American Pharmacists Association

January 5, 2024

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4205-P
P.O. Box 8013
Baltimore, MD 21244

RE: Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Proposed Rule (CMS-4205-P, RIN 0938-AV24)

Dear Administrator Brooks-LaSure:

The American Pharmacists Association (APhA) appreciates the opportunity to submit comments on the "Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Proposed Rule."

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including 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.

Overall, APhA recommends CMS appropriately recognize the medication expertise provided by the pharmacist and encourages CMS to provide greater visibility into the scope and outcomes of the Medicare services currently provided by pharmacists under Part D, MA, and MA-PD programs. For example, APhA recommends CMS ensure medication therapy management (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 pharmacy benefit managers (PBMs), as Part D plans often have MTM requirements that are overly burdensome and counterproductive.

Expanding Network Adequacy Requirements for Behavioral Health (FR 78484)

CMS is proposing to add a new facility-specialty type called "Outpatient Behavioral Health" to the network adequacy standards for Medicare Advantage (MA) plans under § 422.116(b)(2) using time and distance and minimum number standards, including opioid treatment programs (OTPs) and other behavioral health and addiction medicine specialists and facilities." CMS states this new facility-specialty type will "include providers some of which we have data for and some which are new and for which we lack data. Therefore, we cannot quantify the effects of this provision though we expect it may increase access which may qualitatively increase utilization."

CMS proposes adding this combined facility-specialty type instead of individual provider-specialty types. CMS notes "Per § 422.2, the term "provider" means (1) any individual who is engaged in the delivery of health care services in a State and is licensed or certified by the State to engage in that activity in the State; and (2) any entity that is engaged in the delivery of health care services in a State and is licensed or certified to deliver those services if such licensing or certification is required by State law or regulation." CMS will "monitor the appropriateness of maintaining this proposed new behavioral health specialty type as a facility-specialty type (that is, under § 422.116(b)(2)) for network adequacy review purposes," and "as the list of OTPs enrolled in Medicare continues to expand…continue to monitor whether network adequacy for OTPs is best measured under a combined facility type for the purpose of network adequacy reviews."

Many pharmacists are actively caring for patients with opioid use disorder (OUD) at OTPs, yet many barriers prevent patients from receiving care. APhA believes pharmacists and pharmacies can help meet treatment demands and network adequacy requirements but their ability to do so is dependent, in part, on coverage frameworks that encourage better optimization of resources, such as pharmacists. CMS should take action to acknowledge, attribute, and reimburse pharmacist-provided patient care services that can be provided through OTP programs under the newly proposed facility-specialty "Outpatient Behavioral Health" type for MA plan network adequacy standards.

As CMS is aware, patients receiving care in an OTP may have other conditions that require more practitioner time to review medications or coordinate care with other health care practitioners outside of the OTP. APhA encourages CMS to specifically consider how pharmacists' time devoted to treatment planning, modification, and care coordination can be included among the services covered by Medicare Part B as well as Part D. As CMS understands, pharmacists provide substance use disorder (SUD) and OUD services at OTPs,

specialty, and primary care offices, including medication-assisted treatment (MAT) under state scope of practice laws governed by state Boards of Pharmacy. In addition, some pharmacists receive further education and credentialing relevant to SUD/OUD, such as board certification as a psychiatric pharmacist. To achieve CMS' OUD goals, pharmacists providing mental health and SUD/OUD services should receive attribution, recognition, and compensation from CMS, as well as Part D, MA, and MA-PD plans for providing these services.

Requiring NCPDP SCRIPT Standard Version 2023011 as the Part D Electronic Prescribing Standard, Retirement of NCPDP SCRIPT Standard Version 2017071, and Related Conforming Changes in § 423.160 (FR 78489)

Under sections III.B.4. through III.B.9. of the proposed rule, CMS is proposing to require the use of NCPDP SCRIPT standard version 2023011, proposed for adoption at 45 CFR 170.205(b)(2), and retiring use of NCPDP SCRIPT standard version 2017071 for communication of a prescription or prescription-related information supported by Part D plans. CMS' proposal includes a transition period beginning on the effective date of the final rule during which either version of the NCPDP SCRIPT standard may be used that would end on January 1, 2027. If finalized, starting January 1, 2027, NCPDP SCRIPT standard version 2023011 would be the only version of the NCPDP SCRIPT standard available for HHS use and for purposes of the Medicare Part D electronic prescribing program.

APhA supports CMS' adoption of the NCPDP SCRIPT Standard Version 2023011 which includes several new features to improve patient safety and the health care system (added observations to REMS transactions, added support for Rx Bar Code, patient conditions, therapeutic substitution indicators, patient pronouns, etc.).

APhA also supports CMS' approach to update and align e-prescribing standards 45 CFR 170.205(b) by cross-referencing Part D requirements with standards adopted by the Office of the National Coordinator for Health Information Technology (ONC) and the standards for electronic transactions in the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

The revised SCRIPT Standard has the cancelRX feature where a prescriber can cancel a prescription that has been discontinued, which could significantly improve avoiding prescription mix-ups. In addition, the Real-Time-Prescription-Benefit (RTPB) Standard Version 13 would also promote more informed prescribing by placing cost information with the prescriber when they are prescribing a prescription.

Date for Required Use of NCPDP SCRIPT Standard Version 2023011, NCPDP RTPB Standard Version 13, and NCPDP F&B Standard Version 60 (FR 78496)

In section III.B.7., CMS solicits comments on the date by which the use of the updated version of this and other standards in this proposed rule would be finalized.

APhA agrees with the January 1, 2027, implementation timeline by CMS requiring NCPDP SCRIPT standard version 2023011 if this proposed rule is finalized on December 31, 2024. The final date is vital to allow pharmacies, prescribers, and health plans the time necessary to be able to plan to upgrade and modify configurations to their health IT systems, implement changes to their prescribing processes, and train employees by 2027.

Aligned Approach to Standards Adoption (FR 78500-78501)

In CMS' December 2022 proposed rule (87 FR 79552-79557), CMS and ONC discussed a new approach to "alignment of standards under which ONC proposed to adopt and incorporate by reference, on behalf of HHS, the NCPDP SCRIPT standard version 2022011 and the NCPDP RTPB standard version 12 in a single Code of Federal Regulations [CFR] location at 45 CFR 170.205, where CMS proposed to cross-reference these standards for requirements in the Part D program."

APhA agrees that the proposed adoption of these standards in a single CFR location will improve coordination among all stakeholders implementing new standards. Instead of proposing new and updated standards in Part D regulations, this coordinated approach will promote engagement with ONC in their Standards Version Advancement Process (SVAP) permitting ONC to name a standard and CMS to reference this standard to ensure consistency and standardization in the process and collaborate on testing new versions.

Additional Changes to an Approved Formulary—Biosimilar Biological Product Maintenance Changes and Timing of Substitutions (§§ 423.4, 423.100, and 423.120(e)(2)) (FR 78514)

CMS is proposing to add substitutions of "biosimilar biological products," other than interchangeable biological products to the type of formulary changes that apply to all enrollees (including beneficiaries already taking the reference product prior to the effective date of the change) following a 30-day notice. In other words, CMS would permit "biosimilar biological products other than interchangeable biological products to be substituted for their reference products without requiring that enrollees currently taking the reference product [to] be exempt from the change for the remainder of the contract year."

In FDA's September 2023 draft guidance, FDA did not require distinguishing interchangeable biosimilar products from other biosimilar products in labeling for use by health care providers. FDA stated "the Purple Book is available as an easy-to-use resource for pharmacists" and "information about interchangeability is more appropriately located in the Purple Book rather than labeling." APhA agrees and stated in our comments that "[m}ost pharmacists are now familiar with the Purple Book. With appropriate education and awareness, APhA expects that pharmacists will also become familiar with referring to the Purple Book for information regarding interchangeable biosimilar drug products."

As CMS understands, many state laws allow for an interchangeable biosimilar to be automatically substituted for its reference product by a pharmacist (pharmacist-level substitution).

However, APhA remains concerned that any immediate formulary changes, as proposed by CMS, or even those made following a 30-day notice could potentially increase the administrative burden on the pharmacist. To assist pharmacists with any immediate changes made to prescriptions to be dispensed for biosimilar biologic products, APhA recommends, CMS grant pharmacists access to real-time benefit tools (RTBTs), which CMS has required Part D plans to provide to prescribers since 2019. Providing pharmacists with additional information from patients' prescription drug coverage and cost-sharing information will help pharmacists work as members of patient care teams to improve patients' access to either interchangeable or other biological products, through substitutions and/or recommendations under applicable state laws, where FDA has not found any significant difference in the safety profiles or immunogenicity rates in patients.

Improvements to Drug Management Programs (§§ 423.100 and 423.153) (FR 78504-78511)

In the proposed rule, CMS states "[s]ection 1860D-4(c)(5)(A) of the Social Security Act requires that Part D sponsors have a drug management program (DMP) for beneficiaries at risk of abuse or misuse of frequently abused drugs (FADs), currently defined by CMS as opioids and benzodiazepines." To align with the 2022 CDC Guideline regarding applicability in individuals with cancer, CMS is proposing to amend the definition "exempted beneficiary" by replacing the reference to "active cancer-related pain" with "cancer-related pain.," to more broadly refer to enrollees being treated for cancer-related pain to "cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance only."

APhA supports CMS' proposed expansion of "exempted beneficiary" to beneficiaries with "cancer-related pain." In order to leverage pharmacists' expertise, APhA also urges CMS to collaborate with the CDC to address barriers to the integration of pharmacists into pain management teams by providing adequate Medicare reimbursement of pharmacists' patient care services.

Amendments to Part C and Part D Reporting Requirements (§§ 422.516 and 423.514) (FR 78544-78545)

CMS affirms agency authority to collect detailed information from MA organizations and Part D plans under current regulations, including new data regarding service utilization decisions (e.g., information on pharmacy rejections, initial determinations, decision rationales, and plan-level appeals) to understand when plans decide to cover or pay for a service to provide "a better line of sight on utilization management and prior authorization practices."

As CMS is aware, prior authorization and other utilization management tools (e.g., quantity limits, step therapy) can pose administrative hurdles that delay patient access to medical services or their medication(s). There is a significant need for CMS to take a more standardized approach to prior authorization policies to improve patient access and reduce significant administrative burden on health care practitioners, including pharmacists.

Pharmacists are the health care practitioners patients see most frequently and, in some circumstances, can play a more expansive role in helping streamline prior authorization requests based on their medication expertise and knowledge about a patient. However, plans generally require the prescriber to submit the prior authorization request. While APhA is very sensitive to policies that place additional burdens on pharmacists, especially when those requirements are not covered by payers, there may be an opportunity to better utilize pharmacists and proactively provide pharmacists with easier access to information about a patient's prior authorization request.

To address several of these issues, APhA requests CMS implement a more standardized approach to prior authorization and other utilization management requirements that would be more user-friendly and function more efficiently. Currently, each plan and PBM has different requirements for prescribers and pharmacists when a medication requires prior authorization. While some requirements are similar, even minor variability makes it more difficult for prescribers and pharmacists to complete the prior authorization in accordance with a plan's or a PBM's specific policies. When documentation issues occur, valuable, unreimbursed additional time is spent by health care practitioners to identify why a prior authorization request was not

accepted and then to resolve the issue. All these additional steps delay a patient's access to their medically necessary services or prescribed medications and detract from the practitioner's capacity to provide care directly to the patient.

Pharmacists' access to electronic health record (EHR) systems is fundamental to ensuring all members of the patient care team can assist in streamlining prior authorization requirements and lowering the administrative burden on providers. Pharmacists' access to EHRs is necessary for real-time interactions with other health care providers and insurers to provide needed medications and exchange patient information related to overall patient care, transitions of care, immunization (historical and administered), immunization registry reporting, medication lists, medication allergies, allergy reactions, patient problem lists, smoking status, reporting to public health agencies, clinical decision support services/knowledge artifacts, drug formulary checking, social determinants of health, and electronic prescribing.

Our members continue to have concerns that while CMS and private payors have established frameworks to encourage collaboration and team-based care, depending on the practice, pharmacists are frequently blocked from the exchange of relevant clinical information included in EHRs. Such restrictions impede the ability of CMS and patients to benefit from coordinated, team-based care. Therefore, APhA strongly suggests CMS develop policies that facilitate the exchange of relevant health information between the appropriate members of the health care team to streamline prior authorization, care coordination, and billing under MA, MA-PD, and Part D plans.

Proposed Measure Update a. Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR) (Part D) (FR 78558-78559)

CMS is proposing to update the Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR) measure (Part D). Proposed changes would apply (data would be collected and performance measured) for the 2025 measurement period and the 2027 Star Ratings. In the December 2022 proposed rule, CMS proposed changes to the MTM program, that if finalized are estimated to "increase the number and percentage of Part D enrollees eligible for MTM from 4.5 million (9 percent) to 11.4 million (23 percent)." If the changes to eligibility for the MTM program are finalized in a future rule, CMS is proposing to move the MTM Program Completion Rate for CMR Star Rating measure to a display measure for at least 2 years due to substantive measure updates.

APhA continues to strongly support CMS' proposed changes, many of which APhA has advocated to advance for years to improve equitable access to MTM programs under Part D.

As CMS understands, despite clear evidence supporting the value of pharmacist-led MTM services, these programs continue to be significantly underutilized. In the 2022 proposed rule, CMS stated that "most plans now require 3 or more chronic diseases, 8 or more Part D drugs, and target a narrow and variable list of chronic diseases," and that "plans may also limit their targeting criteria to certain diseases, drugs, or both, in addition to the low eligibility rates overall, enrollees with equivalent patient profiles (for example, same chronic diseases, same number of chronic diseases, same number of Part D drugs, and similar estimated drug costs) may or may not be eligible for MTM depending on the criteria their plan requires."

Accordingly, APhA is encouraged by CMS' proposed changes which should improve the number of eligible beneficiaries for MTM (estimated at approximately 23 percent of the Part D population), which is much closer to CMS' originally anticipated participation of 25 percent. It is truly sobering that only 8 percent of beneficiaries are eligible for MTM programs (2020 data).

APhA is also concerned that CMS "cannot definitively score this proposal because there may be other administrative costs attributable to MTM, and MTM program costs are not a specific line item that can be easily extracted from the bid." CMS states that "published studies have found that MTM services may generate overall medical savings, for example, through reduced adverse outcomes including reduced hospitalizations and readmissions, outpatient encounters, or nursing home admissions." However, "CMS is unable to generate reliable savings estimates from the published studies due to limitations in potential study design, including the lack of a control group and numerous intervening variables." It is concerning that CMS cannot receive accurate information on the costs to provide a major plan benefit, such as MTM services.

APhA has been advocating for years that CMS needs to be more transparent about the cost of the MTM program, and more importantly the outcomes to beneficiaries. Accordingly, APhA strongly urges CMS to prioritize identifying these costs on an annual basis to determine the impacts of the changes in the proposal and any finalized rule. APhA continues our offer to serve as a resource to help analyze CMS data to determine the impact of the current and proposed changes to the MTM program.

Thank you again for allowing APhA the opportunity to comment on the CY 2025 proposed rule. If you have any questions or need any additional information, please contact mbaxter@aphanet.org.

APhA
American Pharmacists Association

Sincerely,

Michael Baxter
Vice President, Federal Government Affairs