

March 7, 2022

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

Re: Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs (CMS-4192-P)

Dear Administrator Brooks-LaSure:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the proposed rule to adopt a new definition for the term “negotiated price” and add a definition of “price concession,” intending to bring increased transparency to the Medicare Part D Program and reduce costs at the point of sale for patients. NCPA recognizes the importance of the work of CMS to reduce out-of-pocket prescription drug costs and the ongoing efforts to improve price transparency and market competition under the Part D program. However, we have strong concerns about the proposed rule as currently written, and we believe that without the changes provided by NCPA, it will fail to achieve its intended goals.

NCPA represents America’s community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care settings. Our members represent a \$67 billion health care marketplace, employ 215,000 Americans, and provide an expanding range of health care services to millions of patients every day. Our members are small business owners who are among America’s most accessible health care providers.

NCPA has sought pharmacy direct and indirect remuneration (DIR) fee reform over the past decade. For many years, our members have identified DIR fees as their No. 1 challenge and the biggest threat to their survival. We appreciate the willingness of CMS to continue to discuss the impact of the current reimbursement system on independent community pharmacies and the patients these pharmacies serve. Unfortunately, CMS has been unable to finalize policies

addressing retroactive pharmacy DIR fees through previous proposals undertaken by the agency during previous administrations.¹

As CMS itself notes, pharmacy price concessions, also known as pharmacy DIR fees, have increased more than 107,400 percent over a 10-year period.² This increase in pharmacy price concessions is unsustainable for our members, who serve patients in rural and underserved communities, and must be resolved by CMS through regulatory action.

Pharmacy price concessions are being used by pharmacy benefit managers to subsidize premiums in the Medicare Part D program, hide the true costs of prescription drugs, inflate costs for seniors, and put crushing financial pressure on small business community pharmacies and patients. To preserve the integrity of these programs, these practices must be stopped.

In previous attempts at regulatory changes to address patient costs and pharmacy price concessions, and with this current proposed rule, CMS' uses the terms "performance-based pharmacy payment arrangements" and "performance-based pharmacy price concessions," which represent inaccurate descriptions of pharmacy DIR in the current marketplace. CMS lacks the evidentiary basis for using those terms to describe pharmacy DIR fees or pharmacy price concessions and indeed these payments have nothing to do with measurable performance that will accrue to beneficiaries or the program. CMS has no way of knowing the validity of the measures used by the PBMs in their contracts with pharmacies.

Although NCPA welcomes many of the policies driving this proposed rule, CMS must resolve or clarify the issues highlighted below for the resulting policy changes to have a positive impact on patients, the Medicare program, and community pharmacies.³

- **CMS must ensure transparency of pharmacy reimbursement at the point of sale and ensure the lowest possible reimbursement equals the amount paid on a pharmacy remittance advice, paid within the CMS prompt pay rules of 14 calendar days. Transparency to pharmacies and patients is critical. Therefore, CMS needs to:**
 - clarify that the definition of "other stakeholders" includes the dispensing pharmacy;
 - verify the lowest possible reimbursement will be visible to pharmacies at the point of sale on the paid claim response;
 - require specific claim-level trackable linkages between the lowest possible reimbursement amount on the paid claim response, the amount reported on the prescription drug event (PDE), and the amount paid on the pharmacy remittance;

¹ Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses, CMS 4180-P, <https://www.federalregister.gov/documents/2018/11/30/2018-25945/modernizing-part-d-and-medicare-advantage-to-lower-drug-prices-and-reduce-out-of-pocket-expenses>.

² Proposed Rule: Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, <https://www.federalregister.gov/d/2022-00117/p-714>.

³ NCPA offers these comments on the proposed rule without commenting on CMS' statutory authority to modify the definition of "negotiated prices." NCPA is presently the lead plaintiff in a lawsuit challenging CMS' existing regulatory definition of "negotiated prices," *see NCPA v. Becerra*, No. 1:21-cv-131 (D.D.C.), and nothing in this letter should be construed as a waiver of the arguments that NCPA and the other plaintiffs have made in the litigation challenging the existing regulatory definition.

- require plans to provide consistent claim-level detail in the ASC X12 835 electronic remittance file that details reimbursement payments to pharmacies;
 - provide clear guidance that any post-point-of-sale adjustments must be positive incentive payments for pharmacy performance only;
 - specify that the coordination-of-benefits requirements do not apply to pharmacy incentive payments;
 - confirm that all pharmacy price concessions must be attributable at the claim level even if not computed or assessed at the time of dispensing the Medicare Part D drug;
 - address how CMS guidance would apply if plan sponsors or PBMs were to begin restructuring pharmacy fees on a basis other than claim-level fees;
 - require that pharmacy administrative service fees are properly reported by Medicare Part D plans, as plans are currently incentivized not to report these fees at all;
 - clearly provide a workable and inclusive definition of pharmacy price concession that addresses any fee paid by a pharmacy or deducted from payments to a pharmacy, or any other remuneration received directly or indirectly by the Medicare Part D sponsor or its intermediary contracting organization.
- **CMS must close the coverage gap loophole.** The proposed rule creates a loophole that would treat patients differently depending on their phase in the Medicare Part D benefit, would permit PBMs to continue to play games with pharmacy price concessions for pharmacies and inflate prescription costs for the most vulnerable patients, and would add needless administrative expenses by forcing the use of two systems, one within the coverage gap and the other outside of it.
 - **CMS must address the proposed rule's impact on pharmacy cash flow.** Decreased pharmacy reimbursement could potentially cause issues of solvency for pharmacies in Medicare Part D networks.
 - **CMS must require standardized pharmacy performance measures for incentive payments.** There is currently an inequitable application of metrics for community pharmacies. Even pharmacies that earn high performance ratings are nevertheless punished by pharmacy DIR fees based on arbitrary PBM measures.
 - **CMS must enforce existing network adequacy and contract provision requirements.** Maintaining adequate access for patients to prescription drugs is predicated on the participation of pharmacies in Medicare Part D plan networks.
 - **CMS must address NCPA's concerns and recommendations when promulgating the final rule for small business pharmacies to remain viable participants in the Medicare Part D program.** An "Actuarial Memorandum of the Model and Assumptions in Analyzing the 2023 Proposed Rule Regarding Pharmacy Price Concessions at Point of Sale" was prepared for Avalere Health on behalf of NCPA.⁴ NCPA commissioned this memorandum because CMS failed to adequately test the assumptions that this proposal could result in

⁴ See discussion at p. 14 herein and Appendix attached to this comment letter.

a “modest” potential indirect positive effect on pharmacy payment, and CMS did not consider this proposal’s impact on small business pharmacies. The memorandum reveals that CMS miscalculated the positive impact on pharmacy. If plans lower net reimbursement by 2 percent because of this rule, a reasonable assumption based on PBMs’ long history of reduced pharmacy reimbursement in the Medicare Part D program, the average pharmacy would face a 2 percent reduction in reimbursement.⁵

NCPA provides expanded explanation for our requests to CMS in the following sections.

CMS MUST ENSURE TRANSPARENCY OF PHARMACY REIMBURSEMENT AT THE POINT OF SALE AND ENSURE THE LOWEST POSSIBLE REIMBURSEMENT EQUALS THE AMOUNT ON A PHARMACY REMITTANCE ADVICE PAID WITHIN THE CMS PROMPT PAY RULES OF 14 CALENDAR DAYS.

The benefits of applying all pharmacy price concessions in the negotiated price definition are only achievable if all price concessions are transparent and known to the pharmacy. The requirements for the net price to be used for the calculation of patient cost sharing and reported on the PDE for government subsidy calculations are relatively clear in the proposed rule and the purposes for doing so are ascertainable. CMS also states that its goals for the proposed rule include price transparency for “other stakeholders.”⁶ **CMS must clarify that the definition of “other stakeholders” includes the dispensing pharmacy.**

Price transparency for beneficiaries

CMS states that “beneficiaries would see lower prices at the pharmacy point-of-sale and on Plan Finder for most drugs,”⁷ but it remains unclear how and what specific CMS requirements would make price concessions visible to beneficiaries.

CMS must require the *net prices* be available on the pharmacy receipt, on the explanation of benefits, and displayed in Plan Finder to provide price transparency for beneficiaries.

Increased transparency for patients allows them to make more informed choices on their health care and potential drug costs. NCPA has supported making as much information related to the costs of drugs available to the patient and holding PBMs accountable for their actions in inflating drug costs.⁸

Price transparency for pharmacy

To provide price transparency for “other stakeholders,” including pharmacy, CMS must verify that the lowest possible reimbursement will be visible to pharmacies at the point of sale on the paid claim response. Pharmacies would need this type of detail to achieve CMS’ stated goal of transparency.

⁵ Actuarial Memorandum of the Model and Assumptions in Analyzing the 2023 Proposed Rule Regarding Pharmacy Price Concessions at Point of Sale, prepared for Avalere Health and commissioned by NCPA, p. 9 & Table 7 (Appendix to comment letter).

⁶ Proposed Rule: Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, <https://www.federalregister.gov/d/2022-00117/p-750>.

⁷ Id., <https://www.federalregister.gov/d/2022-00117/p-950>.

⁸ NCPA Comments to HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, CMS-2018-0149 (July 16, 2018), available at <http://www.ncpa.co/pdf/ncpa-comments-to-blueprint.pdf>.

NCPA also requests that CMS require specific claim-level trackable linkages between the lowest possible reimbursement amount on the paid claim response, the amount reported on the PDE, and the amount paid on the pharmacy remittance.

This system-wide transparency would help stabilize and make the operating environment more predictable for pharmacies, as CMS notes it has previously heard in public comments.⁹ What this means in practice is making the minimum pharmacy reimbursement available on a per claim level. Additionally, this transparency would help provide a level playing field of implementation expectations among industry trading partners and expedite decision making as stakeholders adjust to the changes for CY2023.

NCPA continues to question how the data ensuring the lowest possible reimbursement will be transmitted to the pharmacy and how the data will map to the PDE and to the pharmacy remittance. **The negotiated price due the pharmacy at the point of sale needs to match the remittance paid to the pharmacy within the 14-day prompt pay timeline. CMS must be clear that such mapping must occur within the 14-day payment window.** For instance, if price concessions are to be itemized at the point of sale, NCPA recommends use of the NCPDP Other Amount Paid (565-J4) field with a unique Other Amount Paid Qualifier (564-J3). **CMS must also require plans to provide consistent claim-level detail in the ASC X12 835 electronic remittance file that details reimbursement payments to pharmacies.**

NCPA encourages CMS to engage the National Council for Prescription Drug Programs to identify an existing Other Amount Paid Qualifier, such as 04 – Administrative Cost, to ensure timely accommodation of the proposed rule until a unique qualifier can be published in the code list at a later date.

In other words, the unique Qualifier for the Other Amount Paid field could be used to:

- illustrate how much each PBM extracts per claim,
- simplify reconciliation,
- map to the PDE,
- map to the NCPDP 835 pharmacy remittance, and
- allow for more accurate cost and revenue accounting from primary billing systems relative to what to expect in the bank deposit.

“Negotiated price” definition

NCPA supports the proposed definition of negotiated price to include all price concessions from network pharmacies. Requiring all pharmacy price concessions to be applied at the point of sale would provide much needed predictability and stabilization to pharmacy operations. The current retroactive nature of pharmacy price concessions by most PBMs at the pharmacy level rather

⁹ Proposed Rule: Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, <https://www.federalregister.gov/d/2022-00117/p-720>.

than the claim level eliminates a pharmacy's ability to account for profit or loss at the per-prescription level.

While CMS specifies in the proposed rule how the gross and net costs must be applied to cost sharing and reported on the PDE, it does not specify how the net cost is to be paid to the pharmacy. In the implementation of the final rule, CMS must provide clarity for community pharmacy. Clarity provides stability, which in turn provides for a robust network of pharmacies for participation in Medicare Part D networks to serve patients. CMS should affirm that once the lowest price at the point of sale has been determined, no plan or PBM may make any adjustments that lower the price from the one at the point of sale. NCPA believes it is the intent of CMS that the negotiated price reflects the actual lowest net reimbursement to a pharmacy. However, CMS never explicitly states in the proposed rule that any post-point-of-sale adjustments can only be positive payments to the pharmacy. It is critical that CMS include such a statement in the final rule.

CMS must provide a clear, explicit statement that any post-point-of-sale adjustments can only be positive incentive payments for pharmacy performance. NCPA suggests such positive adjustments be settled within a timeframe of six months or sooner.

Additionally, NCPA calls for CMS to clarify that incentive payments, whether determined at the claim level or Provider Level Benefit level, do not necessitate that a pharmacy reprocess a claim which may affect reimbursement from a secondary payer in a coordination-of-benefits transaction. Pharmacy incentives are not considered drug cost therefore any post adjudication adjustment would not be subject to the coordination-of-benefits requirements. Further, NCPA requests that if it can be determined that a secondary payer over-paid based on a claim-level adjustment, the overpayment should be reconciled between the payers as an incentive for the primary payer to minimize the impact to the secondary payer, should this situation occur.

CMS suggests, but does not specify, that the requirement for negotiated prices to be inclusive of all pharmacy price concessions means that sponsors must make all pharmacy DIR deductions attributable at the claim level *even if fees are not computed/assessed at the claim level*. NCPA fears if CMS adopts the proposed rule, PBMs will draw a distinction between claim-related and non-claim-related fees and restructure the contractual language for existing pharmacy DIR to transform it into non-claim-related fees deducted from the pharmacy remittance to avoid their reporting and disclosure obligations.

CMS must confirm that all pharmacy price concessions be attributable at the claim level even if not computed or assessed at the time of dispensing the Part D drug. NCPA also asks CMS to address how its guidance would apply if plan sponsors or PBMs were to begin restructuring pharmacy fees to a basis other than claim-level fees or otherwise circumvent CMS' apparent intent in this proposal.

Further, we suggest that CMS actively conduct oversight over the operation of the changes to the negotiated price definition by requiring plans to provide an attestation from the CEO, CFO, COO, or other delegated individual with a fiduciary and legal responsibility as to the accuracy and

completeness of the pharmacy price concessions included in the negotiated price at the point of sale. HHS has, through other regulations, provided similar safeguards to ensure accurate reporting. This requirement would be no different and would provide CMS with further documentation of impropriety if all such price concessions are not included in the negotiated price.

Pharmacy administrative service fees

CMS reiterates that “pharmacy administrative service fees” should be included in a plan’s bids because they offset the sponsor’s or its intermediary’s operating costs under Medicare Part D. CMS states that failure to report these costs as administrative costs in the bid would allow a sponsor to misrepresent the actual costs necessary to provide the benefit.

NCPA members should not be required to pay administrative fees that accrue only to the plan or PBM and which provide no additional value to the pharmacy or the beneficiary beyond the ability to participate in the Medicare Part D plan’s pharmacy network. Examples include claim transaction fees, application fees, network enrollment fees, customer service fees, network administration fees, payment processing fees, credentialing fees, recredentialing fees, and remittance reporting fees. The operating costs of a plan should not be the responsibility of a contracting pharmacy.

CMS must require that pharmacy administrative service fees are properly reported by Medicare Part D plans, as plans are currently incentivized not to report these fees at all. NCPA asks that CMS clarify how the agency intends to ensure that these fees are being properly recognized and reported. CMS should utilize Medicare Part D Reporting Requirements to ensure fees charged to pharmacies are properly reported as either administrative costs or price concessions.

Pharmacy “price concession” definition

NCPA appreciates CMS defining price concession to ensure the Medicare Part D plan sponsors and PBMs do not merely relabel fees to manipulate bids. Without a definition of what constitutes a “price concession” and what should therefore be included in the negotiated price, NCPA is concerned that plans will reclassify or redefine pharmacy price concessions in a manner that excludes them from negotiated prices, thereby increasing beneficiary drug costs and leaving small business pharmacies with unpredictable retroactive fees.

It is important to note most fees charged to pharmacies are rarely included in a pharmacy’s contract terms. Instead, they are placed in the provider manual, which many times are “included” in the contract terms by merely mentioning the provider manual in the contract. The PBMs are allowed to change the provider manual throughout the contract year, changing fees or other provisions when they decide and without giving notice to the contracted pharmacy.

Therefore, if a pharmacy cannot avoid paying or being assessed the fee while being a participant in a Medicare Part D network, that is a price concession and must be accounted for at the point of sale which, in turn, needs to be accounted for in the definition of “price

concession.” In other words, any fee deducted from a drug claim remittance or otherwise assessed to a pharmacy at any time is a price concession, whether it represents a fixed fee amount or the lowest possible value of a contingent amount, such as effective rate contracting or a performance-based payment withhold/penalty amount. Accordingly, CMS should clarify that no additional amount that has not been applied to the basis for coinsurance at point of sale and reported on the PDE can later be deducted from the pharmacy remittance.

CMS must avoid creating any loopholes via the price concession definition which allows PBMs to shift fees from one form to another to avoid complying with the purpose and intent of the rule. NCPA also requests CMS make available to pharmacies a mechanism to report inconsistencies with assessments of pharmacy price concessions. To ensure plans include all price concessions in the negotiated price in a uniform manner, pharmacies need to be able to report any inconsistent application directly to CMS.

NCPA recommendation: In sum, CMS needs to make clear that any financial amount that will be deducted from the drug claim remittance or otherwise charged to a pharmacy at any time must be treated as a price concession, regardless of its purpose or classification, and must be fully disclosed in the negotiated price as:

- **the amount on which coinsurance is calculated at the time of initial claim adjudication,**
- **the amount in the “ESTIMATED REBATE AT POS” field reported on the final action PDE,**
- **an amount separately visible on the adjudicated claim response, and**
- **the amount must be equal to the reported amount on the remittance advice.**

CMS MUST CLOSE THE COVERAGE GAP LOOPHOLE.

CMS has proposed to exclude drugs purchased during a patient’s coverage gap from the new definition of “negotiated price.” Creating a bifurcated system — with different treatment of pharmacy price concessions for patients depending upon where they are in the coverage continuum — would cause instability, beneficiary confusion, and increased costs to stakeholders. NCPA is concerned about the bifurcation of the system as PBMs may construct contractual arrangements that shift post-point-of-sale pharmacy price concessions to the coverage gap to capitalize on lost revenue from CMS’ proposed changes.

NCPA opposes CMS’ proposal of providing plans the flexibility to determine how much of the pharmacy price concessions to pass through at the point of sale for applicable drugs in the coverage gap. Although it appears CMS is hoping to reduce the scope and cost of the proposed policy changes and to dampen the impact on premiums, the extension of the application of pharmacy price concessions at the point of sale to all phases of the benefit would promote consistent outcomes for stakeholders across the industry, including pharmacies and patients. It would lower administrative costs and eliminate a basis for PBMs to manipulate the new rules to the detriment of patients and pharmacies.

The consistent application of pharmacy price concessions at the point of sale to all phases of the benefit will also reduce the burden of operating and complying with two separate systems, which increases administrative costs that do not enhance patient care. Introducing a bifurcated system will only confuse patients in the coverage gap and place pharmacists in the awkward position of informing patients of potentially increased copays and discrepancies in costs for out-of-pocket drugs. NCPA is unsure how such a bifurcated system would provide accurate information on Plan Finder for Medicare Part D patients. This is especially troubling for patients in the coverage gap with chronic conditions and significant costs who require prescriptions yet will not receive the benefit of the rule changes. The bifurcated system runs counter to the intended purpose of the proposed rule: reducing out-of-pocket costs for the sickest patients.

Finally, by creating a loophole for the coverage gap, CMS incentivizes PBMs to place costlier drugs in a more advantageous position on their formularies, driving patients through the initial phase quicker and increasing the costs for patients and the Medicare Part D program.

NCPA recommendation: CMS must finalize an alternative to the proposed approach and require that Medicare Part D sponsors apply pharmacy price concessions to the negotiated price of applicable drugs in the coverage gap.

CMS MUST ADDRESS THE PROPOSED RULE'S IMPACT ON PARTICIPATING PHARMACIES' CASH FLOW

Because the proposed rule requires the pass-through of price concessions to patients at the point of sale, NCPA remains concerned about the real-world consequences for the transition period from CY2022 to CY2023. It can be expected that pharmacies will have a difficult time weathering the financial strain caused by the change, especially for the first six months of 2023. By implementing the proposed rule, pharmacies will receive the lowest possible reimbursement while PBMs continue to collect pharmacy DIR fees from 2022, thereby creating cash flow issues for pharmacies.

Pharmacies have experienced this type of interruption before. When Medicare Part D was established hundreds of pharmacies closed because of cash flow issues, necessitating congressional action to establish prompt pay rules. Additionally, pharmacies face pressures from PBMs as reimbursement on some Medicare Part D drugs is below cost. NCPA is concerned finalization of the proposed rule will create a similar situation where pharmacies cannot remain open due to financial burdens. During this transition year, CMS needs to recognize the burdens facing community pharmacies and work to resolve them in a timely manner.

NCPA recommendation: CMS must require PBMs to offer payment plans for pharmacies for a reasonable period to collect CY2022 pharmacy DIR fees in CY2023. CMS needs to act to prevent serious cash flow issues and potential impacts on beneficiary access to care while community pharmacies acclimate to the new way of receiving payments and continue serving patients in our communities.

CMS MUST REQUIRE STANDARDIZED PHARMACY PERFORMANCE MEASURES FOR INCENTIVE PAYMENTS

CMS acknowledges in the proposed rule that pharmacies rarely receive an incentive payment above the original reimbursement rate for a covered claim and that performance under most arrangements dictates only the magnitude of the amount by which the original reimbursement is reduced. NCPA agrees with CMS that current pharmacy performance measures don't evaluate pharmacy performance that improves quality.

On January 15, 2021, CMS finalized a rule requiring Medicare Part D plans to disclose to CMS pharmacy performance measures and how they are applied to pharmacies.¹⁰ CMS will be able to make those measures publicly available to increase transparency in the Part D space and utilize the information to begin development of standardized pharmacy performance measures. The requirement became effective on January 1, 2022.

CMS reiterates its previously published intention to provide public transparency on pharmacy performance measures via this rule, even though the 2022 Medicare Part D Reporting Requirements¹¹ have been issued without the regulatorily mandated collection. **NCPA requests CMS clarify its intent and timeframe to implement the previously finalized regulatory requirement for plans to report pharmacy performance measures used for pharmacy payment adjustments.** Transparency as to performance-based measures will help CMS and policymakers better understand the role of these metrics with respect to quality. **Also, CMS must require sponsors to disclose in detail each pharmacy performance metric being used, or the requirement may not prove useful.**¹²

According to PDE guidance, the only types of costs that CMS has approved to be treated as drug costs for payment purposes are the ingredient cost, dispensing fee, vaccine administration fee, sales tax, and any incentive fee paid. Pharmacy-related costs not included in the dispensing fee, such as for pharmacists' clinical interventions to optimize medication therapy and adherence, may be more properly reimbursed to plan sponsors through projected administrative costs in the bid for medication therapy management or other quality improvement activities, and then included in the medical loss ratio.

Consistent with CMS statements on the inappropriateness of treating administrative costs as drug costs under its bidding guidance¹³, pharmacy performance measure data could also help CMS determine whether the measures used to calculate pharmacy price concessions have any basis for reducing drug costs at all. Arguably, deductions from drug costs should be limited to cost components that are included in the drug cost payments in the first place. **Therefore, NCPA requests that CMS explain how deductions can be made from drug costs when the costs for**

¹⁰ <https://www.federalregister.gov/d/2021-00538/p-1076>

¹¹ Medicare Part D Reporting Requirements. <https://www.cms.gov/files/document/cy2022part-d-reporting-requirements012022.pdf>.

¹² Information Collection Request on Medicare Part D Reporting Requirements (CMS-2021- 0042-0001, CMS-10185). [NCPA Comment to https://ncpa.org/sites/default/files/2021-05/NCPA_Comment_CMS_PartD_Pharmacy_Performance_Reporting_05-18-21_FINAL.pdf](https://ncpa.org/sites/default/files/2021-05/NCPA_Comment_CMS_PartD_Pharmacy_Performance_Reporting_05-18-21_FINAL.pdf).

¹³ Proposed Rule: Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, <https://www.federalregister.gov/d/2022-00117/p-763>.

which the deductions are being made are not included in the definition of drug costs. Measures used to justify pharmacy price concessions do not seem to be anchored to any CMS allowed cost.

NCPA remains concerned that PBMs will continue to manipulate pharmacy performance measures to negatively impact pharmacy reimbursement, rather than incentivize pharmacies providing high quality outcomes. As CMS has recognized,¹⁴ pharmacies are not positively rewarded for performance; the concession is only lessened.

Currently, there is wide variance and a complete lack of standardization across sponsors and PBMs in the performance measures utilized, terminology, timing, attribution methods, number of patients required to capture a metric, and calculation methods. In the environment our members operate in today, Medicare Part D plans and PBMs create their own “homegrown” measures with unrealistic thresholds and unattainable cut points. Because of “bell curves” and lack of standards, pharmacies can be very effective in assisting patient health outcomes but still lose money on dispensing because the methodology is not aligned with the incentive. All pharmacies performing at a high level should be rewarded for improving patient health outcomes, not just the limited number of pharmacies on the PBMs’ self-serving bell curves.

Whereas sponsors and PBMs have a clear and defined understanding of how they are being judged by CMS and measured in the Star Ratings, pharmacies are afforded no such opportunity by sponsors and PBMs. The “quality-based” measures often being used were developed for use in population health measurement at a health plan level, not developed for use in community pharmacies with much smaller numbers of patients that are not a valid measure of an individual pharmacy’s overall quality. There is growing evidence PBMs use measures in an arbitrary way that only serves to enrich the PBM at the expense of community pharmacy. CMS has the authority to ensure that pharmacy quality measures imposed by Medicare Part D plans and their contracted PBMs are standardized, validated, consensus based, clearly defined, and truly incentivize performance improvement. Pharmacy performance measures should be evidence-based and focused on patient health outcomes rather than drug costs.

NCPA recommendation: CMS must require standardized pharmacy performance measures for incentive payments. The measures must be validated, consensus based, and clearly defined, and they must be used by PBMs to impact only positive incentive fees paid to pharmacies, focusing on true assessment of pharmacy performance, separate from the dispensing or cost of a particular drug.

CMS MUST ENFORCE EXISTING NETWORK ADEQUACY AND CONTRACT PROVISION REQUIREMENTS

Medicare Part D network adequacy is directly impacted by PBM market dominance. The three largest PBMs control at least 77 percent of the health plan pharmacy benefit market.¹⁵ A PBM,

¹⁴ Id., <https://www.federalregister.gov/d/2022-00117/p-749>.

¹⁵ Fein, Adam. “The Top Pharmacy Benefit Managers of 2020: Vertical Integration Drives Consolidation.” Drug Channels. April 6, 2021. <https://www.drugchannels.net/2021/04/the-top-pharmacy-benefit-managers-pbms.html>

as part of a vertically integrated entity with a health plan and mail-order, specialty, and retail pharmacies, has market power in the majority of markets and serves as gatekeeper to those markets in which community pharmacies try to compete and serve patients.¹⁶ Consequently, community pharmacies are forced to sign take-it-or-leave-it contracts in order to have access to the health plan subscribers.

In many markets, one health plan is dominant. In other markets, there may only be two health plans.¹⁷ If an independent pharmacy rejects the terms offered by the market-dominant health plan or their PBM, it will lose access to a significant percentage of its potential customers and patients will be without pharmacy access and will lose the benefits of innovation that come from competition. Most of the time a pharmacy will be forced by the PBM to agree to participate in each pharmacy network before they know what plans the PBM will assign to that network.

PBM anticompetitive practices negatively impact pharmacy reimbursement, network adequacy, and patient access to care. PBMs regularly steer patients to their own affiliated or owned pharmacies and foreclose access by Medicare Part D participants to pharmacies of their choice. PBMs are also known to extract higher pharmacy DIR fees for participation in certain preferred Medicare Part D networks. High performing pharmacies in preferred cost-share networks cannot make up the difference for the costs from being a member of the preferred network.

The implementing statute of Medicare Part D requires¹⁸ a robust pharmacy network to assure access to covered Medicare Part D drugs. Additionally, CMS requires contracts to have “reasonable and relevant terms and conditions of participation”¹⁹ for any willing pharmacy. Contract terms that make it impossible for a pharmacy to break even for the costs to dispense a drug are not reasonable.

There has been a movement to create a reimbursement floor in other drug programs, including federally funded Medicaid. For instance, Medicaid fee-for-service programs require pharmacy reimbursement be based on actual acquisition cost plus a commensurate professional dispensing fee. Many states have adopted such a requirement in Medicaid managed care, and we are even seeing states require commercial plans reimburse pharmacies using this fair and equitable benchmark. Incorporating such a reimbursement floor in Medicare Part D may be a logical extension.

The inability of CMS to address the ongoing issues with pharmacy DIR fees has endangered community pharmacies in rural and underserved areas. In these areas, one in eight pharmacies

¹⁶ <https://www.ama-assn.org/system/files/2020-10/competition-health-insurance-us-markets.pdf>, see e.g., Table 1 (in 92% of markets, at least one insurer with PBM has 30% market share; in 50% of the MSAs, one insurer has at least 50% market share).

¹⁷ *Id.*

¹⁸ [42 CFR § 423.120](#).

¹⁹ [42 CFR § 423.505 \(b\)\(18\)](#).

closed between 2009 and 2015²⁰, limiting access for patients and creating significant impacts on patient prescription adherence. Where a pharmacy is not present, adherence to a prescription regime decreases²¹, leading to additional costly hospitalizations and emergency room visits.

Patients in rural and underserved areas should have an additional licensed medical professional available who shares knowledge about the community and the people who live there. The lack of pharmacies in these areas due to closure and other economic factors puts these communities at risk and places additional burdens on patients to travel greater distances to receive care.

NCPA has partnered with the University of Southern California School of Pharmacy and Leonard D. Schaeffer Center for Health Policy and Economics²² to study pharmacy deserts – geographic areas where pharmacy access for patients is limited. We will continue to work with this Pharmacy Access Initiative, and other stakeholders, to pursue policy solutions to reduce barriers and ensure equitable access for Medicare Part D patients in rural and underserved areas. Additionally, as the administration²³ addresses health equity in federal programs like Medicare Part D, it is imperative that CMS recognize the financial pressures the current system places on community pharmacies and move to address them.

NCPA recommendation: CMS must evaluate if the lowest possible reimbursement reflected at the point of sale covers a pharmacy’s costs, to ensure that plans maintain adequate network access and compliance with the any willing pharmacy mandate in Medicare Part D.

CMS MUST ADDRESS NCPA’S CONCERNS AND RECOMMENDATIONS WHEN PROMULGATING THE FINAL RULE IN ORDER FOR SMALL BUSINESS PHARMACIES TO REMAIN VIABLE PARTICIPANTS IN THE MEDICARE PART D PROGRAM

An “Actuarial Memorandum of the Model and Assumptions in Analyzing the 2023 Proposed Rule Regarding Pharmacy Price Concessions at Point of Sale” was prepared for Avalere Health on behalf of NCPA²⁴, because CMS failed to address the basis of assumptions that this proposal could result in a “modest” potential indirect positive effect on pharmacy payment, nor did CMS contemplate this proposal’s impact on small business pharmacies. The report, prepared by Harold Neil Lund, who has over 50 years of experience in the United States health care and insurance markets, including experience in the Medicare Part D program since its creation, indicates that plans will claw back the loss of network DIR. The average pharmacy likely faces a 2

²⁰ Guadamuz, Jenny S. MS; Alexander, G. Caleb MD, MS; Zenk, Shannon N. PhD; Qato, Dima M. PharmD, MPH, PhD. Assessment of Pharmacy Closures in the United States From 2009 Through 2015.

https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2753258?guestAccessKey=9f0d3d86-193b-40b4-a8de-5d015f8842ab&utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_content=tfi&utm_term=102119

²¹ Qato DM, Alexander GC, Chakraborty A, Guadamuz JS, Jackson JW. Association Between Pharmacy Closures and Adherence to Cardiovascular Medications Among Older US Adults. JAMA Netw Open. April 19, 2019;

<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2730785>.

²² NCPA Press Release on Pharmacy Access Initiative. Published September 9, 2021. <https://ncpa.org/newsroom/news-releases/2021/09/09/ncpa-usc-school-pharmacy-collaborating-pharmacy-access-initiative>.

²³ Executive Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.

<https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>.

²⁴ Actuarial Memorandum of the Model and Assumptions in Analyzing the 2023 Proposed Rule Regarding Pharmacy Price Concessions at Point of Sale,” prepared for Avalere Health and commissioned by NCPA. (Appendix to comment letter).

percent *reduction* in reimbursement if plans lower net reimbursement by 2 percent or more. This is based on PBMs' long history of reduced pharmacy reimbursement in the Medicare Part D program.

NCPA was surprised to see in the proposed rule that CMS estimates assume "that pharmacies will seek to retain 2 percent of the existing pharmacy price concessions they negotiated with plan sponsors and other third parties to compensate for pricing risk and differences in cash flow" and "that these business decisions will result in a slight increase in pharmacy payments of 0.1-0.2 percent of Part D gross drug cost." This statement runs directly counter to our members' actual history with the Medicare Part D program, which shows constant downward pressure on pharmacy reimbursement. Reimbursement for community pharmacies in the Medicare Part D program has only trended downward and is a leading cause of local community pharmacies closing. NCPA questions the basis of CMS' assumptions and asks that CMS provide the math it relied on to arrive at this estimate. NCPA seeks the calculations used in order to clearly understand and verify CMS' assumptions.

Additionally, NCPA is concerned that CMS did not conduct a regulatory flexibility analysis to determine the proposed rule's impact on small business pharmacies and did not show how many small business pharmacies would be impacted by this proposed rule.

The attached actuarial memorandum models the impact of the rule on pharmacies, concluding that the average pharmacy faces a 2 percent reduction in reimbursement, if plans lower net reimbursement by 2 percent, based on PBMs' long history of reduced pharmacy reimbursement. However, this reduction in reimbursement increases to 5.3 percent for a high performing pharmacy, again assuming plans lower reimbursement by 2 percent, while a low performing pharmacy's reimbursement would have an improvement of 2.6 percent.

Table 7 of the attached actuarial memorandum shows the potential for perverse effects on pharmacy. Under either assumption from the modeling, high performing pharmacies would bear the unintended consequences of the proposed rule, facing an even more significant decrease in reimbursement as the rule forces all concessions to the point of sale and likely prevents those pharmacies from "earning back" any incentive. The memorandum also concludes that smaller independent pharmacies would face greater strain from cash flow without the negotiating power to mitigate the situation.

Lastly, NCPA points out that Table 7 modeling is based on the CMS model without gap application. This means that if the CMS proposal is ultimately applied in the coverage gap, pharmacy reimbursement may be further reduced as plans seek to make up for a greater pharmacy DIR shortfall. This makes it even more important that CMS implement mitigation strategies to blunt the harm to small business pharmacies.

On behalf of the 19,400 independent community pharmacies across the country, NCPA urges CMS to address the concerns we have raised in this letter in the final rule for CY2023 to ensure

the continued vibrancy and financial solvency of the independent pharmacies serving millions of patients in their local communities every day.

CONCLUSION

NCPA greatly appreciates the opportunity to share our thoughts on the proposed rule. We recognize the short turnaround time for finalizing and implementing the rule for the upcoming contract year. **NCPA respectfully requests CMS address these concerns and recommendations when finalizing the rule for Contract Year 2023 in order for NCPA to support the proposal and for small business pharmacies to remain viable participants in the Medicare Part D program.**

A move of this magnitude would demonstrate the administration's dedication to providing immediate savings for seniors at the pharmacy counter and needed support to small business pharmacies and the patients we serve. Should you have any questions, please contact Ronna Hauser, Senior Vice President of Policy and Pharmacy Affairs, at ronna.hauser@ncpa.org or (703) 838-2691.

Sincerely,

A handwritten signature in black ink, appearing to read "B. Douglas Hoey". The signature is fluid and cursive, with a large initial "B" and a stylized "H".

B. Douglas Hoey RPh, MBA
CEO, National Community Pharmacists Association

Actuarial Memorandum of the Model and Assumptions in
Analyzing the 2023 Proposed Rule Regarding Pharmacy
Price Concessions at Point of Sale

Prepared for Avalere Health on Behalf of NCPA

H. Neil Lund FSA, MAAA, FCA

March 2, 2022

Statement of Qualifications

I am Harold Neil Lund (also known as Neil Lund or H. Neil Lund). I am a Fellow in the Society of Actuaries (FSA), a Member of the American Academy of Actuaries (MAAA), and a Fellow in the Conference of Consulting Actuaries (FCA). A copy of my Curriculum Vitae is available upon request.

In addition to my actuarial training and education, I have over 50 years of experience in the United States healthcare and insurance markets. I began my career in insurance in 1972. I have remained involved in the healthcare market after my retirement by serving as a Senior Advisor to Avalere Health on a limited hours basis.

Scope and Background

Avalere Health engaged me, on behalf of National Community Pharmacists Association (NCPA), to model the impact on the various impacted parties of the 2023 Proposed Rule regarding pharmacy price concessions. The Proposed Rule was published in the Federal Register on January 12, 2022 (87 FR 1842, starting on page 1958). The model discussed here (alternative model) provides an alternate analysis to what CMS has provided in the Federal Register. This memorandum comments on the CMS model; describes the alternative model; comments on findings and differences in the two approaches; and discusses assumptions, inputs, outputs, and reconciliations used in the alternative model. This memorandum also comments on the CMS approach and contrasts it against the approach taken by the alternative model.

Limitations

This report is limited to comments on the models and assumptions used by Avalere Health and is only an adjunct to, not a summary of any presentations or reports made by Avalere Health with regard to pharmacy price concessions. This report is to be used only in conjunction with the engagement of Avalere Health by NCPA for the examination of impact of the Proposed Rule on pharmacy price concessions. NCPA, and its members, may extract data, comments, and other materials in this report for inclusion in comment letters on and/or presentations about the Proposed Rule and related issues after review by and expressed approval from Avalere. This report may be shared by NCPA with third parties as part of any discussions about pharmacy price concessions as presented by the Proposed Rule and related issues under the conditions that this entire report is provided. No other use is authorized.

Actuarial Standards of Practice

Professional actuaries practicing in the US are bound by the American Academy of Actuaries Code of Professional Conduct and by the Actuarial Standards Board's Actuarial Standards of Practice (ASOPs). All aspects of the Code of Conduct must be met, however most ASOPs are practice specific. For example, some ASOPs cover only pension work, others are specific to life insurance, and others are specific to health

insurance. ASOPs considered in this report include: ASOP 23 Data Quality; ASOP 25, Credibility Procedures; ASOP 41, Actuarial Communications; ASOP 56, Modeling.

Reliance

I have relied upon Rebecca Yip and Yiwen He of Avalere Health who pulled a 20% sample of the 2020 Part D Prescription Drug Event (PDE) files for use in this model. They provided a reconciliation of the data pull. I have independently verified this data.

I have also relied on the various discussions provided in the Proposed Rule as published in the Federal Register, including the following tables in the Proposed Rule:

- Table 3: Pharmacy Price Concessions by Year (2010-2020),
- Table 15: Impact (in Billions) of Concessions Excludes Application to Applicable drugs in Coverage Gap,
- Table 16: Total Impacts for 2023 Through 2032 Without Application to Applicable Drugs in Coverage Gap,
- Table 17: Total Impacts to Enrollees for 2023 through 2032 with Application to Applicable Drugs in Coverage Gap,
- Table 18: Total Impacts to Manufacturers for 2023 Through 2032 with Application Coverage Gap, and
- Table 19: Total Impacts to Government for 2023 Through 2032 with Application to Applicable Drugs in the Coverage Gap.

Discussion of the CMS Model

The information provided in the Federal Register is based on an undescribed prospective model. The model forecasts for years 2023 through 2032, accounting for the workings of the Part D program, and examines the impact of the proposal against a baseline forecast. As with any forecast, assumptions have been made about the composition of future Part D membership, trends in drug utilization, drug cost, network contracting, manufacturer rebates, drug mix, benefit designs, general inflation, plan expense and profit margins as well as others. This is a valid approach to modeling, but with the long-term assumptions, it does introduce volatility in the forecasted outcomes. The various tables in the Proposed Rule are very helpful but limited in precision in that values are presented in billions of dollars, and percentages are rounded to the nearest percent. Table 16, a very important table, presents averages across the years 2023 through 2032, and assumes the proposed changes do not apply in the coverage gap discount phase. In rough terms, this can be an approximation for the impact for year 2027. CMS unfortunately did not provide a table similar to Table 16, with adjustments to display the results with application to applicable drugs in coverage gap discount phase.

Discussion of the Alternative Model

The alternative model is a retrospective model. Unlike the CMS model, this work examines actual 2020 PDE experience and adjusted 2020 cost for provisions of the Proposed Rule. With the retrospective model, claims experience and network DIR are known from available data. Relatively few assumptions are needed to complete the model. These assumptions include plan expense and profit margins and manufacturer rebates for the year 2020, and can be estimated from public sources. This alternate look at the impacts means that per member per year component impacts are not directly comparable, but percentage changes in the components should provide for a comparison. A detailed description of the alternative model and assumptions are presented later in this memorandum, with direct impacts on pharmacies presented in Table 7 of this memorandum.

Comparison of CMS Model and Alternative Model

In the Proposed Rule, CMS provided a summary of impacts for 2023 through 2032 without applying the proposed negotiated price definition to the coverage discount phase (“without application to the gap”). Table 16 in the Federal Register is replicated below as Table 1 of this document. Unfortunately, CMS did not provide a corresponding table summarizing results applying the proposed negotiated price definition to the coverage discount phase (“with application in the gap”). For purposes of comparisons, we have derived such a table using Tables 16, 17, 18, and 19 from the Federal Register, reflected as Table 2 of this document.

Table 1

CMS Model Without Gap Application			
	(\$Billions)	PMPY	% Change
Beneficiary Cost	(21.30)	(\$36.66)	-3%
Cost Sharing	(33.10)	(\$57.03)	-6%
Premium	11.80	\$20.37	5%
Government Cost	40.00	\$69.18	3%
Direct Payment	76.70	\$132.47	83%
Reinsurance Cost	(15.80)	(\$27.27)	-2%
LI Cost Sharing	(24.40)	(\$42.15)	-5%
LI Premium	3.50	\$6.13	7%
Manufacturer Cost	(14.60)	(\$25.19)	-6%
Pharmacy Net Reimbursement	N/A	N/A	N/A
Plan Cost	N/A	N/A	N/A

Table 1 is copied directly from the Proposed Rule. It assumes the revised definition of negotiated price does not apply in the coverage gap discount phase.

Table 2

Derived CMS Model With Gap Application			
	(\$Billions)	PMPY	% Change
Beneficiary Cost	(29.10)	(\$50.09)	-3.7%
Cost Sharing	(44.30)	(\$76.33)	-8.0%
Premium	15.20	\$26.24	6.4%
Government Cost	50.70	\$87.69	3.6%
Direct Payment	97.60	\$168.57	105.6%
Reinsurance Cost	(19.30)	(\$33.31)	-2.4%
LI Cost Sharing	(32.20)	(\$55.62)	-6.6%
LI Premium	4.60	\$8.06	9.2%
Manufacturer Cost	(17.90)	(\$30.88)	-7.4%
Pharmacy Net Reimbursement	N/A	N/A	N/A
Plan Cost	N/A	N/A	N/A

Table 2 is derived from Table 1 as noted above. It assumes that the revised definition of negotiated price would apply in the coverage gap discount phase.

CMS did not disclose their assumptions in developing the tables. These would include future Part D membership, trends in drug utilization, drug cost, network contracting, manufacturer rebates, drug mix, benefit designs, and general inflation. CMS did disclose that they assumed pharmacies would seek to retain 2% of the existing pharmacy concessions for risk and cashflow. Most importantly, CMS did not disclose how lowest reimbursement was applied in the model.

Tables 3 and 4 below represent the alternative model output and looks at how the Proposed Rule would play out against actual 2020 Part D experience. Therefore, this work did not include estimated costs. It did include per member per year (PMPY) calculation for the alternative model. PMPYs are determined by dividing the total cost for a category by the average number of members for the year. It is a commonly used metric in healthcare. The PMPYs can be looked at as directional between the models but cannot be compared in absolute value. CMS PMPYs are an average of years 2023 through 2032, while the alternative PMPYs represent 2020. To make them comparable, we would need to know the assumptions noted above in the CMS model.

However, the “% Change” column does give reasonable comparatives between the CMS model and the alternative model. Note also that we have calculated the impact on

net pharmacy reimbursement and net plan benefit cost, while CMS has not. We use these additional fields to inform our analysis of possible plan actions.

Further, Tables 3 and 4 assume that point of sale reimbursement would revert to a mean net payment for all pharmacies. We derived the average net pharmacy concession as 5.8% by dividing the \$9.5 billion year 2020 concession in Table 3 of the Proposed Rule by the actual 2020 gross drug spend for individual members (excluding EGWP and PACE plans) of \$164.4 billion. To make these comparable to the CMS model, we incorporated their assumption of pharmacies negotiating a 2% of the concession offset for cashflow and risk. This adjustment (2% x 5.8%) results in a 0.1% adjustment resulting in a net concession of 5.7%.

Table 3

Alternative Model Without Gap Application			
	(\$Billions)	PMPY	% Change
Beneficiary Cost	N/A	(\$40.84)	-3.6%
Cost Sharing	N/A	(\$20.14)	-2.6%
Premium	N/A	(\$20.69)	-5.6%
Government Cost	N/A	\$41.81	2.6%
Direct Payment	N/A	\$72.64	42.9%
Reinsurance Cost	N/A	(\$17.46)	-1.9%
LI Cost Sharing	N/A	(\$6.96)	-1.5%
LI Premium	N/A	(\$6.42)	-5.6%
Manufacturer Cost	N/A	(\$0.23)	-0.1%
Pharmacy Net Reimbursement	N/A	\$4.37	0.1%
Plan Cost	N/A	\$49.16	12.8%

Table 3 is comparable to Table 1.

Table 4

Average Model With Gap Application			
	(\$Billions)	PMPY	% Change
Beneficiary Cost	NA	(\$36.53)	-3.2%
Cost Sharing	NA	(\$26.68)	-3.4%
Premium	NA	(\$9.85)	-2.7%
Government Cost	NA	\$64.36	3.9%
Direct Payment	NA	\$109.33	64.6%
Reinsurance Cost	NA	(\$18.84)	-2.1%
LI Cost Sharing	NA	(\$23.08)	-5.1%
LI Premium	NA	(\$3.05)	-2.7%

Manufacturer Cost	NA	(\$20.13)	-5.7%
Pharmacy Net Reimbursement	NA	\$5.43	0.1%
Plan Cost	NA	\$94.16	24.6%

It is helpful to compare the percent changes for Beneficiary Cost, Government Cost, and Manufacturer Cost. Despite CMS providing percent changes in Table 1 at the nearest percent and limiting the level of precision possible, the CMS model and the alternative models agree directionally and are reasonably close to each other for beneficiary and government costs. The average beneficiary benefits from lower costs, while costs are higher for the government. The area of disagreement is the impact on manufacturers where the proposed change in definition is not applicable in the coverage gap discount phase. Since the drug cost applied to the manufacturer discount is unchanged from the current process, it is hard to understand CMS' 6% drop in manufacturer cost in Table 1.

We also examined an alternative approach to the application of lowest cost at point of sale. Here we assumed the lowest possible pharmacy reimbursement was a 10% reduction of current spend. This was applied to all pharmacies at point of sale. We also assumed that on average, pharmacies would receive a bonus of 4.3% (this would leave net cost in these models equal to the 5.7% discount used in Tables 3 and 4). The bonus would be recorded as negative Direct and Indirect Remuneration (DIR) by the plan. Note that, based on performance, some pharmacies would receive a smaller bonus and some a larger bonus. Tables 5 and 6 reflect this low POS with bonus approach.

Table 5

Alternative Model Without Gap Application Bonus Approach			
	(\$Billions)	PMPY	% Change
Beneficiary Cost	N/A	(\$52.40)	-4.6%
Cost Sharing	N/A	(\$37.01)	-4.8%
Premium	N/A	(\$15.39)	-4.2%
Government Cost	N/A	\$56.77	3.5%
Direct Payment	N/A	\$101.00	59.7%
Reinsurance Cost	N/A	(\$28.56)	-3.2%
LI Cost Sharing	N/A	(\$10.90)	-2.4%
LI Premium	N/A	(\$4.77)	-4.2%
Manufacturer	N/A	(\$1.53)	-0.4%
Pharmacy Net Reimbursement	N/A	\$3.00	0.1%
Plan Cost	N/A	\$81.00	21.1%

Table 5 is comparable to Tables 1 and 3.

Table 6

Alternative Model With Gap Application			
	(\$Billions)	PMPY	% Change
Beneficiary Cost	N/A	(\$44.21)	-3.9%
Cost Sharing	N/A	(\$46.20)	-5.9%
Premium	N/A	\$1.98	0.5%
Government Cost	N/A	\$92.62	5.7%
Direct Payment	N/A	\$167.27	98.9%
Reinsurance Cost	N/A	(\$38.26)	-4.2%
LI Cost Sharing	N/A	(\$37.00)	-8.2%
LI Premium	N/A	\$0.62	0.5%
Manufacturer	N/A	(\$35.01)	-9.9%
Pharmacy Net Reimbursement	N/A	\$3.73	0.1%
Plan Cost	N/A	\$160.19	41.8%

Table 6 is comparable to Table 2 and 4.

Comments made about Tables 1, 2, 3, and 4 above hold for Tables 5 and 6 regarding lower costs for the average beneficiary and higher costs for the government. Overall, the CMS model and the alternative models are directionally in alignment, except for the impact on manufacturers in Table 3, and generate similar impact magnitudes. With these comparisons, we feel comfortable with our supplemental observations based on the alternative model.

Discussion of Alternative Model

Part D Plans

The first comment is not drawn from the models, but rather the timing of the proposed rule, which proposes an effective date starting in plan year 2023. Bids for the 2023 plan year are due June 6, 2022. Assuming the rule is finalized in early to mid-April, there is little time for plans to adjust their bids, re-negotiate networks, make program changes to systems, revise pharmacy performance measures and modify plan finder submissions. This would imply that only simple, easy to implement changes would be made by plans. The timing also means that CMS would have to modify the bid pricing tool and the plan benefit package as well as issue guidance on all aspects of the rule.

As acknowledged by CMS, the premium is an important factor – perhaps the most important factor – in the purchase decisions of members. Therefore, plans strive for low premiums. The impact on plan cost in Tables 3, 4, 5, and 6 gives insight on the best strategy for plans.

- Table 3: 12.8% increase in plan costs
- Table 4: 24.6% increase in plan costs

- Table 5: 21.1% increase in plan costs
- Table 6: 41.8% increase in plan costs

Plan cost changes translate directly to bid impacts for the plan and ultimately to premiums paid by the member. The increases shown above indicate that a mean-based pharmacy reimbursement strategy always is better than a bonus based variable reimbursement and that a “without gap application” also is better for plans.

There are important takeaways from these observations. Plans will likely eliminate performance-based payments. Plans are also likely to adopt the more complex “without gap application” approach. Because of the expense and complexity of implementing the “without gap application” program, smaller, less sophisticated plans will become even less competitive with large plans.

Pharmacies

We have also modeled the impact on pharmacies. When solely matching the CMS assumption that pharmacies will be compensated for reduced cashflow, Tables 3, 4, 5, and 6 show a trivial 0.1% increase in average pharmacy reimbursement. However, we feel an adjustment of this extent and in this direction is unlikely. Plans will likely seek to claw back the loss of network DIR by utilizing some combination of reduced pharmacy reimbursement, increased manufacturer rebates, narrower formularies, and narrower networks. Plans, often through their PBMs, have a long history of reducing pharmacy reimbursement. For modeling purposes, we have assumed a 2% reduction in network reimbursement as an illustrative example. We believe this is a conservative estimate of actions that could be taken by plans

We also note the potential for perverse pharmacy impacts, as seen in Table 7. If we assume no change in plan behavior as does CMS, a high performing pharmacy with a net charge back of 2.5% of reimbursement would see its reimbursement lowered by 3.4%. Correspondingly, a low performing pharmacy with a net chargeback of 10% would be reimbursed 4.7% more. An average performing pharmacy (which sees a 5.8% charge back) would see no change in reimbursement. Each pharmacy would fall somewhere on this continuum. This range of chargebacks is based on Mr. Lund’s Medicare Part D experience beginning with the passage of the Medicare Modernization Act in 2003, through today.

However, if the plan lowers net reimbursement by 2% (we believe some significant reduction in reimbursement is likely), the high performing pharmacy’s reimbursement would fall by 5.3%, the low performing pharmacy’s reimbursement would have a smaller improvement of 2.6%, and the average pharmacy’s reimbursement would fall by 2%.

Under either assumption, high performing pharmacies would bear the unintended consequences of the Proposed Rule.

It is important to note that the impacts faced would vary by different types of pharmacies. For example, smaller independent pharmacies would face greater strain

from cash flow without the negotiating power to mitigate the situation. This would be exacerbated for smaller pharmacies that dispense a large volume of specialty, high-cost drugs.

Table 7 – Illustrative Examples of Alternative Findings

(Assuming reimbursement of \$100)	Current	Change in Reimbursement Under Proposed Rule	
		No Change in Plan Behavior	Plan Reduces Reimbursement by 2%
Low Performing (10%)	\$90.00	+ \$4.20 (+ 4.7%)	+ \$2.32 (+2.6%)
Mean (5.8%)	\$94.20	No Change	-\$1.88 (-2%)
High Performing (2.5%)	\$97.50	- \$3.30 (- 3.4%)	-\$5.18 (-5.3%)

Summary

- The CMS model and the alternative model appear to be compatible
- The proposed definition of negotiated price biases plans away from pharmacy incentive programs
- The complexity and cost burden of implementing the “without application in the gap” proposal likely widens the gap between large plans and small plans rather than improving the competitiveness of small plans
- The rule does not improve pharmacy reimbursement in aggregate
- Plans will claw back the loss of network DIR
- It is likely that plans, and their PBM vendors, will claw back some of the loss through lower network reimbursement
- Other means of claw back impacting pharmacies include narrowing of networks and implementing more restrictive terms and conditions
- The rule would have the effect of lowering reimbursement to higher performing pharmacies while increasing reimbursement to lower performing pharmacies
- The rule would also lower reimbursement to average performing pharmacies if plans move to lower reimbursement levels

Alternative Model

The alternative model looks at the Medicare Part D benefit on a phase-by-phase basis split by Low Income Subsidy (LIS) and non-LIS benefit structures. For each phase we calculated as a PMPM (per member per month):

1. Pharmacy reimbursement at point of service
2. Manufacturer rebate
3. Network DIR
4. Member coinsurance
5. CMS Low Income Cost Sharing (LICS) payment
6. Manufacturer coverage gap discount payment
7. Gross CMS catastrophic reinsurance
8. Gross plan liability
9. Net plan liability (gross plan liability minus plan share of manufacturer rebates and network DIR)
10. CMS net reinsurance liability (Gross minus CMS share of manufacturer rebates and network DIR)

A Defined Standard benefit for plan year 2020 was used to determine the appropriate values.

These values for each phase were then weighted by the percentage of drug spend for each phase. To determine this, we utilized a 20% sample of the 2020 PDEs, parsed by all claims fully within each phase and straddle claims by straddle. (That is, deductible to initial coverage phase, deductible to coverage gap discount phase, etc.) Single straddles were allocated on a 50%/50% basis. More complex straddles were adjusted by the using of the full length of intervening phases and partial in the beginning and ending phase. Part D Employer Group Waiver Plans (EGWPs) and Program of All-inclusive Care for the Elderly (PACE) plan spending were eliminated from the 20% sample.

For each scenario, the phase weights are modified. In theory, as total spending is reduced, spending in each phase will be reduced, but will cascade spending to a prior tier. Thus, the largest benefit would accrue to the catastrophic phase and a lesser benefit to each prior phase. Re-weightings were determined by using the reduction in pharmacy reimbursement from the model and applying that reduction percentage to the total spend from the 20% sample. Lower reductions were applied to the coverage gap discount phase and an even lower reduction to the coverage phase. No reduction was made to the deductible phase. Drug spend in the catastrophic phase was the balancing item between the sum of the first three phases and scenario adjusted total spend.

NABA was determined as net plan liability plus \$10.50 PMPM plus 5.5% of NABA to cover expenses and margin. Catastrophic reinsurance was set equal to CMS net reinsurance liability (CAT). Member premium (MP) was set as defined by CMS. That is $MP = .255 \times (NABA + CAT)$. The CMS subsidy is then set as $NABA - MP$.

All PMPM values were converted to a PMPY (per member per year) to compare to the values presented in the Federal Register.

Assumptions

Several assumptions were made in the model:

- Average monthly drug spend per member was set at \$390.00. This was derived from the Medicare Part D 2020 drug spend dashboard. It equals total drug spend divided by the July 2020 Part D enrollment divided by 11, rounded to the nearest \$10.00.
- Plan expenses were set at \$10.50 PMPM plus 5.5% of premium. This was based on my experience with Part D bids for CVS Health as well as working with Caremark client plans. I believe it to be a reasonable estimate.
- Network DIR was estimated as 5.8% of drug spend. This was derived from Table 3 on page 1910, of the Federal Register listing \$9.5 billion of pharmacy price concessions for 2020 divided by total Part D drug spend (about \$164.4 billion) for 2020 excluding EGWPs and PACE plans,
- Manufacturer rebates were estimated as 32.9% of drug spend. This was used as a balancing item in the model, but is also based a general estimate that rebates are in the low 30's for Part D.
- For some scenarios, we assumed that lowest reimbursement rate, net of all possible concessions, would be 90% of negotiated reimbursement. Pharmacies would receive a bonus based on performance that would, on average, pay 4.2%.

Reconciliations

Several reconciliations are contained in the model to insure internal consistency and cross footing. There are two key reconciliations that are of particular importance. First the 20% sample, when multiplied by 5 ties within 0.02% of the CMS 2020 Part D drug spending dashboard. Second, the NAB and reinsurance calculations were reconciled against the 2020 restated benchmarks. I do not expect to tie because the model is based on actual 2020 experience while the restated benchmarks are based on 2020 bids. They should, however, be reasonably close. Restated benchmarks are used because the restatement reflects actual 2020 membership by plan rather than the 2019 membership that is used in published benchmarks. The restated NABA for 2020 is \$44.64 and the reinsurance is \$76.11. The corresponding figures from the model are \$44.70 and \$75.30.

Certification

Based on my education and experience, I believe the alternative model presents both a reasonable approach and reasonable results for evaluating the impact of the Proposed Rule on members, plans, manufacturers, pharmacies, and the government.

H. Neil Lund, FSA, MAAA, FCA