APhA
American Pharmacists Association

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[Submitted electronically via Response Format at https://www.cms.gov/medicare-regulatory-relief-rfi]

Stephanie Carlton
Deputy Administrator and Chief of Staff
Centers for Medicare & Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Unleashing Prosperity Through Deregulation of the Medicare Program Request for Information

Dear Deputy Administrator Carlton,

The American Pharmacists Association (APhA) appreciates the opportunity to provide additional information to CMS in response to "Unleashing Prosperity Through Deregulation of the Medicare Program Request for Information." APhA reiterates some of its previous points made to CMS regarding its concerns with the Medicare Transaction Facilitator (MTF) system and incident to billing.

APhA is the only organization advancing the entire pharmacy profession. APhA represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

Medicare Transaction Facilitator

APhA has significant concerns regarding the financial and operational challenges pharmacies will face following the implementation of the Medicare Drug Price Negotiation Program and the MTF system. The current framework mandates that plan sponsors require pharmacies to be

enrolled in the MTF Data Module (DM), subjecting pharmacies to significant financial losses and forcing them to float the costs of the program's operation while waiting for reimbursements that may also be lower than their acquisition costs. These two aspects, along with the others raised in our previous comments, if not addressed, will contribute to more pharmacies closing across the country, making it more difficult for patients to access the medications within the confines of this program and the essential care and services that pharmacists provide to their communities.

Regarding codifying network pharmacy participation in the MTF DM, APhA has emphasized that mandatory participation without further intervention by CMS will lead to significant and unsustainable financial hardship for many pharmacies, leading to additional pharmacy closures, which will decrease seniors' access to health care as well as federal pharmacy access standards under § 423.120 for the entire Part D program. The uneven access issues CMS is trying to avoid by mandating pharmacy enrollment will be vastly overshadowed by the access issues caused by the closure of additional pharmacies following the implementation of this rule. As such, APhA strongly reiterates our previous comments, urging CMS to reconsider mandating pharmacy participation in the MTF DM.

Concerning payment, APhA urges CMS to issue rulemaking addressing the scope of these critical issues to the success of the Medicare Drug Price Negotiation Program and use any applicable authority to ensure that pharmacies are paid no less than the MFP plus a commensurate dispensing fee and that payment is prompt to ensure that already struggling pharmacies are not left carrying the financial burden of this program. APhA's previous comments strongly recommended that CMS require payments to pharmacies not to exceed the 14-day prompt pay requirement under Medicare Part D to minimize the time pharmacies are floating these reimbursement costs. APhA appreciates CMS's efforts to require prompt payment for these reimbursements, as timely payment will help alleviate some of the financial and operational burdens imposed on pharmacies by this rule. However, CMS's most recent draft guidance notes, "CMS will not float or issue funds to a dispensing entity on the Primary Manufacturer's behalf in anticipation of a future MFP payment."[1] CMS provides alternatives for "interested parties to provide timely payment, potentially focused on dispensing entities that self-identify as anticipating having material cash flow concerns at the start of the initial applicability year," but they are inadequate and result in additional administrative burdens on the pharmacy.[2] APhA will be submitting more in-depth comments pertaining to this draft

[1] Draft Guidance on the Medicare Drug Price Negotiation Program, CMS (May 12, 2025). Available at: https://www.cms.gov/files/document/ipay-2028-draft-guidance.pdf.
[2] *Id.* Available at: https://www.cms.gov/files/document/ipay-2028-draft-guidance.pdf.

guidance before the June 26, 2025, deadline to CMS. APhA's concerns remain regarding the impact this will have on pharmacies, as studies have shown that pharmacies are considering or are already not stocking drugs with prices negotiated under Medicare Part D because of the cash flow problems and delays in payment due to the IRA.[3] Other studies have estimated that, on average, pharmacies will bear the burden of prefunding the program at the cost of almost $11,000 per week, with the estimated revenue loss to be between $40,279.04 and $46,475.82 per pharmacy per year.[4] As for reimbursement, APhA urges CMS to utilize its full authority to ensure that pharmacies do not receive zero or underwater reimbursements that will result in pharmacy closures, further decreasing access to care nationwide.

Lastly, APhA points out that CMS has stated the agency cannot act to protect pharmacies from underwater reimbursements made by PBMs due to the noninterference clause in section 1860D-11(i) of the Social Security Act. However, CMS is "interfering" here by requiring that any contract between the sponsor or its PBM and a pharmacy include a provision requiring a pharmacy to be enrolled in the MTF DM. Accordingly, pharmacy participation in the MTF DM should be voluntary to avoid confusion and alignment with other policies, or CMS should use this same discretion to prohibit PBMs from paying pharmacies below their acquisition costs under the Medicare Part D program.

Incident To Billing

The current incident to billing framework undervalues the role of pharmacists within the health care team. Accordingly, APhA recommends CMS remove the restriction on physicians and other physicians and nonphysician practitioners (NPPs) utilizing pharmacists under incident to models to bill at the lowest E/M code (99211), with an estimated time commitment of 7 minutes that was imposed by the 2021 physician fee schedule (PFS) final rule (FR 84583) to reduce the administrative burden on physicians to maximize the of team-based care. CMS should permit physicians or nonphysician practitioners (NPPs) to bill for pharmacists' E/M services under incident to arrangements at higher levels of complexity or time than CPT 99211 (e.g., 99212-215) when the care provided supports the use of the higher code. Pharmacists are currently providing care and directly billing for services to complex patients in various state and commercial health plans at a level of complexity or time that aligns with E/M codes 99212-

[3] *Report for January 2025 Survey of Independent Pharmacy Owners/Managers*, National Community Pharmacists Association (Jan. 27, 2025). Available at: https://ncpa.org/sites/default/files/2025-01/1.27.2025-FinalExecSummary.NCPA_.MemberSurvey.pdf.

[4] *Unpacking the Financial Impacts of Medicare Drug Price Negotiation: Analysis of Pharmacy Cash Flows*, Three Axis Advisors (Jan. 2025). Available at: https://ncpa.org/sites/default/files/2025-01/January2025-ThreeAxisAdvisors-Unpacking-the-Financial-Impacts-of-Medicare-Drug-Price-Negotiation.pdf.

99215. Pharmacists' medication management services are more time-intensive and complex than described under E/M CPT code 99211. Despite strong evidence to support positive outcomes from pharmacists' care, this restriction is preventing their incorporation into team-based care models due to a lack of financial viability and billing coders' concerns that pharmacists' services include medical decision-making, which is not currently included in CPT code 99211.

The following brief case description highlights a common type of visit pharmacists are providing incident to physician services. Pharmacists often spend 15-60 minutes in visits with patients, depending on the patient's level of complexity and whether the patient's visit is an initial encounter with the pharmacist or a follow-up visit. Eliminating the 7-minute restriction limiting team-based care models to code 99211 would reduce administrative tasks for physicians and free up other health care team members to provide more patient care services.

Case example from an APhA member pharmacist in a state where pharmacist services are recognized for direct payment: Patient is a 77-year-old male with type 2 diabetes, heart disease, hypertension, and hyperlipidemia referred by a physician to the pharmacist for a follow-up visit. Patient is experiencing increased fatigue, nocturia, and weight loss. Patient is currently taking 6 medications. Pharmacist reviewed symptoms, evaluated the patient's medication regimen, and discontinued two medications and initiated two new medications in collaboration with the physician. The pharmacist provided education on diet and exercise and counseling on the new medications. The patient does not currently conduct self-blood glucose monitoring (SBGM), and the pharmacist also worked with the patient to initiate SBGM with a plan to consider continuous blood glucose monitoring (CGM) to monitor progress in the future. A one-month follow-up visit was scheduled. The pharmacist's visit details were reviewed and approved by the supervising provider. **Total patient visit time: 42 minutes.**

APhA appreciates the opportunity to provide CMS with the information outlined above. If you have any questions or would like to meet with APhA to discuss these comments, please contact Corey Whetzel, APhA's Senior Manager, Regulatory Affairs, at cwhetzel@aphanet.org.

Best,

Michael Baxter

Michael Baxter
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