the past decade for drugs taken by Medicare beneficiaries with five common, expensive chronic conditions.[5]

CMS states that beneficiaries are not well-informed in choosing a plan: "… the disparate ways that Part D sponsors manage pharmacy price concessions reduces transparency of the POS cost to the beneficiary and can cause beneficiary confusion" when choosing plans thus "undermin[ing] beneficiaries' ability to making meaningful price comparisons and efficient choices when considering the combined cost sharing and premiums."[6] However, CMS also notes that most plans are motivated by the desire to keep premiums low so most plans are using DIR today to lower premiums. Therefore, there would *not* seem to be the wide variability among plans that CMS is asserting if most plans are currently using DIR to lower premiums.

Further, Prime understood that the purpose of the revamped *Medicare.gov* was to help beneficiaries make better decisions in choosing Part D or MA-PD plans that best meets their needs. However, the revamped *Medicare.gov/plan-compare* has only been around since 2019 when it ran parallel with an older version. We recommend that CMS analyze more years of data and try to use this new plan finder to better guide beneficiaries before making drastic changes to its program. Additionally, premium increases, if not clearly communicated to members on *Medicare.gov*, may lead members to making inappropriate selections as they react to the increased premiums and do not understand cost-sharing at POS changes.

The purported benefits of the proposal do not outweigh their likely costs. CMS estimates[7] that requiring PPCs in the negotiated price will reduce beneficiary costs by $21.3 billion over ten years or approximately 2%. A new Milliman analysis estimates that premiums will increase by 6-11% over the next decade. Milliman also estimates that approximately two-thirds of beneficiaries would experience a real *increase* in their overall costs when looking at both premiums and cost-sharing,[8] thereby making few beneficiaries better off. This estimate is not surprising given that approximately 90% of prescriptions dispensed to Medicare beneficiaries are generics which are generally not high cost.

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[5] *JAMA Intern Med.* 2022;182(2):185-195. doi:10.1001/jamainternmed.2021.7457 downloaded from Assessment of Hypothetical Out-of-Pocket Costs of Guideline-Recommended Medications for the Treatment of Older Adults With Multiple Chronic Conditions, 2009 and 2019 | Geriatrics | JAMA Internal Medicine | JAMA Network

[6] page 1914 of the proposed rule

[7] page 1849 of the proposed rule

[8] https://www.milliman.com/en/insight/medicare-part-d-pharmacy-price-concessions-at-the-point-of-sale

Prime's plans mostly use cost-sharing rather than co-insurance so if this proposal is finalized, Prime's plans' Medicare members would see either no or nominal cost-sharing reductions and these are not likely to affect medication adherence or persistence. In Prime's specific case, almost all our clients' Part D members have flat co-pays for the top 10 generic drugs and therefore will not see changes in cost-sharing for the most commonly dispensed drugs. While some members taking specialty drugs and non-preferred brand drugs may benefit because they pay coinsurance rather than flat co-pays, there are far fewer of these members than those who will *not* see a change in benefit. Instead of finalizing this proposal, CMS should work with Congress to modernize the Part D benefit so that a comprehensive cost- sharing solution can be enacted.

Finally, we would urge CMS to consider the effects of premium increases on Part D enrollment. According to the Kaiser Family Foundation, 12% of people eligible for Part D coverage do not sign up for the program and do not have other coverage.[9] Any increase in premiums could make this number of uncovered beneficiaries even larger.

Pharmacy Predictability

We understand that policymakers, including CMS, are concerned about predictability for pharmacies and about the retroactive nature of DIR. Unfortunately, one solution Prime uses to address these issues would *not* be allowed if CMS finalizes its proposal as written. Our plan, which we have already implemented with some pharmacies, pays PPCs at the point of payment of the pharmacy based on performance in the prior quarter with a true-up mechanism for new pharmacies. We have found, where implemented, this method enhances pharmacy predictability as opposed to taking the DIR in the same quarter or waiting until the end of the year. In addition, this approach minimizes retroactive collection of pharmacy price concessions from pharmacies, which has been a significant concern for pharmacies.

As Milliman states, pharmacy DIR arrangements can help with pharmacy cash flow as pharmacies receive full reimbursement for the full POS drug costs at the time of dispensing and reimburse plan sponsors for a portion of the drug costs after the POS allowing pharmacies to leverage the spread between the POS cost and DIR payment.[10] The proposed rule, if finalized, would eliminate this leverage opportunity.

We would like to reiterate that requiring DIR to be set at the lowest possible reimbursement will significantly negatively affect pharmacy reimbursement at a time when they are already working under overwhelming circumstances due to the pandemic. Most payors will swap current pharmacy DIR tied to performance for simple price concessions in order to minimize increases in premiums. [11] Given limitations in our ability to cut reimbursement given network adequacy requirements, premiums, as mentioned above, will increase significantly.

Proposal Would Destabilize Preferred Pharmacy Networks (PPNs)

Pharmacy DIR is often tied to PPN participation. Beneficiaries often benefit from lower cost sharing by utilizing preferred pharmacies. PPNs may become less attractive to beneficiaries if the discounts

[9] https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/.
[10] https://www.my-milliman.com/en-GB/insight/a-regulatory-push-to-lower-part-d-costs-at-the-pharmacy-counter-in-2023
[11] *Ibid,* Milliman*, "A Regulatory Push to Lower Part D Costs at the Pharmacy Counter"*

between preferred and non-preferred pharmacies narrow as a result of this rule. PPNs are now being used to improve overall outcomes and quality metrics.[12] According to a recent Wharton study, preferred pharmacies receive 8% greater market share among non-LIS beneficiaries due to preferred status alone. The Wharton study also found that preferred network contracting alone saved plans $9 per enrollee per year equaling 1% annual savings for the average enrollee.[13]

In Prime's case, over half of our claims go through PPNs. The proposed changes to DIR would effectively force us to move to straight discounts instead of quality-based metric and, as explained above, force us to lower reimbursement so much that pharmacies will likely not be willing to accept these reductions and will not wish to participate in our PPNs.

Pharmacy Price Concessions in the Coverage Gap

CMS proposes to not require PPCs to be passed on at POS in the coverage gap. Prime is opposed to having different rules for PPCs for different stages of the benefit. Such an approach would create significant confusion as beneficiaries would cross into the coverage gap at different times in the year, necessitating further tracking and communication to pharmacies. Plans and PBMs would be required to manage two different sets of prices for every pharmacy depending on the stage of the benefit each beneficiary is in, adding significantly to administrative costs. Most importantly, having two different sets of rules would be hard to explain to beneficiaries and create beneficiary confusion.

Plan and Pharma Incentives

CMS states that by redefining "negotiated price" to require PPCs to be counted as DIR thus lowering beneficiary cost-sharing, beneficiaries would move more slowly through the phases of the Part D benefit. As a result, government costs would be reduced in the catastrophic phase of the benefit. Such an approach also results in a windfall for pharmaceutical companies, as CMS itself notes that manufacturers would save about $14.6 billion over ten years. Given active Congressional legislative debates over responsibility in Part D, we would urge CMS to defer to Congress over the respective roles/responsibilities of manufacturers, plans, beneficiaries, and taxpayers. Even in catastrophic phase of the benefit, plans still *do* have incentives to control costs because plans are liable for 15% of costs and given the rising cost of and number of specialty drugs, the dollars can be significant.

Implementation Calendar Is Unrealistic

If the proposal is finalized, CMS must delay implementation of this proposed rule to January 1, 2024, at the very earliest. The proposed rule requires the administration of four separate prices in CMS's view: two 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). This change introduces major claims system enhancements, significant room for error with multiple rates due to the rule and post-payment reconciliation. Contracts will have to be renegotiated with pharmacies to implement the requirements of the proposed rule due to pharmacies unwillingness to accept the new discounts required under the lowest possible reimbursement requirement. Many pharmacies are refusing to negotiate with us without a final rule, thus further shortening the timeframe to go live. There are

[12] https://www.amcp.org/policy-advocacy/policy-advocacy-focus-areas/where-we-stand-position-statements/preferred-pharmacy-networks
[13] https://repository.upenn.edu/cgi/viewcontent.cgi?article=1065&context=pennwhartonppi)

immense communication and programming challenges associated with implementing CMS proposed rule.

Given that plans and their PBMs are already in the middle of the bid cycle for 2023, CMS is forcing us to develop separate bids with and without these changes. CMS has also failed to give us and our plans key tools to make adequate bids incorporating these proposed changes. As illustrative examples of the many incomplete or missing tools, we do *not* have complete information on either the Draft Bidding Tool (BPT) or the final notice. CMS has already released the BPT for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP). The BPT treats all DIR-pharmacy and other types of DIR the same. CMS would have to make modifications to the BPT to implement its proposed changes to pharmacy DIR.

On February 2, 2022, CMS released the Advance Notice (AN) of Methodological Changes for Calendar Year (CY) 2023 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. There are Part D bidding and payment policies in the AN that would be impacted by the pharmacy DIR rule being finalized, but the AN is silent on the contemplated changes to DIR. For example, the RxHCC model would be calibrated on prior data that does not reflect pharmacy DIR being applied at POS. We expect the issuance of the Final Notice in early April, ahead of the release of the final rule. The Final Notice is the guidance plans need to construct their bids, but the lack of a final rule on PPCs will force plans to bid somewhat blindly.

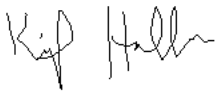
Prime also believes that the middle of the pandemic is not the time for such a drastic change in the Part D program. PBMs are busy implementing new programs to keep up with changing vaccination schedules to ensure appropriate payment and root out fraud, waste, and abuse and to pay for over-the-counter (OTC) tests, while pharmacies are stretched to the limit similarly to meet pandemic needs. This rule will result in pharmacy reimbursement reductions and premium increases that could endanger access at a critical time.

Conclusion

Prime appreciates the opportunity to comment on this important rule**. We implore CMS *not* to finalize this very flawed proposal given its likely impact on pharmacy quality, beneficiary premiums and costs to the health care system. At the very least, CMS must give stakeholders more time to implement the rule and delay the effective date.**

Should you have any questions on these comments, please contact Julie Cantor-Weinberg, Advisor, Federal Government Affairs at julie.cantor-weinberg@primetherapeutics.com.

Respectfully submitted,



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