January 4, 2024

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The Honorable Xavier Becerra
HHS Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Ms. Chiquita Brooks-LaSure
CMS Administrator
U.S. Centers for Medicare & Medicaid Services
Attention: CMS–4190–P
P.O. Box 8013
Baltimore, MD 21244–8013

RE: Medicare Program; Contract Year 2025 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; Health Information Technology Standards and Implementation Specifications (CMS-4205-P)

Dear Secretary Becerra and Administrator Brooks-LaSure:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to comment on the U.S. Centers for Medicare & Medicaid Services' (CMS) proposed rule titled "Medicare Program; Contract Year 2025 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; Health Information Technology Standards and Implementation Specifications" (hereafter referred to as proposed rule), as published in the *Federal Register* on November 15, 2023.[1]

PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans (PDPs) and operate specialty pharmacies for more than 275 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and the Exchanges established by the Affordable Care Act.

In this letter, PCMA provides discussion and recommendations on the following topics:

I. **Annual Health Equity Analysis of Utilization Management Policies and Procedures:** CMS should provide additional detail on why it is collecting these data, how it will use them, and follow a path forward that partners with plan sponsors.

II. **Amendments to Part C and Part D Reporting Requirements:** CMS should specify why it is making this proposal and follow through on previous information collection requirements.

[1] 88 Fed. Reg. 78476, November 15, 2023.

III. **Additional Changes to an Approved Formulary—Substituting Biosimilar Biological Products:** We greatly appreciate CMS's efforts to streamline the adoption of biosimilars that are not interchangeable with the reference biologic. We recommend CMS consider additional steps in future rulemaking.

IV. **Amendments to multilanguage insert requirements:** CMS should require the same language requirements across the country by perhaps expanding the list of languages to more than 15 to cover a broader population, rather than customize it by state. CMS should also consider a targeted list of materials with which to include the Notice of Availability.

V. **Proposals intended to streamline the adoption of electronic health information interchange:** PCMA appreciates CMS's efforts to align electronic standards by cross-referencing Part D requirements with standards adopted by the Office of the National Coordinator for Health Information Technology (ONC) and the U.S. Department of Health and Human Services (HHS) and proposing a longer runway for compliance by January 2027. However, in recognition of Inflation Reduction Act (IRA)-related resource requirements, PCMA requests that the new compliance date be January 1, 2028, instead of January 1, 2027.

VI. **Changes to the Medicare Part C & D Star Ratings program:** CMS should not finalize the Medication Therapy Management (MTM) program expansion. In addition, CMS should consider potential methodological issues related to measure changes stemming from programmatic expansion. Any MTM program expansion would exponentially increase the number of eligible beneficiaries and exacerbate existing issues related to pharmacy provider shortages, program administration requirements, and challenges with engaging certain hard-to-reach beneficiary cohorts. CMS's efforts to increase data accuracy and address data concerns are appreciated. To guarantee data completeness necessary for accuracy, CMS should set the 2025 measurement year annual review of sponsor's data deadline for June 18 to facilitate compliance with Prescription Drug Event (PDE) data completeness.

Thank you for the opportunity to provide these comments. We look forward to working with you on your ongoing efforts to improve the Part D program and implement the Inflation Reduction Act.

Sincerely,

Tim Dube

Tim Dube
Vice President, Regulatory Affairs

cc: Jonathan Blum
Meena Seshameni, MD
Cheri Rice
Kristin Bass
Debjani Mukherjee

I. Annual Health Equity Analysis of Utilization Management Policies and Procedures

CMS is proposing several changes to the Utilization Management Committee, initially required for Medicare Advantage (MA) plans beginning in contract year 2024. Namely, CMS would require that the committee include health equity considerations when evaluating proposed utilization management and undertake an annual evaluation of prior authorization in terms of its effect on health equity. CMS seeks comment on specific topics including what constitutes expertise in health equity, and the contents and timing for posting the annual report on prior authorization.

The proposed regulations would be entered at 42 CFR 422.137; this section speaks only to Medicare Advantage regulations. While PCMA generally comments on only the prescription drug benefit aspect of CMS's regulations, we believe these regulations are of interest to both PBMs and the Medicare beneficiaries they serve because health equity considerations continue to be a key priority for the entire healthcare system.

PCMA shares the Administration's commitment to improve the quality of care provided to all beneficiaries, without regard to (or in order to overcome) their specific circumstances. PCMA's mission is aligned with this fundamental principle: our members seek to increase affordable access to prescription drugs for everyone. We believe care should be patient-focused, equitable, and affordable. We commit to industry action and support of policies that advance a more equitable healthcare system, lower costs, reduce disparities in clinical outcomes, and improve the quality of pharmaceutical care. Our vision for a more equitable healthcare system is built on four patient-centered goals, including addressing disparities in access, disease burden and outcomes, and promoting equitable and affordable pharmacy benefit design.[2] These include investing in and using access, utilization, and outcomes data to improve person-centered pharmaceutical care management along commonly understood areas of disparities prevalence.[3]

Our main concerns with this new regulation is the added burden it imposes upon plan sponsors. Transparency of this nature is meaningful to the extent that it's meaningful and actionable. In the interest of crafting a final requirement that would be both, we provide CMS the following recommendations, questions, and suggestions:

- We support the proposed regulatory text on health equity expertise. While the preamble names specific credentials as examples, it is appropriate that they are not specified in the regulations themselves.

[2] PCMA, https://www.pcmanet.org/equitable-health-care-system/, last accessed October 10, 2023.
[3] PCMA, "Working Together for a More Equitable Health Care System," 2022. Available at https://www.pcmanet.org/wp-content/uploads/2022/02/PCMA_Health-Equity.pdf.

- How will CMS use these reports? The final rule should specify CMS's intent, so plans are aware.

- We believe CMS should consider having plans report the information to them, under an Information Collection Review (ICR),[4] and for CMS to produce an aggregated annual report that would eventually include trends. A retrospective report from the prior plan year is not actionable to a current or former (or even future) enrollee of the plan. Complaints tracking is already built into Star ratings, and we are concerned about an eventual linkage to the annual enrollment period (AEP) "double counting" a validated, specific performance measure.

- As proposed, the reports would include information that is generally available to an interested party through other means, including the Independent Review Entity (IRE) appeals decision database.[5] CMS should allow plan sponsors to qualify any findings from the report in this manner.

- CMS should limit the reporting to cases that are fully resolved so as not to bias the results, and to include the final results of all levels of appeals. For instance, if the IRE or Administrative Law Judge (ALJ) agrees with plan's decision, that should be included in the report.

- CMS should not add populations to the health equity analysis until the data collection and methodology for existing demographic information (such as race and ethnicity, LGBTQ+ populations, limited English proficiency, and others) have been piloted, tested, and found to be reliable in the context of the Medicare Advantage population.

- In finalizing any requirement for public reporting, CMS should create guardrails that protect plan sponsors from spurious claims of discrimination.

- We recommend CMS require plans to provide confidential reports to CMS in 2025, that CMS provide feedback to plans, and that CMS delay public reporting until 7/1/26.

***PCMA recommendation*: We support additional meaningful and actionable transparency to identify ways to make the provision of Medicare benefits more**

[4] We discuss necessary parameters for CMS's proposal regarding additional plan reporting requirements later in this letter.
[5] Available at https://www.cms.gov/medicare/appeals-grievances/appeals-decision-search-part-c-d. We acknowledge this database is limited to closed cases that reached this level of appeal, but this is the result of our industry's advocacy that the IRE process needed further transparency.

equitable. Any final rule should include additional information as requested above.

II. Amendments to Part C and Part D Reporting Requirements

CMS proposes changes, which it terms "clarifying modifications," to its existing reporting authority over MA organizations and Part D sponsors, including seeking more granular information, with greater frequency, and closer to real-time than it has historically collected. This proposal includes a statement that its authority to collect information is not limited to statistical or aggregated data, and that it is entitled to collect information regarding MA organization and Part D sponsor "procedures related to and utilization of" items and services provided to beneficiaries.

Notwithstanding these regulatory clarifications, CMS notes that it is not proposing to make any specific changes to the content of the information to be collected at this time, and that such changes, if any, would be addressed through the customary process that provides stakeholders with advance notice and separate opportunities to comment.

As with the previous section regarding additional plan reporting on prior authorizations, specifically, we find this proposal somewhat underbaked. We welcome additional reporting that helps CMS administer the Part D program but reporting that is conducted to meet some external request without meaningful action is burden for burden's sake. We ask CMS to consider the following questions and suggestions as it further assesses changes to Part D plan reporting:

- CMS should more clearly lay out its purpose for "clarifying" that it has much broader authority than it has historically used. Is this related to the prior authorization reporting proposal in this rulemaking? The public is better served understanding why CMS feels there's something unclear about its authority when responding to these kinds of proposals.

- As CMS thinks about finalizing any proposals on this topic, it should also consider specific guardrails about what it is *not* proposing. PCMA believes that any information collection should be in the service of ensuring plan compliance with statutory and regulatory requirements, rather than informing CMS of plan operations that are not subject to its oversight.

- Similarly, any increased perception of authority should be accompanied by an increased commitment to transparency on CMS's behalf. Plan sponsors report multitudes of information, and CMS does not often report out on annual trends it identifies. For example, CMS has collected information from plan sponsors regarding Medication Therapy Management (MTM) programs for

over ten years and has yet to produce a report on these findings. As CMS considers changes to the MTM program, it should first look to all of the data it has already collected to determine whether there is an observable improvement in patient outcomes.[6]

- Relatedly, CMS has proposed and finalized several additions to the Part C and D plan reporting requirements but has yet to implement them. We would prefer that CMS close the loop on these additions before proposing new collections. For example, in the 2022 final rule (which finalized select proposals from the 2021 proposed rule), CMS adopted a requirement that plans report the pharmacy performance measures upon which they calculated pharmacy price concessions.[7] Plan sponsors and PBMs responded thoughtfully and constructively to this proposal and believe it can provide CMS with useful information as it evaluates the change to pharmacy price concessions finalized for 2024.[8]

***PCMA recommendation*: We can support CMS's clarification that its authority extends to additional collections and of different forms and manners, if CMS can better explain its rationale for the change and work with the industry to minimize and reduce reporting burdens overall.**

III. Additional Changes to an Approved Formulary— Substituting Biosimilar Biological Products

CMS proposes several changes as part of an effort to codify existing guidance regarding mid-year formulary changes related to "biosimilar biological products." It would treat substitution of biosimilars other than interchangeable biological products as maintenance changes, with a 30-day notice requirement for existing users of the reference product. CMS would amend the definition of "maintenance changes" to require that if a reference product is substituted for a biosimilar other than an interchangeable biological product, the biosimilar must be added to the same or a lower cost-sharing tier and with the same or less restrictive utilization management requirements. The rule would remove requirements that negative formulary changes associated with biosimilars occur "at the same time" as the maintenance change, in recognition of how biosimilar adoption can best be facilitated, instead providing for a 30- or 90-day off-ramp to remove the reference product, if warranted.

[6] We discuss CMS's expansion proposal and its proposed use of MTM measures for Star ratings later in this letter.
[7] 86 Fed Reg 5864 (January 19, 2021)
[8] 87 Fed Reg 27704 (May 9, 2022)

PCMA is supportive of these changes, overall. In response to the 2023 proposed rule, we commended CMS on its narrower proposal to codify its 2021 guidance to consider the addition of an interchangeable biological product and removal of a reference product as a maintenance change,[9] and implored CMS to go farther given the relative paucity of interchangeable biologics. Last year, we wrote "CMS should expand its proposal, to also allow for the immediate substitution of biosimilar products for their reference product." We are grateful to the agency for understanding the role it can play in fostering biosimilar adoption and look forward to this expanded proposal's finalization. This proposal strikes the right balance given where the biosimilar market is today. In advance, we have a few questions and suggestions for CMS to consider:

- A significant number of beneficiary interactions with health plans occur around mid-year formulary changes. Since this regulatory change is net-positive to beneficiaries, can CMS consider exempting "complaints" about the notifications beneficiaries receive from Star ratings calculations?

- To help combat any negative perceptions of these notifications, we suggest that CMS consider offering plans some additional flexibilities to smooth switching. For instance, CMS could recommend that Medicare Advantage Prescription Drug (MAPD) plan sponsors contact the prescribing physician within its network. PDP sponsors have less ability to do this, so CMS could consider allowing for prior authorization waivers for refills of biosimilars (while still in place for new prescriptions).

- While this proposal matches the current state of the biosimilar market, CMS should work with industry (including manufacturers, pharmacies, and plan sponsors) to consider what regulatory changes might be needed to continue the adoption of biosimilars. Continued experience with biosimilars for prescribers is the key toward greater adoption. Also, as CMS is surely aware, the Food and Drug Administration (FDA) has proposed labeling changes that will reduce the visibility of a product's interchangeability status,[10] which if finalized could change how prescribers view biosimilar biological products.

***PCMA recommendation*: We support CMS's proposal to also allow for the immediate addition of biosimilar biological products for their reference product as maintenance changes, and to temper the negative change process to account for differences in perceptions of biosimilar and reference biological products. We look forward to working with CMS on further efforts to increase biosimilar uptake.**

[9] See Q5 in HPMS, CY 2022 Formulary Information, December 27, 2021.
[10] 88 Fed. Reg. 63957 (September 18, 2023)

IV. Quality Rating System (Stars)

PCMA supports CMS's goals for the delivery of equitable and consistent, high-quality coordinated care to Medicare beneficiaries through ongoing measure updates. However, measure changes need to be justified based on data assessments, quality trends, and non-clinical rationale such as administrative efficiency.

A. Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR) (Part D):

CMS proposes that if previously proposed changes to expand the Medication Therapy Management (MTM) program criteria are finalized, the agency would move the MTM Program Completion Rate for CMR measure to a display measure for at least two years due to substantive changes. The MTM program expansion proposals from CY2024[11] were not finalized and were parked to be revisited in the future.

PCMA cautions against any MTM eligibility expansion and continues to oppose the previously proposed expansion (see our CY 2024 comment letter[12] for more detail) without data to support the need for and benefit of expansion. Any MTM program expansion would increase the number of eligible beneficiaries and affect access, thereby undermining health equity goals of MTM. In addition, expansion would be hindered by pharmacy provider shortages, program administration requirements, and challenges with engaging certain hard-to-reach beneficiary cohorts.[13] Given these potential negative impacts of expansion, PCMA continues to ask CMS for data on the benefit and cost-effectiveness of the current MTM program. Before further investments are made, plans need to see the true value and cost-effectiveness of the current program.

Furthermore, we are concerned that when the measure is moved from the display page to the Stars page in 2027, there will be methodological issues related to cut points. Finally, because the MTM Program Completion Rate for CMR measure is part of the Health Equity Index (HEI), any changes to this measure will also impact HEI associated assessments.

PCMA recommendation: CMS should not finalize the MTM program expansion or move the MTM measure from the display page. In addition, CMS should consider potential methodological issues related to measure changes stemming from programmatic expansion.

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[11] 87 Fed. Reg. 79452, December 27, 2022.
[12] https://downloads.regulations.gov/CMS-2023-0019-0003/attachment_2.pdf
[13] National Community Pharmacists Association: Survey: Three-Quarters of Community Pharmacies Report Staff Shortages (accessed January 2023): ncpa.org

B. Patient Safety measures and Sociodemographic Status (SDS):

For patient safety measures, sociodemographic adjustments and underlying administrative data reviews are necessary for accuracy and impact assessment. To facilitate this process, CMS is proposing to set annual deadlines for sponsor's administrative data review requests. This deadline will afford CMS adequate time to review all the administrative data and ensure accuracy of all final patient safety measure calculations. For the 2025 measurement year (2027 Star Ratings), CMS is proposing a May 18, 2024 deadline.

PCMA appreciates the spirit with which the deadline is set but requests an extension of 30 days with the new deadline being June 18. This request is based on potential data lag issues, especially since the May 18 file will be incomplete with data through March only. Instead, the June 18 data files will include data through the end of April given that Prescription Drug Event (PDE) data for performance measurement are complete by April of the following year. This will help facilitate compliance with the requirement that plan sponsors have administrative data through the end of April.

PCMA recommendation: CMS should set the 2025 measurement year annual review of sponsor's data deadline for June 18 for 2024 to facilitate compliance with PDE data completeness.

V. Telecommunications Standards and Interoperability for Real-Time Benefit Tools (RTBT)and Electronic Prescribing Tools

CMS is proposing an alignment focused approach to updating e-prescribing standards by cross-referencing Part D requirements with standards adopted by the Office of the National Coordinator for Health Information Technology (ONC) and the U.S. Department of Health and Human Services (HHS) for electronic transactions under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The rule withdraws previous, unfinalized proposals, and instead proposes the adoption of several National Council for Prescription Drug Programs (NCPDP) standards for retail transactions, real-time prescription benefits (RTPB), and formulary and benefit (F&B) standards. NCPDP and other affected entities offered this recommendation in response to the CY2024 proposed rule and continues to support the use of these updated standards rather than the prior proposal's.[14]

PCMA appreciates CMS's efforts to align across agencies and the thoughtfulness of a longer runway for compliance by January 2027. However, full compliance with all three standards by 1/1/2027 is burdensome given that resources and manpower will be

[14] [Please link to their Cy2024 letters. Here is Surescript's: https://www.regulations.gov/comment/CMS-2022-0191-0561.]

diverted to comply with and implement IRA-related requirements through 2025 and 2026. In recognition of IRA-related resource requirements, we request a one-year extension to be able to give the standards alignment the attention it deserves. Also, a longer implementation period is necessary because many of the same resources will be utilized to implement and test both the new e-prescribing and the RTBT standards. We request that the new compliance date be January 1, 2028. Additionally, post standards alignment, there needs to be process alignments across agencies. Most importantly, ONC needs to coordinate with CMS to ensure that CMS needs are considered by and incorporated into ONC regulations.

***PCMA recommendation*: CMS should extend the multiple standards alignment compliance date to January 1, 2028.**

VI. Amendments to Multilanguage Insert Requirements

CMS is proposing to amend its current Multi-Language Insert (MLI) regulation to replace references of MLI with "Notice of Availability." This amendment requires that the Notice of Availability be provided in English along with the 15 languages most commonly spoken by individuals with limited English proficiency (LEP) at the state level as well as alternate formats for individuals with disabilities. In addition to the 15 languages most commonly spoken in a state, plans must also provide a translated Notice of Availability in any language spoken by more than 5% of a specific service area. Prior MLI regulations combined with certain state requirements often results in lengthy, confusing, and distracting LEP translation notices within enrollee materials. CMS anticipates that the updated Notice of Availability provision will streamline LEP efforts by plans, enhance the accessibility of the notice, and increase the overall ability of individuals to understand the benefits available to them and make informed health care decisions.

The adoption of OCR's 1557 requirements could lead to more than 50 versions of this notice, especially if every state requires a unique list of 15 languages. While the flexibility of not requiring a standardized communication is much appreciated, this still significantly increases operational complexity, especially since CMS has indicated that they will not be publishing state-specific languages like they do HPMS reports for the 5% threshold. CMS should consider including the state level requirement due to the operational complexity for plans to create so many versions of the notice because it will have to change based on the state and then be narrowed down even further by plan benefit package. One way to address this would be to have the same language requirements across the country by perhaps expanding the list of languages to more than 15 to cover a broader population rather than customize it by state.

The 1557 proposed rule has a slightly different list of materials from the CMS-defined list of required materials. Given that the CY24 Final Rule accommodates non-English and accessible format preferences on a standing basis, we recommend CMS consider a more limited and targeted list of materials with which to include the Notice of Availability, focusing on initial or high-impact points of contact, such as Enrollment documents, rather than inundating members with extra pages in a large list of communications.

<u>PCMA recommendation</u>: CMS should require the same language requirement across the country by perhaps expanding the list of languages to more than 15 to cover a broader population rather than customize it by state. CMS should also consider a targeted list of materials with which to include the Notice of Availability.