American Pharmacists Association

June 24, 2024

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard Baltimore, MD 21244

RE: Medicare Drug Price Negotiation Program Draft Guidance

Dear Dr. Seshamani:

The American Pharmacists Association (APhA) is pleased to submit the following comments on the "Medicare Drug Price Negotiation Program Draft Guidance," for implementation of the Negotiation Program for initial price applicability year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027.

Sections 40.4 Providing Access to the MFP in 2026 and 2027 and 90.2 Monitoring of Access to the MFP in 2026 and 2027

Section 40.4 of the guidance states "CMS requires that the Primary Manufacturer establish safeguards to ensure that entities dispensing drugs to MFP-eligible individuals—including pharmacies, mail order services, and other dispensing entities—have access to the MFP for the selected drug in accordance with section 1193(a) of the Act and as further described in this section and section 90.2 of this draft guidance. CMS defines "providing access to the MFP" as ensuring that the net amount paid by the dispensing entity for the selected drug is no greater than the MFP."

Section 90.2 further states "[c]onsistent with section 40.4 of this draft guidance, the Primary Manufacturer may make MFP available, including to 340B covered entities and their contract pharmacies consistent with section 40.4.2 of this draft guidance, by: (1) using retrospective reimbursement to issue refunds to dispensing entities as required to ensure the MFP is made available to dispensing entities, (2) providing access to the MFP through prospective sale of selected drugs at prices no greater than the MFP, or (3) using some combination of these two approaches."

CMS issued initial guidance in March 2023, solicited feedback through a request for information (RFI) on the Medicare Transaction Facilitator (MTF) and issued a June 2023 memorandum (updated guidance).

CMS clarified in section 40.4 of its revised guidance "that it intends to engage with an MTF to facilitate the exchange of data between pharmaceutical supply chain entities to help effectuate access to the MFP through a retrospective refund model. CMS is also exploring allowing the use of a standardized refund amount from the manufacturers to the pharmacies under a retrospective refund model and confirms it will require the use of a 14-day prompt pay standard for the refund from manufacturers to pharmacies and other dispensing entities to reimburse dispensing entities for passing through the MFP."

As such, there are currently two proposed payment facilitation options. The first has the MTF collecting dispensing entities' banking information and providing it to manufacturers. The second has the MTF receiving aggregated refund amounts from manufacturers and passing them through to dispensing entities, including pharmacies.

Implementing MFP without hurting pharmacies

Recently, expert analysis has confirmed that both models present challenges for pharmacies.

APhA agrees that "CMS should monitor pharmacy participation in Medicare by region and plan for safeguards should participation decline in response to how manufacturers provide access to MFP."

In addition, CMS should also increase/require enhanced dispensing fees from Part D plans to cover the increase in operating costs for pharmacies to manage inventory and generate the reporting necessary to manufacturers under both options. In particular, if pharmacies are also subject to manufacturer audits. If a manufacturer chooses to provide the pharmacy with access to the drug at MFP, then the pharmacy will only make gross from the dispensing fee – which is not standard and is negotiated across health plans. Accordingly, APhA respectfully recommends that CMS require a dispensing fee at a minimum of ($11.29/Rx).

Stakeholders have called for CMS to use a publicly available pricing benchmark, such as wholesale acquisition cost (WAC), or an estimate of the manufacturer's list price for a drug to wholesalers or direct purchasers that does not include discounts or rebates to facilitate MFP calculations. However, manufacturers in the future may engage in different WAC pricing

strategies or wholesalers may also change their discounting. Therefore, CMS would need to revise a "WAC – MFP" if pharmacies do not receive 4-5% off of WAC discounts.

As APhA has recently emphasized to CMS, current underwater payment rates by PBMs received through Pharmacy Services Administration Organizations (PSAOs), currently at a minimum 3% below cost on dispensing brand medications, have only led to increased pharmacy closures (January 2014 to March 2024 data) and are already jeopardizing Part D plans' ability to meet Part D pharmacy access requirements. Given the consolidation in the PBM marketplace and the potential for discrepancies in pharmacy MFP payments, "[i]f plans fail to provide sufficient fees, pharmacies might leave their network or close…," which "would destabilize the market and interrupt beneficiary access."

APhA also strongly urges CMS to avoid scenarios under a retrospective reconciliation option that mimics the current situation with direct and indirect remuneration fees (DIR) fees, which according to CMS increased by more than 107,400 percent from 2010-2020, that are facilitated by pharmacy benefit managers (PBMs) under Part D that would leave "pharmacies holding the risk for payment discrepancies and delays."

Addressing PBM DIR fees

The Inflation Reduction Act (IRA) is clear that pharmacies are not to be reimbursed below the MFP for negotiated drugs. However, APhA is concerned that pharmacies will be reimbursed below the MFP if DIR fees from PBMs are assessed on these drugs. Pharmacy reimbursement should cover acquisition cost plus margin plus and include a commensurate professional dispensing fee (currently, PBMs pay community pharmacies dispensing fees far below the actual cost to dispense - as low as $0).

Pharmacies are already facing significant cash flow concerns in Medicare Part D and failing to establish protections against DIR fees on MFP drugs or to ensure appropriate pharmacy dispensing fees and prompt payment to pharmacies (as required by the IRA) would exacerbate those concerns. **Accordingly, CMS needs to issue guidance that ensures Part D plans and PBMs cannot pay pharmacies at less than that MFP and that PBMs cannot assess pharmacy DIR fees on MFP drugs.**

Thank you for the opportunity to submit comments. The IRA grants CMS flexibility in the rulemaking processes in the first years to adjust the MFP. APhA stands ready to assist CMS in taking proactive steps to monitor pharmacy participation, appropriately adjust dispensing fees, and identify additional pharmacy safeguards to ensure an MFP that does not hurt community

pharmacies and seniors to lose access to Part D plans due to noncompliance with federal pharmacy access standards. If you have any questions or would like to speak further with APhA experts about these requests, please contact me at mbaxter@aphanet.org.

Sincerely,

Michael Baxter

Michael Baxter
Vice President, Government Affairs