American Pharmacists Association

February 13, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS–4201–P, Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Proposed Rule [Docket No. CMS–4201–P]

Dear Administrator Brooks-LaSure,

The American Pharmacists Association (APhA) is pleased to submit comments on the "Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit 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 comments on the MTM Program

APhA is grateful for CMS' ongoing recognition of the value of Medication Therapy Management (MTM). While MTM services do provide cost savings, both for patients and the Medicare program, their primary purpose is to optimize the impact of patients' medications. Studies indicate that for every $1 spent on MTM services, up to $12 is saved. In addition to cost savings, patients also realize significant improvements in key health measures. However, MTM services in Part D do not have the incentives, nor the structure to comprehensively manage a patient's medications, as seen in Medicaid, commercial plans and medical home/Accountable Care Organization (ACO) models. APhA strongly urges CMS to increase more transparency in the costs of the MTM program (how much plans are reaping vs. how much they are allocating to paying pharmacists for the services), given the chronically low payment to pharmacists/pharmacies. Absent transparency, it's difficult to know how Part D plans are

incentivized to offer robust MTM services. .Increasing payment is vital to encouraging pharmacists to invest the time necessary to provide MTM services. APhA also encourages CMS to reference state Medicaid MTM/CMR programs, such as Wisconsin, which are very successful and cover a number of value-added professional services provided by a pharmacist. CMS also needs to appropriately recognize the medication expertise provided by the pharmacist and ensure MTM payments 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). Often Part D plans have MTM requirements that are overly burdensome and counterproductive.

MTM Eligibility Criteria (§ 423.153(d)(2)) (FR 79543)

After an extensive analysis to identify potential disparities in MTM program eligibility and access, CMS is proposing changes to the MTM targeting criteria at § 423.153(d)(2) "to promote consistent, equitable, and expanded access to MTM services" Under the proposed rule, CMS is proposing: "(1) requiring plan sponsors to target all core chronic diseases identified by CMS, codifying the current 9 core chronic diseases in regulation, and adding HIV/AIDS for a total of 10 core chronic diseases; (2) lowering the maximum number of covered Part D drugs a sponsor may require from 8 to 5 drugs and requiring sponsors to include all Part D maintenance drugs in their targeting criteria; and (3) revising the methodology for calculating the cost threshold ($4,935 in 2023) to be commensurate with the average annual cost of 5 generic drugs ($1,004 in 2020)." APhA strongly supports CMS' proposed changes, many of which APhA has advocated 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 proposed rule, CMS states "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 currently eligible (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 get 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 most 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 proposed rule. APhA also offers to serve as a resource to help analyze CMS data to determine the impact of the current and proposed change to the MTM program.

Multiple Chronic Diseases

APhA supports expanding the core chronic diseases required for targeting to 10, including the new addition of HIV/AIDS. These changes should provide more consistency in eligibility between plans and broaden the beneficiaries eligible in each plan. Based on 2020 enrollment data, CMS found that "only 1 percent of the Part D population was enrolled in a plan that targeted all 9 core chronic diseases, a decrease from 3 percent in 2015." In addition, CMS administrative claims data found "a significant proportion of the Part D population that we identified as having 3 or more core chronic conditions and using 8 or more drugs (approximately 9 million beneficiaries) were not eligible to be targeted for MTM (6 million)." Therefore, APhA strongly supports CMS' proposal to "amend the regulations at § 423.153(d)(2) by adding a new paragraph (iii) to require all Part D sponsors to include all core chronic diseases when identifying enrollees who have multiple chronic diseases, as provided under § 423.153(d)(2)(i)(A)," including HIV/AIDS, which is long overdue, for a total of 10 core chronic diseases. Overall, CMS found that Part D enrollees "have an average of 2 core chronic diseases (including the 9 core chronic diseases in the current guidance along with the proposed addition of HIV/AIDS)." APhA also supports CMS including cancer as a core chronic condition, or specific cancers likely to be treated with Part D oral drugs. APhA also urges CMS to consider expanding the category of "Alzheimer's disease" to "Alzheimer's and other dementia diseases," which include complex medication regimens.

CMS also solicits "comments on whether MTM services furnished under a Part D MTM program are an effective mechanism for management of certain diseases (for example, those with high use of Part B drugs or frequently changing medication regimens) given the statutory goals of the MTM program—specifically, reducing the risk of adverse events, including adverse

drug interactions, and ensuring that covered Part D drugs prescribed to targeted beneficiaries are appropriately used to optimize therapeutic outcomes through improved medication use." On its face, it appears CMS is proposing to use Part D MTM to manage Part B medications. APhA strongly urges CMS to enhance and incentivize MTM services provided by pharmacists through Part B and compare Part B vs. Part D (assuming the ability to accumulate sufficient data on Part D). When pharmacists and pharmacist-provided patient care services are treated the same as other recognized health care providers under Part B, it is likely that CMS will find patient outcomes will improve when provided under Part B as Part D continues to be a siloed benefit, in many cases, without comprehensive information on care for the patient.

Multiple Part D Drugs (FR 79544)

APhA also strongly supports CMS' proposal to revise § 423.153(d)(2)(i)(B) to decrease the number of maximum number of medications from 8 to 5, including all maintenance drugs, beginning on or after January 1, 2024. CMS data supports this change as "only 13 percent of Part D plans (4 percent of the Part D population) included all covered Part D drugs in their criteria, while 81 percent of plans (87 percent of the Part D population) limited their criteria to chronic/maintenance drugs, and 7 percent of plans (9 percent of the Part D population) limited their criteria to specific drug classes only."

APhA has advocated for years that evidence shows taking 5 or more medications puts patients at higher risk and that the target number should be lower than 8. CMS confirms research has found "concurrent and/or prolonged use of 5 or more drugs has been associated with significant increases in adverse events." APhA agrees these changes should "reduce potential gaps in eligibility due to utilization disparities, and take into account Part D utilization trends." Similarly, APhA encourages CMS to consider lowering the number of medications even further in order to maximize the services' benefits to both patients and the larger health care system. As CMS accurately concludes, this is also a health equity issue, where "[B]lack and Hispanic individuals tend to use fewer prescription drugs and incur lower prescription drug costs than Non-Hispanic White individuals," which "may be an access barrier for those populations, as well as other populations with similar utilization patterns."

Annual Cost Threshold (FR 79545)

For years, APhA has strongly encouraged CMS to revisit the cost threshold as it excludes many beneficiaries with complex conditions, but smaller drug spends, as mentioned in the previous paragraph, who could benefit from MTM services. CMS confirms "[t]he cost threshold has increased substantially since it was established in regulation, while the availability of lower cost generics and the generic utilization rates have also increased significantly since the Part D program began." This has "resulted in a cost threshold that is grossly misaligned with CMS'

intent and inappropriately reduces MTM eligibility among Part D enrollees who have multiple chronic conditions and are taking multiple Part D drugs." APhA agrees that "lowering the cost threshold is especially important to help ensure MTM access for the targeted population contemplated in the statute." Setting the MTM cost threshold at the average cost of 5 generic drugs, as defined at § 423.4, and codifying that CMS will set the MTM cost threshold for a plan year beginning on or after January 1, 2024, by calculating the average daily cost of a generic drug using the prescription drug event (PDE) data, specified at § 423.104(d)(2)(iv)(C), is very much on target and should increase the number of eligible beneficiaries.

Requirement For In-Person or Synchronous Telehealth Consultation (FR 79547)

APhA strongly supports CMS' proposal to amend § 423.153(d)(1)(vii)(B)(1)(i) to require that the comprehensive medication review (CMR) be performed "by a pharmacist or other qualified provider," either in person or via synchronous telehealth "to clarify that the CMR must include an interactive consultation that is conducted in real-time, regardless of whether it is done in person or via telehealth," to update current practice with the growth of telehealth capabilities to provide effective patient-centered care and to affirm that MTM services requires the involvement of the beneficiary.

MTM Program Technical Changes (FR 79548)

APhA also supports CMS' proposal to do away with "MTMP," and use the terminology "MTM program," to ensure the terminology is used consistently. As CMS understands, there is a lot of confusion between MTM programs and services and the use of the acronym is confusing for many individuals who do know about the MTM program.

APhA appreciates CMS' ongoing efforts to expand MTM uptake and we hope CMS will continue to work collaboratively with pharmacists, plans, and beneficiaries to improve and streamline MTM eligibility criteria and increase payments to encourage participation of more pharmacists/pharmacies in the program.

Standards for Electronic Prescribing (§ 423.160)

CMS is proposing "after a transition period, requiring the National Council for Prescription Drug Plans (NDPDP) SCRIPT standard version 2022011 proposed for adoption at 45 CFR 170.205(b), and retiring the current NCPDP SCRIPT standard version 2017071, as the e-prescribing standard for transmitting prescriptions and prescription-related information (including medication history and electronic prior authorization (ePA) transactions) using electronic media for covered Part D drugs for Part D eligible individuals; (2) requiring the NCPDP Real-Time Prescription Benefit (RTPB) standard version 12 proposed for adoption at 45 CFR 170.205(c) as the standard for prescriber real-time benefit tools (RTBTs) supported by Part

D sponsors; and (3) revising current regulatory text referring to standards for eligibility transactions."

APhA supports CMS' adoption of the NCPDP SCRIPT Standard Version 2023011, as the e-prescribing standard for transmitting prescriptions and prescription-related information for Part D drugs for Part D eligible individuals, and NCPDP Real-Time Prescription Benefit (RTPB) Standard Version 13 as the standard for prescriber RTPBs supported by Part D sponsors. However, APhA recommends that both the 2017071 and 2023011 versions be available for HHS until January 1, 2026 rather than January 1, 2025 date in the proposed rule to allow implementations of other standards, such as for claims, formulary and benefit and RTPB, which will greatly impact pharmacies to ensure the industry can adequately program, test and implement the changes so that patient care is not disrupted.

APhA also supports the comments submitted by the Pharmacy Health Information Technology Collaborative.

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 RTPB Standard Version 13 would also promote more informed prescribing by placing cost information with the prescriber when they are prescribing a prescription.

Medication Adherence for Diabetes Medication, Medication Adherence for Hypertension (RAS Antagonists), Medication Adherence for Cholesterol (Statins) (Part D)—Substantive Change (FR 79616-17)

CMS is proposing to implement risk adjustment based on sociodemographic status (SDS) characteristics to the three Part D medication adherence measures for the 2028 Star Ratings (2026 measurement year) based on the Pharmacy Quality Alliance's (PQA) specifications. CMS also intends to incorporate the SDS risk adjustment operationally to these measures reported by CMS to Part D sponsors in the last monthly patient safety report for the measurement year. If finalized, the legacy medication adherence measures would remain in the Star Ratings and the updated adherence measures with the SDS risk adjustment would be on

the display page for at least 2 years (beginning with the 2024 measurement year for the 2026 display page). Beginning with the 2026 measurement year and 2028 Star Ratings, CMS would then move the re-specified measures from display page to Star Ratings and the legacy measures would be removed under this proposal. CMS contracted with PQA to examine the adherence measures for potential risk adjustment. The impact on Part D prescription drug plan (PDP) contracts was neutral or positive; 63% of PDP contracts retained the same Part D summary rating star level while 37% increased by a half a star. No PDP contracts had a decrease in their Part D summary rating. APhA supports the risk adjustment for the three PQA adherence measures, which also take into account health equity issues.

Concurrent Use of Opioids and Benzodiazepines (COB), Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH), and Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults (Poly-CNS) (Part D) (FR-7916-20)
CMS proposes to add the following measures to the 2026 Star Ratings (2024 measurement year: Concurrent Use of Opioids and Benzodiazepines (COB); Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH), and Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults (Poly-CNS). Regarding COB, pharmacists should be able to dispense both opioids and benzodiazepines where clinically appropriate, appropriately dosed and through communication with the beneficiary's physician. In addition, pharmacies should not be penalized as high dispensers of opioids due to their patient mix, or the fact that they are near pain clinics alone. APhA urges CMS to monitor this measure for unintended consequences. For example, neither of these drug classes can be stopped immediately and must be tapered gradually. CMS should also ensure that Part D plans do not encourage providers to get a patient off of one medication, or the other quickly simply to improve their quality scores.

Patient Experience/Complaints and Access Measures (§§ 422.166(e)(1)(iii) and (iv), 423.186(e)(1)(iii) and (iv)) (FR 79623-24)
CMS proposes to change the weight of patient experience/complaints and access measures from four to two. APhA recommends CMS further analyze this proposal to ensure it does not undermine the importance of beneficiary care.

Health Equity Index Reward (§§ 422.166(f)(3) and 423.186(f)(3)) (FR 79626-32)
APhA generally supports CMS' development of a health equity index (HEI) for use in the Part C and Part D Star Ratings for the 2027 Star Ratings that would reward contracts for obtaining high measure-level scores for the subset of enrollees with specified social risk factors (SRFs). APhA appreciates the HEI reward is a methodological enhancement using data from existing Star Ratings measures and not a proposal to add a new measure with an additional burden for

contracts. APhA recommends CMS continue to update stakeholders as the agency moves forward with the application of the HEI to PDP Star Ratings.

Thank you for the opportunity to provide comments on the Proposed Rule. Please contact APhA at mbaxter@aphanet.org if you have any questions or require additional information.

Sincerely,

Michael Baxter

Michael Baxter
Acting Head of Government Affairs