Submitted electronically to IRARebateandNegotiation@cms.hhs.gov

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Re: Medicare Drug Price Negotiation Program Guidance

Deputy Administrator Seshamani,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide feedback on CMS' *Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments*.

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 (LTC) settings. Together, our members represent a $78.5 billion healthcare marketplace, employ 240,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.

NCPA supports the intention of the Inflation Reduction Act to lower patient's out-of-pocket costs. To further that end, NCPA supports having PBMs pass through rebates and discounts that they receive directly to patients, and has long supported state and federal legislation to require PBMs to implement a pass-through pricing model. Under the Medicare Drug Price Negotiation initial guidance, the basis for calculating patient cost sharing will be maximum fair price (MFP), not list price, which would be good for patients' out-of-pocket costs.

Community pharmacies are eager to serve an active role in implementing the Inflation Reduction Act. But for this initial guidance to work, and to preserve patient access to beneficiaries' pharmacy of choice to drugs under this guidance, pharmacies must be made whole to remain economically viable and maintain patient access to MFP drugs.

Independent pharmacies are integral to Part D plan network accessibility. The average independent pharmacy derives 36% of script volume from Part D, and LTC pharmacies derive 60 – 70% of script volume from Part D. Hundreds of pharmacies are closing each year, and the majority of these are independents, leading to pharmacy deserts. There are many causes for this, including vertical integration, PBMs steering to their affiliate pharmacies, below-cost reimbursement from PBMs, and restricted/preferred networks that block independent pharmacies.

At the same time, independent pharmacies are in pain and at an inflection point with increased stress from pharmacy DIR fees. Medicare Part D pharmacy DIR fees now account for approximately 5-6 percent of gross prescription revenue from *all* payers, representing the third highest expense after COGS (78%) and payroll (13.1%). According to MedPAC's March 2023 Report to Congress, pharmacy DIR fees were $12.6 billion for 2021 (a $3.1 billion (+33%) increase from $9.5 billion in 2020).[1]

Harmful DIR trends are only getting worse. For Medicare Part D CY24 contract offerings, our members are seeing approximate reimbursements at AWP-26% + $0 dispensing fee (30ds) and AWP-31% + $0 dispensing fee (90ds) for brands. These reimbursement rates represent pricing significantly below community pharmacies' cost to purchase brand drugs. Rates such as this coupled with year-over-year double-digit increases in DIR fees will make the first 3-6 months of 2024 unbearable for independent pharmacies, as they continue to pay DIR fees from CY23. Pharmacies will have to draw from more lines of credit/building reserves, and cash flow is a dire concern.

After reviewing the guidance, NCPA is unclear how pharmacies will ultimately be reimbursed for MFP-eligible drugs. For example, NCPA is unclear how pharmacies would be protected from losing money under the Medicare Drug Price Negotiation program. NCPA is concerned that pharmacies could experience negative cashflow when the actual acquisition cost of the medication to the pharmacy is more than reimbursement based on MFP. As MFP is the Part D negotiated price ceiling, the MFP could (and likely will) go lower at pharmacies' expense.

NCPA is concerned that this is essentially a pass-through model for pharmacy payment, without professional dispensing fee protections. We notice that pharmacies will be paid MFP plus "any" dispensing fee, making dispensing fees to pharmacies optional. It is crucial that CMS require dispensing fees that adequately cover the actual costs of dispensing the prescriptions. We believe that it is essential that pharmacy be engaged and compensated to cover costs of acquiring and dispensing drugs to make this program successful. Lastly, since there is no formal rulemaking, CMS will not conduct a small business impact analysis. How does CMS know the true impact of this guidance on small business community pharmacy?

[1] See MedPAC March 2023 Report to the Congress: Medicare Payment Policy, page 399.

Below are our initial comments, subject to change as CMS develops its policy. When CMS has a more definitive policy on the Medicare Drug Price Negotiation program, the National Council for Prescription Drug Programs (NCPDP), could be a forum to discuss how NCPDP's standards can be used to effectuate these policies.

It will be important to identify new business processes that would be the most viable for the industry to operationalize to ensure that pharmacies have access to the MFP by 2026, and are made financially whole.

The Inflation Reduction Act created an exception to the non-interference in Part D clause in Section 1860D–11(i) of the Social Security Act (42 U.S.C. 1395w–111(i)), so that the Secretary of HHS "may not institute a price structure for the reimbursement of covered part D drugs, except as provided under part E of title XI" [the Medicare Drug Price Negotiation Program provisions].[2] **NCPA requests that CMS use this exception to establish a price structure for the Medicare Drug Price Negotiation Program, specifically a financially viable model of pharmacy reimbursement including but not limited to an MFP that accounts for margin on the ingredient cost of the drug, plus a required and economically viable professional dispensing fee, and to ensure that supply chain entities cannot impose terms on pharmacy including but not limited to pharmacy DIR fees on MFP drugs**.

NCPA supports the following guiding principles to protect beneficiary access to independent pharmacy in the Medicare Drug Price Negotiation program:

- Pharmacy should not be responsible for the costs and related risks of operationalizing any MFP effectuation options
- Any entities responsible for payment effectuation should have a fiduciary responsibility to pharmacies
- CMS should consistently apply any MFP with CMS oversight, guardrails and governance
- All manufacturers must follow the same MFP structure of payment
- This guidance and its implementation should cause no disruption to pharmacy
- Plans, PBMs, manufacturers and wholesalers should not be able to disadvantage pharmacy
    - CMS should implement this guidance into seamless point of sale transactions
    - Pharmacies should not report acquisition cost nor reimbursement
    - Supply chain entities cannot impose additional MFP terms in pharmacy contracts
    - Plans/PBMs cannot steer or limit coverage of MFP drugs to affiliate pharmacies
    - Pharmacies should have reimbursement protections against egregious contracting practices such as BER (brand effective rate) clawbacks

[2] See Section 1198(b)(1)(C), at https://www.congress.gov/117/plaws/publ169/PLAW-117publ169.pdf, page 36.

- Pharmacies should not be loaning or floating money
- Pharmacy should not pay any fees to effectuate MFP
- Pharmacies should not be reporting using spreadsheets; any reporting should use NCPDP standards with automation in mind to maximize efficiencies
- Pharmacies should not fall victim to underwater payment on claims for MFP drugs/protections if MFP goes lower
- Pharmacies should be reimbursed commensurate professional dispensing fees
- Clear dispute resolution process for pharmacies regarding any grievances with supply chain entities
- Reimbursement for MFP drugs should not be subject to DIR fees/retrospective clawbacks

40.4 Providing Access to the MFP

According to the initial guidance, CMS intends to require that Primary Manufacturers provide access to the MFP in one of two ways: (1) ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP; or (2) providing retrospective reimbursement for the difference between the dispensing entity's acquisition cost and the MFP.

Feedback on option #1 (ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP)

NCPA has some reservations about this option, especially the likely need for pharmacies to have separate virtual inventory, like what exists under the 340B program. NCPA would appreciate CMS guidance on how it envisions the role of a virtual inventory as part of this option. NCPA is also aware that some partners in the supply chain would not favor option #1.

What our members do appreciate about this option is that it allows pharmacies to conserve cashflow and not be subjected to paying the wholesaler's regular price for the drug being dispensed for an MFP-eligible claim. Our members appreciate this option in that pharmacies would not be subject to loaning or floating money (i.e., through pharmacy paying a surplus payment that is later credited back to the pharmacy from the wholesaler, as highlighted in the Initial Guidance's "chargeback" example). Many of our members pay staff daily and weekly and have carrying costs. Furthermore, due to inflation and the time value of money, such chargebacks work against pharmacies.

If CMS moved forward with option #1, NCPA advises that CMS should ensure that plans pay a reasonable reimbursement rate that factors in the MFP, the actual costs of dispensing the drug, to avoid merely creating a product cost pass-through program that does not actually cover the pharmacy's operating costs. What is labeled a "dispensing fee" in the vast majority of Part D contracts is not adequate to cover the actual costs of dispensing a prescription. Claims paid under any option should be excluded from pharmacy direct and indirect remuneration (DIR) fees or retrospective clawbacks.

Concerns with option #2 (providing retrospective reimbursement for the difference between the dispensing entity's acquisition cost and the MFP)

NCPA has the following concerns with a wholesaler chargeback program to provide retrospective reimbursement.

Concerns with growing managerial control of pharmacy by wholesalers. With the implementation of DSCSA and controlled substance laws, among other factors, independent pharmacists are seeing wholesalers' managerial control of pharmacies grow. Furthermore, generic and brand compliance rates requiring a certain percentage of drugs be purchased from a given wholesaler make it so that pharmacies contract with wholesalers in a bundled, non-transparent fashion. If option #2 is done through a reconciliation process with the wholesalers, wholesalers will have even more managerial control over the revenue of pharmacies, and pharmacies would need to have added protections.

Concerns with wholesaler chargeback model. If CMS were to implement a wholesaler chargeback model, CMS should structure it so that pharmacy is assured it will be made financially whole. NCPA is concerned with the potential lack of transparency of a wholesaler chargeback model, with potential varying, convoluted, and non-transparent wholesaler fees, administrative costs, rebates and metrics. Furthermore, wholesalers are not HIPAA-covered entities and in the absence of a business associate agreement, do not have access to pharmacies' patient-specific claim-level transaction data. Entering into business associate agreements to disclose HIPAA protected health information is a risk as well as administrative burden for pharmacies, and they are justifiably wary of sharing claim data with wholesalers. Additionally, one pharmacy may have multiple wholesalers, which would greatly complicate the viability of a wholesaler chargeback model.

CMS provides the following example of how a chargeback would work:

> For example, a pharmacy may purchase a medication for $100 per bottle and the MFP as applied to this selected package is $80. The Medicare beneficiary is enrolled in a Part D plan under which coverage of the selected drug is available, thus the beneficiary is an MFP-eligible individual. For this example, the plan has not negotiated a lower price for the medication. The pharmacy provides the negotiated price (i.e., MFP plus a dispensing fee) at the point of sale to the Medicare beneficiary. As a result of this transaction, the pharmacy is owed $20 by the manufacturer. **The pharmacy would submit the information regarding the $20 chargeback amount to its wholesaler and receive a credit from the wholesaler for that amount.** The wholesaler would be compensated by the manufacturer after billing the manufacturer for the chargeback amount. **[NCPA emphasis]**

Protections needed under wholesaler chargeback model. If CMS decides to go forward with such a model, NCPA strongly advocates for protections for pharmacy from wholesalers. NCPA would suggest the following:

- Wholesalers should bear the financial risk of creating, maintaining and operating any wholesaler clearinghouse and/or chargeback model;
- Pharmacies should be able to freely lodge complaints to CMS about wholesalers and others;
- Pharmacies should be paid with interest for the time between dispensing the MFP prescription and the time they are made whole, given the time value of money and inflation;
- CMS should integrate any chargebacks with the claims process, so as not to unduly burden pharmacies; and
- The chargeback should be automatically initiated following the pharmacy submission of a claim.
    - The pharmacy should not be burdened with initiating the chargeback process, as is given in CMS' example above (see bold text).
    - It is not feasible for pharmacies to evaluate RxBIN and RxPCN numbers to manage the process; pharmacies should not be expected to identify which BIN-PCN combinations tie to a Part D Plan and indicate in the claim they do or do not claim MFP reimbursement for the claim, as the list of combinations is large.[3]

In sum, NCPA does not support a wholesaler chargeback model to effectuate the MFP.

NCPA's Alternative Recommendations to Effectuate MFP

Proposal #1 - Central clearinghouse

The Medicare Drug Price Negotiation program could be processed by a central clearinghouse managed and governed by CMS, similar to Palmetto in the Medicare Part D coverage gap discount program. This would entail CMS providing PDE data to the facilitator, who then calculates the amount owed to the respective pharmacy, and then invoices the manufacturer, while pharmacies are paid at the same time the claim is adjudicated. The manufacturer could prefund payments for pharmacies. Pharmacy would be reimbursed based on the actual cost of dispensing the drug. This reimbursement would be based on publicly available benchmarks, where the clearinghouse would only need the NDC number, quantity dispensed, and claim identifier for each drug. No Protected Health Information under HIPAA, nor reimbursement fields, would be or need be shared. A fair and commensurate professional dispensing fee is needed, because Part D dispensing fees are oftentimes zero to pennies, offered in take it or leave it contract terms. Using a reference price established by the manufacturer such as WAC protects the confidential nature of an individual pharmacy's actual acquisition cost and is simpler to administer than trying to account for an individual pharmacy's prescription medication purchasing arrangements.

Such a clearinghouse should be a disinterested party, and should not be either a PBM or a wholesaler or related party. With a clearinghouse, a payment processor would be responsible for

[3] See https://www.cms.gov/files/zip/binpcn2023.zip.

processing and facilitating payment from the manufacturer to pharmacies. Payments should be transparent to the pharmacy and itemized at the claim-level on the 835 remittance advice. Pharmacies should not charged any administrative or transaction fees.

Proposal #2 – Secondary claims adjudicator/MFP refund facilitator

The NCPDP Telecommunication standard is currently leveraged to offer an electronic voucher program for manufacturer copay discounts in the commercial plan marketplace. If pharmacies transmit a claim for a brand medication that is eligible for an electronic voucher, the switch knows it is a Medicare Part D claim (based on the Part D processor identification number (RxBIN) and Part D processor control number (RxPCN), and the pharmacy receives a message that is it is ineligible for an electronic voucher. The electronic voucher is currently unavailable in Medicare Part D.

The existing system could, through modified computer language and programming, similarly act to identify drugs in the Medicare Drug Price Negotiation program. A claims switch or processing facilitator could continue to reject Medicare Part D drugs, but not the drugs in the Medicare Drug Price Negotiation program. Claims could be adjudicated at point of sale, without needing full disclosure to PBMs and wholesalers.

A secondary claims adjudicator/MFP refund facilitator will not hurt cash flow for pharmacies. If set up correctly, no additional work is needed by the wholesalers, this process is very easy for pharmacies, and pharmacies are not required to submit additional data. However, this proposed electronic voucher program would need cooperation from the switch(s) and manufacturers.

Proposal #3 – CMS collects MFP directly from manufacturer

As an alternative option to the electronic voucher proposal above, CMS could collect directly from the Primary Manufacturer the difference between the MFP and the price CMS would pay but for the existence of the MFP (i.e., price without MFP or MFP rebate). This would be the simplest, cleanest, and most cost-effective mechanism for manufacturers to provide access to the MFP for the selected drug to pharmacies with respect to MFP individuals who are dispensed the drugs, as it would impose the minimal possible burden on wholesalers, Part D plans, pharmacies and, most importantly, patients. However, NCPA has concerns that pharmacy reimbursement would essentially be a product cost pass-through model in this proposal.

Proposal #4 – Separate NDC numbers

Manufacturers could create secondary NDCs for the drugs in the Medicare Drug Price Negotiation program, and make those NDCs available to wholesalers and system vendors at the MFP. Pre- and post- editing would catch them on matching, and using RxBIN and RxPCN numbers, these drugs could be paid on MFP plus a dispensing fee. We understand the concerns from manufacturers with setting up separate Medicare and non-Medicare NDCs, which is historically burdensome. We also understand the concerns manufacturers have with making this a prospective payment system that can result in misidentifying product resulting in mis-applied discounts.

NCPA Additional Comments, Concerns, and Recommendations

Pharmacy cannot be collateral damage to patients having access to MFP. NCPA has concerns about the economic viability of this guidance for pharmacies. Reimbursement for brand drugs is often solely based off AWP while purchasing of brand drugs is often based on the WAC published price. NCPA is concerned that pharmacy reimbursement for MFP eligible drugs may be inadequate for pharmacies, especially if there are not mandatory dispensing fees to factor in the actual cost of dispensing. Additionally, the MFP is the maximum negotiated price for these drugs in the Medicare Drug Price Negotiation Program, and CMS stated in the guidance that manufacturers can offer a price lower than the MFP for these drugs.

NCPA is concerned that the MFP is not financially sustainable for pharmacies. For example, NCPA does not see protections in this guidance preventing the PBM from reimbursing below MFP, nor preventing wholesalers from selling to pharmacy above MFP, nor preventing manufacturers for negotiating discounts off MFP which can lead to the MFP going lower than the negotiated price at the pharmacies' expense, all of which will affect pharmacy reimbursement and the ability of pharmacies to be made whole.

NCPA also has concerns that PBMs and commercial plans could adopt the MFP, which will be public, for those drugs, causing similar financial concerns for pharmacy stated above in non-Medicare Part D plans. Nevada has introduced AB 250 which would broaden the applicability of MFP to apply to purchasers within the state, and similar states may follow.

Dispensing fees must be required and economically viable. **NCPA is concerned that under this guidance, pharmacies will not be compensated with a fair and commensurate professional dispensing fee.** According to CMS' Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs final rule,[4] effective January 1, 2024, the negotiated price includes any dispensing fees.[5] CMS also stated in the initial guidance that "Under section 1860D-2(d)(1)(D) of the Act, as amended by section 11001(b) of the IRA, the negotiated prices used in payment by each Part D plan sponsor for each selected Part D drug must not exceed the applicable MFP plus any dispensing fees for such drug."

Dispensing fees may be included in current Part D contracts, but are not adequate to cover the cost of dispensing. Furthermore, Medicare Part D contracts are take-it-or-leave it to the

[4] 2022-09375.pdf (govinfo.gov), at 27899.

[5] 423.100 Definitions. Negotiated price means the price for a covered Part D drug that— (1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the lowest possible reimbursement such network entity will receive, in total, for a particular drug; (2) Meets all of the following: (i) Includes all price concessions (as defined in this section) from network pharmacies or other network providers; (ii) Includes any dispensing fees; and (iii) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices; and (3) Is reduced by non-pharmacy price concessions and other direct or indirect remuneration that the Part D sponsor passes through to Part D enrollees at the point of sale.

pharmacy, leaving the pharmacy little choice but to accept unfair dispensing fees, however there may be opportunity for margin on the ingredient cost of the drug being dispensed to partially offset the virtually non-existent dispensing fees in Part D. However, not having a fair dispensing fee when there is no markup on the ingredient cost for MFP eligible drugs could result in pharmacies not stocking the drugs and therefore reducing access, as is the case with pharmacies reluctant to stock Paxlovid (pharmacies are not allowed to charge for the drug and thus rely solely on dispensing fees that more often than not do not cover the cost of dispensing the drug). Dispensing fees should be adequate as in fee-for-service Medicaid programs to cover the pharmacy's business operation costs, especially when dispensing MFP eligible drugs may lead to a complete pass-through reimbursement model for pharmacy on the ingredient cost portion of pharmacy reimbursement.

LTC pharmacy concerns. NCPA has additional concerns that LTC pharmacies will be disproportionately affected by this guidance, given LTC pharmacy's higher dispensing costs compared to the retail setting, based on following CMS' ten criteria for LTC pharmacy.

Acquisition cost. In its guidance, CMS states that it intends to require that Primary Manufacturers provide access to the MFP in one of two ways: (1) ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP; or (2) providing retrospective reimbursement for the difference between the dispensing entity's acquisition cost and the MFP. **NCPA opposes using pharmacy acquisition cost as proposed in the guidance**. The acquisition cost proposal is a pass-through model which does not leave room to cover operating costs for the pharmacy, as pharmacies would be trued up to cost and most part D plans currently do not pay a dispensing fee, much less one based on the actual cost of dispensing the drug. Plus, pharmacy purchasing arrangements with their wholesaler vary. Trying to track down acquisition costs to the penny for nearly 20,000 independent pharmacies would be logistically difficult and burdensome. Using acquisition cost would cause disruption to the supply chain, and create misaligned incentives. For example, pharmacies disclosing acquisition costs would undermine contracting and could result in lower pharmacy reimbursement. Also, as discussed above, NCPA members are not supportive of a wholesaler chargeback model that would presumably be based on actual pharmacy acquisition cost. **Instead, we support CMS using a more widely reported reference price - WAC.**

Reasonable rate of reimbursement. In the Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs final rule, CMS noted that many commenters requested that CMS establish safeguards to guarantee that pharmacies participating in Medicare Part D receive a "reasonable rate of reimbursement."[6] CMS noted that these commenters urged the administration to ensure that the negotiated price at a minimum cover the pharmacy's costs of purchasing and dispensing covered items and providing covered services, and that some commenters requested that CMS establish a flat dispensing fee or an

[6] See 2022-09375.pdf (govinfo.gov) at 27845.

alternative such as pharmacy reimbursement based on a public drug pricing benchmark such as national average drug acquisition costs (NADAC) plus a fair dispensing fee in line with those in state Medicaid fee-for-service programs. In response, CMS stated that it would consider these suggestions for future rulemaking. **NCPA urges CMS to take this into consideration as the agency moves forward with implementation of the Medicare Drug Price Negotiation program.**

Reasonable and relevant terms and conditions. Furthermore, Part D plans are required to provide "reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy."[7] **NCPA likewise urges CMS to take this into consideration as the agency moves forward with implementation of the Medicare Drug Price Negotiation program.**

Timely Reimbursement

NCPA appreciates CMS stating in the guidance that it intends to require that a Primary Manufacturer ensure that pharmacies and others are reimbursed timely for the full amount of the difference between their acquisition cost for the selected drug and the MFP within 14 days. **NCPA asks CMS clarification as to what the 14-day timeframe measures specifically. Does the 14-day clock start when the pharmacy adjudicates the qualifying prescription drug claim to the Part D plan?** This recommendation to begin at the point of adjudication is consistent with Part D prompt pay requirements and the language of the IRA that requires pharmacies to be reimbursed within a certain timeframe after the dispensing of a drug, which typically is contemporaneous with the adjudication of the drug claim.

Community pharmacies operate with very tight cashflows and cannot afford to float and loan money to supply chain entities. NCPA asks CMS to elaborate on the 14-day timeframe to ensure prompt payment to pharmacies, consistent with current Part D policy.

No Transaction Fee

CMS also states that manufacturers or their contracted entities shall not charge any transaction fee for this process, of which NCPA is appreciative. NCPA advises CMS to be wary of supply chain entities to circumvent the provision against transaction fees by charging "general claims processing" or "switch" fees. **NCPA advises that CMS elaborate on what constitutes a transaction fee for purposes of effectuating the MFP and have a clear mechanism for enforcement.**

40.4.1 Nonduplication with 340B Ceiling Price

NCPA believes it is imperative to avoid duplication of discounts between the 340B program and the Medicare Drug Price Negotiation program. Many of our members act as Contract Pharmacies for Covered Entities (CEs) but pharmacies are not the source of truth for determining the drug dispensed was eligible for 340B pricing. The way the 340B program is currently administered is too complicated to rely on an indicator for prescription claims and will result in inaccurate information. The current NCPDP Telecommunications Standard Version D.0 for pharmacy claims

[7] eCFR :: 42 CFR 423.505 -- Contract provisions.

does not require a pharmacy to identify which prescription claims were dispensed using drugs purchased at a discount under the 340B program. Although the standard does include a field where a 340B indicator could be provided, it is optional for pharmacies to use, based on trading partner agreements. To proactively include a 340B identifier on a prescription claim, a pharmacy needs to know at the point of sale that the patient, their prescription and the parameters of their arrangement with the covered entity, qualify for the 340B program drug pricing. The indicator exists but there is a significant operational challenge to identifying when pharmacies should use it. Due to the multiple factors that go into determining that a drug dispensed is eligible for 340B pricing, it is not common for a pharmacy to know at the point of sale that a prescription could be dispensed with a 340B-priced drug.

CE Administrators are responsible for preventing our members from contributing to duplicate discounts. The CE should bear sole liability for any duplicate discounts, not the Contract Pharmacy. However, as NCPA has explained to CMS in past comments,[8] there is significant administrative burden posed to pharmacies identifying 340B units both proactively and retroactively. **Instead, NCPA advises CMS either have a third-party administrator identify 340B units for CMS, or have manufacturers report aggregate, approximate 340B units to CMS.**

90.2 Monitoring of Access to the MFP

CMS states that it is the Primary Manufacturer's responsibility to ensure access to the MFP, and mentions that there are various methods by which pharmacies can determine whether they are accessing the MFP for a selected drug.

For example, the MFPs for selected drugs will be published by CMS, giving pharmacies an opportunity to know the MFP for each selected drug, as well as the explanation for each MFP. The MFPs for selected drugs for initial price applicability year 2026 must be published by September 1, 2024. In addition, CMS anticipates that pharmaceutical database companies will publish the MFPs such that they would become more readily accessible to pharmaceutical purchasers. CMS believes such transparency of the MFPs for selected drugs will help pharmacies to know the MFP for a selected drug and determine whether they are able to access the MFP. CMS is seeking comments on additional ways that CMS could help dispensing entities and MFP-eligible individuals know the MFP for a selected drug and determine whether they are able to access it.

First, if MFP is added to compendia drug files, the pharmacy dispensing system could also display the MFP. **Secondly, NCPA believes that wholesalers can put MFP information on their invoices and wholesaler catalogues.**

Chargebacks. CMS states that there is widespread use of chargeback payments and rebate mechanisms among the pharmaceutical stakeholders in the private sector, which allows for entities to receive rebates or discounts on their purchases after those purchases are made, based on the specific population to whom the drug or biological is dispensed. CMS also states that the

[8] comments-cms-part-d-inflation-rebatesL.pdf (ncpa.org)

private sector may make modifications to these existing mechanisms to effectuate access to the MFP. As referenced above, NCPA does not support a wholesaler chargeback model to effectuate the MFP. However, **in any chargeback structure of reimbursement, NCPA requests that credit memos must be available, and include claim reference identifiers to reconcile discounts. Remittance advices in the industry standard format (NCPDP standard 835) must be provided.**

Reporting issues. CMS stated that it intends to establish a process by which pharmacies would be able to report instances to CMS in which the MFP should have been made available to them but was not. CMS is seeking comment on how such a process would operate most effectively. **Under any wholesaler chargeback model, NCPA suggests that CMS communicate directly with wholesalers for this information, as most wholesalers have PSAOs, purchase drugs, and will control chargebacks in "option 2." NCPA also requests that CMS provide guidance on what pharmacies should do if they believe that the chargebacks are inaccurate.**

NCPA also advises that CMS should provide guidance on a dispute/complaint process where pharmacies can initiate complaints for any model used to effectuate the MFP. CMS must have a streamlined, effective complaint process to ensure that disputes are resolved promptly to keep pharmacy's solvent. No matter what model CMS decides to incorporate, chargeback or otherwise, pharmacies must have a way to report issues promptly and efficiently.

Conclusion

In summary, this initial guidance is being issued at a time when pharmacies are on the brink of closure. Medicare Part D plans and PBMs rarely pay dispensing fees, and Part D contracts are worsening. We have additional concerns that LTC pharmacies will be disproportionately affected by this guidance. NCPA is concerned that inadequate reimbursement could result in pharmacies not stocking drugs under the Medicare Drug Price Negotiation Program, which would reduce access.

NCPA thanks CMS for the opportunity to provide feedback, and we stand ready to work with CMS to offer possible solutions and ideas. Should you have any questions or concerns, please feel free to contact me at ronna.hauser@ncpa.org or (703) 838-2691, and my colleague Steve Postal, Director of Policy and Regulatory Affairs, at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

Ronna B. Hauser, PharmD
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National Community Pharmacists Association