American Pharmacists Association

January 27, 2025

Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services (HHS)
Attention: CMS-4208-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: [RIN 0938-AV40] Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, Proposed Rule

The American Pharmacists Association ("APhA") appreciates the opportunity to submit comments to CMS' proposed rule on "Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly."

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.

Vaccine Cost Sharing Changes FR 99341

CMS is proposing to implement section 11401, which amends section 1860D-2 "to require that, effective for plan years beginning on or after January 1, 2023, the Medicare Part D deductible shall not apply to, and there is no cost-sharing for, an adult vaccine recommended by the Advisory Committee on Immunization Practices (ACIP) covered under Part D." APhA strongly supported eliminating all out-of-pocket costs for Medicare vaccines starting in January 2023. This makes vaccine coverage consistent with private insurance plans, the U.S. military, Medicare Part B vaccines (influenza, pneumococcal, Hepatitis B, etc.), and Medicaid. As a member of the Adult Vaccine Access Coalition (AVAC), APhA has emphasized that "had this change been in effect in 2021, the 3.4 million people with Medicare who received vaccines under

Part D coverage would have saved an average of nearly $70 per person, with an estimated $234 million in savings on recommended Part D vaccines. As new vaccines are approved, even more people with Medicare will benefit from this provision. Lower out-of-pocket costs will encourage access to vaccines for more populations to choose to receive life-saving vaccines, leading to fewer hospitalizations and doctor visits, preventing serious health complications and death, and bringing enormous savings to U.S. taxpayers and the health care system.

As AVAC has also emphasized, "[w]ith expanded Medicare vaccine coverage, additional challenges for patients must also be addressed. Providers across the health care system continue to face burdens with purchasing, storing, administering, and billing for vaccines for Medicare beneficiaries, which inhibits access." The lack of availability of immunization providers in rural and underserved areas results in vaccine coverage gaps. APhA joins AVAC in reemphasizing CMS implement the following policy changes:

- Ensure that immunization providers, specifically pharmacists, receive adequate reimbursement for the cost of vaccines and supplies, as well as the time providers spend with patients for vaccine counseling and administration, which will go a long way toward an efficient, robust and cost saving immunization system for Medicare beneficiaries. In December 2023, CMS acknowledged "that the amount plan sponsors and PBMs that serve plans in Medicare…pay pharmacies for some vaccine administrations is causing many pharmacies and other providers of vaccines to lose money administering vaccines, discouraging them from providing these vaccines." CMS also stated the agency "is very concerned about payment practices that may impede access to recommended vaccinations, and it is imperative that plans and PBMs take immediate steps to ensure adequate payment for and access to vaccines." APhA has provided direct data to CMS leadership that current PBM payment policies are underwater every time a pharmacy fills and administers many Advisory Committee on Immunization Practices (ACIP)—recommended vaccines, which clearly disincentivizes pharmacist stocking and administration of vaccines. APhA has also emphasized to CMS that certain plans and PBMs are implementing utilization management tactics for vaccines, such as $0 reimbursement to pharmacies for "less preferred" ACIP-recommended vaccines, which poses significant and harmful barriers to timely and equitable access to vaccines for Medicare beneficiaries. For example, consider the scenario where a Medicare Part D beneficiary presents to a pharmacy for a vaccine, and the pharmacy staff bill for a recommended vaccine that is not preferred – either the pharmacy could provide the service only to find out they were reimbursed $0 for the product and service provided – or if the claim response indicates that another product is preferred, the patient may have to make a return trip in the future to allow the pharmacy time to access the preferred product. Given the critical role of vaccines in safeguarding public health and reducing healthcare costs associated with preventable

diseases, APhA continues to urge CMS not to allow the use of utilization management tactics by Part D sponsors for vaccine coverage and to specifically deny any Part D formulary that proposes utilization management tactics for vaccine coverage.

- Enhance Medicare vaccine data quality and completeness, including improvements to reporting and interoperability between electronic health records (EHRs) and state and local public health data systems, with access for pharmacists. Denying pharmacists' access to EHRs is a clear violation of "information blocking" under the law and as APhA has emphasized "any entities engaging in "information blocking" practices that equate to interfering with pharmacists' ability to appropriately utilize [electronic health information] EHI and administer patient care services within their state scope of practice and training should be subject to the associated penalties and disincentives outlined by ONC, HHS, and OIG," as pharmacists were proposed to be recognized as a "health care provider," by ONC. APhA also notes that a "pharmacist" who is "licensed by a State to practice pharmacy," now includes training and state-based authority for a number of patient-care services including several preventive care services including disease state and medication management, smoking cessation counseling, health and wellness screenings, immunizations, and, in some states, prescribing of medications (buprenorphine (13 states), HIV PrEP/PEP (30 states and D.C.), hormonal contraceptives (37) and emergency use authorization oral antivirals (authorized by the Food and Drug Administration (FDA).

Medicare Prescription Payment Plan FR 99341

CMS is also proposing to "codify agency guidance implementing section 11202 of the IRA, which establishes the Medicare Prescription Payment Plan and requires each PDP sponsor offering a prescription drug plan and each MA organization offering an MA-PD plan to provide to any enrollee of such plan, including an enrollee who is subsidy-eligible, the option to elect with respect to a plan year to pay cost-sharing under the plan in monthly amounts that are capped."

The Medicare Prescription Payment (M3P) program requires all Part D plan sponsors to offer, starting Jan. 1, 2025, shifts of out-of-pocket payments from the pharmacy counter to a monthly payment to the plan. Under this new program, patients and pharmacies are concerned that a plan would attempt to collect the unpaid balance at the pharmacy counter after a required two-month grace period. Accordingly, APhA urges CMS to clarify that any pharmacist or patient who suspects inappropriate cost-sharing calculations after a patient is involuntarily removed from MPPP for missing the grace period can easily file a complaint with CMS.

In addition, APhA members are concerned about audits when a pharmacy receives paid claim responses from Medicare Part D plans with Approved Message Code "057 Beneficiary participating in Prescription Payment Plan," if a subsequent claim for the copay amount is not sent to the Part D plan's Medicare Prescription Payment Plan processor. APhA strongly urges CMS to clearly communicate to all pharmacists how to check for Approved Message Code 057, and where to look to find the MPPP processing information in the Coordination of Benefits (COB)/Other Payer segment. CMS should also avoid audits for pharmacists who are attempting to comply with these new requirements for good faith efforts. APhA generally recommends that CMS take all actions available to the agency to lower the administrative burden for pharmacists' interactions and reimbursements for beneficiaries who voluntarily choose to enroll in the M3P program.

Promoting Transparency for Pharmacies and Protecting Beneficiaries from Disruptions FR 99343 and **Network Transparency for Pharmacies FR 99381**

CMS proposes to Part D plans and their PBMs to "notify network pharmacies which plans the pharmacies will be in-network for in a given plan year by October 1 of the year prior to that plan year and to require sponsors to provide pharmacies a list of these plans to network pharmacies on request after October 1." CMS is "also proposing to require contracts with pharmacies for participation in Part D networks that allow the Part D sponsor or FDR to terminate the contract without cause to also allow pharmacies to terminate the contracts without cause after providing the same notice that the contract requires the sponsor or FDR to provide the pharmacy."

APhA strongly recommends CMS strengthen this proposal by redefining § 423.505(8) to:

"(8) Any contract between the sponsor and a pharmacy, or between a first tier, downstream, or related entity and a pharmacy on the sponsor's behalf, for participation in one or more of the Part D sponsor's networks must allow the pharmacy to terminate the contract or its participation in a particular network without cause after providing commercially reasonable (e.g., sixty (60) days) notice of termination without cause."

APhA appreciates CMS' efforts to "address concerns raised by pharmacies about their ability to provide accurate information to beneficiaries." Due to PBMs' documented history of not negotiating network agreements, provider manuals, etc., the network pharmacy still needs to terminate a contact given the market power of the vertically merged PBMs. Strengthening this proposal will help CMS achieve its goals to "help protect beneficiaries from disruptions in care that occur when network pharmacies stop providing services before formally terminating their contracts."

Medicare Transaction Facilitator Requirements for Network Pharmacy Agreements FR 99343 and FR 99441-45

CMS is proposing "to amend § 423.505 by adding paragraph (q) to require that Part D sponsors' network contracts with pharmacies require such pharmacies to be enrolled in the Medicare Drug Price Negotiation Program's ("Negotiation Program") Medicare Transaction Facilitator Data Module ("MTF DM")" to "promote access to negotiated maximum fair prices under the Negotiation Program for both beneficiaries and dispensing entities, and help ensure accurate Part D claims information and payment."

APhA appreciates that this proposed rule would allow pharmacies in limited circumstances to terminate a Part D contract or participation in a particular network without cause to counter the often one-sided nature of PBM Part D contracts. APhA also applauds CMS for requiring Part D sponsors/PBMs notify pharmacies which plans the pharmacies will be in-network for in a given plan year by October 1 of the year prior to that plan year. While well-intended, APhA remains concerned with CMS' proposal that would require plan sponsors/PBMs to include in their pharmacy contracts a requirement for pharmacies to be enrolled in the MTF DM. Mandatory participation in the program will likely force pharmacies to take substantial losses. For reference, APhA has documented to CMS that PBMs already reimburse pharmacies at unsustainable rates far below their cost to dispense those same drugs – often at a minimum of 3% below cost on dispensing brand medications! Pharmacies that are forced to enroll in and lose money under the negotiation program while floating reimbursement costs for a minimum of 21 days, and likely over 30 days, for the manufacturer to refund payments will only restrict pharmacy and medication access for beneficiaries. To avoid these scenarios, pharmacies must be reimbursed within 14 days of adjudicating the claim at the pharmacy and cannot be forced to float the negotiation program. Accordingly, APhA strongly recommends that CMS require that MTF payments to pharmacies do not exceed the 14-day prompt pay requirement under Medicare Part D.

CMS has stated in other communications to APhA that the agency cannot act to protect pharmacies from PBMs' underwater reimbursements due to "the non-interference clause in section 1860D-11(i) of the Social Security Act [that] generally prohibits CMS from interfering in the negotiations between drug manufacturers and pharmacies and PDP sponsors, or from instituting a price structure for the reimbursement of covered Part D drugs." At the same time, CMS is "interfering," in PBM/pharmacy contracts by requiring that any contract between the sponsor or its PBM and a pharmacy must include a provision requiring the pharmacy to be enrolled in the MTF DM. APhA encourages CMS to reexamine its full authority under § 423.505(b)(18) that "[t]he contract between the Part D plan sponsor and CMS must contain…(b) Requirements for contracts. [where] The Part D plan sponsor agrees to—" "(18) To agree to have a standard contract with ***reasonable and relevant terms and conditions of participation***

[emphasis added] whereby any willing pharmacy may access the standard contract and participate as a network pharmacy," and use this authority to require "reasonable" and fair market-based evidence that brand medications can be procured at proposed contract rates to ensure pharmacies are not reimbursed less than the cost it takes them to acquire medications from wholesalers and dispense to Medicare beneficiaries.

Part D Medication Therapy Management (MTM) Program Eligibility Criteria (§ 423.153(d)(2) FR 99381-83)

CMS proposed to "modify the regulatory text at § 423.153(d)(2)(iii)(A) identifying "Alzheimer's disease" as a core chronic disease to include "Alzheimer's disease and dementia" effective January 1, 2026, "for eligibility for MTM enrollment. CMS references evidence-based studies that have found for dementia that "[a] CMR with a pharmacist or other trained clinician could help reduce [potentially inappropriate medication] PIM use in this population." APhA agrees with CMS and continues to recommend CMS appropriately recognize the medication expertise provided by the pharmacist and provide greater visibility into the scope and outcomes of the Medicare services currently provided by pharmacists under Part D, MA, and MA-PD programs. As an immediate step, APhA recommends CMS ensure MTM payments to pharmacists are commensurate with the care and expertise provided to the patient, not based on generating cost-savings for the plans and the PBMs, as Part D plans often have MTM requirements that are overly burdensome and counterproductive. APhA continues our offer to serve as a resource to help analyze CMS data to determine the impact of the current and any proposed changes to the MTM program.

Part D Sponsors Must Provide Network Pharmacies Reciprocal Rights to Terminate Contracts Without Cause and Request for Information on Access to Pharmacy Services and Prescription Drugs FR 99383-4

As stated above, APhA thanks CMS for its December 2023 letter and reminder that "under section 1860D-4(b)(1)(A) of the Act and § 423.505(b)(18), they [plans] must offer a standard contract with reasonable and relevant contract terms whereby any willing pharmacy may participate as a network pharmacy. Additionally, under section 1860D-4(b)(1)(C) of the Act and § 423.120(a), plans must have a contracted pharmacy network that is sufficient to ensure that Part D beneficiaries have convenient access to pharmacy services." APhA shares CMS' concern "about the sustainability of these businesses, especially small and independent pharmacies, and their potential closures that may leave Part D beneficiaries without convenient access to pharmacy services—especially in rural and underserved areas."

CMS releases quarterly Medicare Part D Retail Pharmacy Access Analysis for Prescription Drug Coverage Contracting that appears to display Part D plan compliance with federal pharmacy

access standards. Under § 423.120 "[a]t least 70 percent of Medicare beneficiaries, on average, in rural areas served by the Part D sponsor [must] live within 15 miles of a network pharmacy that is a retail pharmacy." It's 90 percent, on average, within 2 miles of a network pharmacy for urban areas and 90 percent, on average, within 5 miles for suburban areas. Part D plans that do not meet this standard are out of compliance, and the goalposts cannot be shifted.

As APhA emphasized to CMS in our meeting last year with eight Pharmacy Services Administration Organizations (PSAOs), the University of Pittsburgh School of Pharmacy has released an updated, searchable map utilizing NCPDP data that illustrates closed pharmacies, which are our nation's healthcare infrastructure for most of the country, between January 2014 and March 2024.

APhA continues to urge CMS to utilize this updated data on ongoing pharmacy closures to assist CMS in determining Part D plan compliance with federal pharmacy access standards. APhA again requests CMS share its process for analyzing retail pharmacy access and if the pharmacy locations from the publicly available National Plan and Provider Enumeration System (NPPES) Full Replacement Monthly NPI file are up to date with real-time pharmacy participants based on newly available data sets for compliance with § 423.120. APhA also requests CMS audit Part D plans' weekly "Incremental NPI Files," to align, reflect, and conform federal pharmacy access standards under § 423.120 with ongoing data and public reports of pharmacy closures. In addition, Part D plans' and PBMs' use of preferred pharmacy status should not be used as a mechanism coupled with anti-competitive business practices (pharmacy steering, spread pricing, etc.) by PBMs to thin down the market of participating pharmacies (mainly independents) as much as they can, force patients to use mail order for their medications (which raises medication and patient safety, waste, and other concerns), and then move the goal posts to redefine or misrepresent compliance with CMS' network adequacy standards under § 423.120.

APhA also emphasizes the report language from Congress in H.Rept. 118-585 under "Convenient Access Standards for Medicare Part D Beneficiaries-," which states:

> "The Committee is concerned that existing convenient access standards for Medicare Part D beneficiaries based on geographic distance do not take into consideration true access to life-saving medications, including those that are less common or facing shortages. The Committee supports efforts by CMS to limit barriers to medication and pharmacist access for Medicare patients and make, as appropriate, updates to the Medicare Part D pharmacy access standards to improve patient access to pharmacy services offered by pharmacies not affiliated with a Pharmacy Benefit Manager. The Committee urges CMS to consider what updates to Part D network adequacy standards,

including those that do not rely on physical distance, could improve patient access to drugs and the expertise of pharmacists."

A recent research collaboration between Colorado and Utah recently published new findings that help demonstrate that regardless of why a pharmacy closes, when a pharmacy closes, patients may be harmed. Using the Colorado All-Payer Claims Database (APCD), including Medicare data, the analysis found that patients taking an anticonvulsant medication that were exposed to one of the 39 Colorado pharmacy closures from 2018-2022 saw a reduction in medication fills (~15% reduction) and days supplied (~14% reduction). In other words, over a six-month period, a patient taking an anticonvulsant would miss an entire month of medication, and shifting to mail-order did not meaningfully mitigate this risk. CMS needs to recognize that a pharmacy closure puts patients at risk for poorer outcomes. Pharmacists can be a vital part of the solution. APhA is happy to connect with you to discuss these findings and the impact of pharmacy closures on Medicare beneficiaries' health.

CMS also includes an RFI, "on what additional data or information to consider—such as reimbursement rates, underlying costs, steering, contracting terms, and other elements which may affect pharmacies' ability to continue providing Part D drugs to beneficiaries—to improve our ability to protect beneficiaries' convenient access to Part D drugs consistent with current access standards at § 423.120." APhA recommends CMS reference the Federal Trade Commission's (FTC) first interim PBM report, which found PBMs may be steering patients to their affiliated pharmacies and away from smaller, independent pharmacies, and FTC's second interim staff report, which found that PBMs charge significant markups for cancer, HIV, and other critical specialty generic drugs, and leverage the full authorities of CMS to take immediate action to move towards more reasonable PBM contracts.

Timely Submission Requirements for Prescription Drug Event (PDE) Records (§ 423.325) FR 99438-42

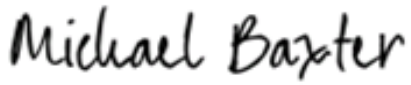
CMS is proposing "to codify the existing 30-day and 90-day general PDE submission timeframes," with two modifications: 1) That the 30-day and 90-day requirements refer to calendar days, as opposed to business days and 2) The timing of the initial PDE records submission, which currently begins from the date the claim is received by the Part D sponsor or the date of service, whichever is greater.

APhA recommends CMS shorten the current 30-day window of the time that Part D plan sponsors have to submit complete Part D PDE records to CMS' Drug Data Processing System (DDPS), to 7 days, rather than codifying the existing timeframes. In order to improve the payment to pharmacies, CMS should also prefund the MTF, rather than relying on pharmacies to do so. Alternatively, APhA recommends CMS shorten the PDE reporting period from 30

days to 1 day, and require the MTF to provide the requisite data to the Primary Manufacturers on a daily basis.

APhA thanks CMS for its efforts and appreciates the opportunity to comment on the proposed rule. Please contact APhA at mbaxter@aphanet.org with any additional questions or arrange a meeting to discuss our recommendations.

Sincerely,



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