January 5, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4201-P
P.O. Box 8013
Baltimore, Maryland 21244-8013

Submitted electronically

RE: Comments to "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"

Dear Administrator Brooks-LaSure:

The MAPRx Coalition (MAPRx) appreciates the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with comments to the proposed rule, **Contract Year (CY) 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**, published on November 15, 2023.

Our group, MAPRx, is a national coalition of beneficiary, caregiver, and healthcare professional organizations committed to improving access to prescription medications and safeguarding the well-being of Medicare beneficiaries with chronic diseases and disabilities. The undersigned members of the MAPRx Coalition are pleased to provide CMS with our official commentary regarding the CY 2025 Medicare Advantage (MA) and Part D proposed rule. Specifically, MAPRx would like to address the following issues CMS raised in the proposed rule:

- **Substituting biosimilar biological products for their reference products as maintenance changes**
- **Codification of complaint resolution timelines**
- **"Anti-competitive" perks and payments to MA and Part D plan agents and brokers**
- **Beneficiary choice of Parts C/D effective date if eligible for more than one election period**

In addition to the provisions within this proposed rule, we also are raising some of our concerns around maintaining beneficiary protections through the agency's implementation of the Inflation Reduction Act (IRA). While CMS has generally implemented key provisions through the subregulatory process, we believe it is critically important to ensure that the agency maintains beneficiary protections, as Part D plans are likely to push more access restrictions on beneficiaries, given Part D plans' higher financial liability under the redesign.

Substituting biosimilar biological products for their reference products as maintenance changes

CMS is proposing to allow Part D plans to substitute biosimilar biological products—other than interchangeable products—for their reference products as maintenance changes to their formularies. The added flexibility will allow Part D plans to be nimble and take advantage of the availability of biosimilar biological products as soon as they are approved by the Food and Drug Administration, rather than waiting for CMS to approve formulary changes through a non-maintenance change. By allowing Part D plans to make this type of formulary change, CMS will help to lower costs to plans, beneficiaries, and the federal government.

However, we would like to note that there is reluctance among many within the provider and patient communities regarding switching patients who are stable on their medication to a non-interchangeable biosimilar. As such, we believe a strong exceptions process is imperative and that as part of the notification period, CMS should urge plan sponsors to ensure they are engaging in robust patient education to instill confidence and a higher level of comfort in transitioning to a biosimilar. Furthermore, we urge CMS to ensure that when a maintenance change occurs substituting a biosimilar biological product for a reference product that that reference product remain on formulary to maintain and further patient choice and flexibility.

Further, our coalition believes that this should be more broadly applied to all biosimilar products, including interchangeable ones. To that end, MAPRx also supports a related change in the proposed **Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications**, published on December 27, 2022.[a] In that proposed rule, CMS proposed to allow Part D plans to treat formulary substitutions of reference products with their interchangeable biological products as maintenance changes. MAPRx encourages CMS to finalize that change to become effective by January 1, 2025, as it discussed in the CY 2023 MA and Part D proposed rule.

Finally, we recommend that CMS work with the U.S. Food and Drug Administration to come to a consensus on the definitions and data surrounding biosimilarity, the presence/absence of interchangeability, and whether additional studies are required to make an interchangeability determination.

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[a] Centers for Medicare & Medicaid Services. Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications. Proposed rule. December 27, 2022. Accessed December 13, 2023. https://www.federalregister.gov/d/2022-26956

Codification of complaints resolution timelines

MAPRx supports CMS' proposal to codify existing guidance for the timeliness of complaint resolution by plans in the Complaints Tracking Module. MAPRx supports CMS' proposals to codify the following definitions and timelines for the resolution of complaints to Part D plans:

- Plans make first contact with patients submitting non-urgent complaints within **3 days**. Non-urgent complaints must be resolved within **30 days.**
- A complaint in which the patient has 2 days or fewer in drug supply is defined as **"Immediate,"** and plans must resolve the complaint in **2 days.**
- A complaint in which the patient has 3 to 14 days' drug supply is defined as **"Urgent,"** and plans must resolve the complaint in **7 days.**

Standardization of the definitions and resolution timelines for complaints will provide beneficiaries with a predictable response by their Part D plans and will help reinforce accountability by Part D plans, thus likely improving beneficiaries' care and satisfaction.

"Anti-competitive" perks and payments to MA and Part D plan agents and brokers

MAPRx appreciates CMS' commitment to ensure fair marketing practices by MA and Part D; therefore, we support CMS' proposed changes to ensure the agency is complying with its statutory requirement to ensure compensation paid to agents and brokers incentivizes them to enroll individuals in the MA and/or Part D plan that best meets their healthcare needs. MAPRx shares CMS' concerns that new financial incentives presented to agents and brokers may influence which MA or Part D plan an agent encourages a beneficiary to select during the enrollment process.

Specifically, MAPRx supports CMS' proposals to ensure agents and brokers are incentivized to help beneficiaries select the best MA and Part D plans for them by implementing the following.

- Count all payments to an agent or broker as "compensation," which would stipulate the maximum payments for initial and renewal enrollments.
- Beginning in 2025, provide a one-time increase in the base compensation rate by $31 to account for administrative costs associated with mandatory activities that include licensing, training, testing, and call recording.
- Limit contracts between MA plans and agents, brokers, or other third-party marketing organizations.

Beneficiary choice of Parts C/D effective date if eligible for more than one election period

MAPRx supports CMS' proposal to codify long-standing sub-regulatory guidance dictating how MA and Part D plan sponsors should handle enrollment or disenrollment requests in cases where the beneficiary is eligible for more than one election period and the election periods allow for more than one effective date. MAPRx appreciates that existing regulations do not address what the MA organization or Part D plan sponsor should do when a beneficiary is eligible for more than one election period, resulting in more than one possible effective date for their election choice. We support CMS' proposals to rectify those scenarios by requiring plans to:

- Allow the beneficiary to choose the election period that results in the desired effective date,
- Attempt to contact the beneficiary and document these attempt(s) to determine the

beneficiary's choice,
- Annotate the outcome and retain the record as part of the individual's enrollment or disenrollment request,
- Use a specific ranking of election periods to assign an election period if the beneficiary does not make a choice, and
- Assign an election period that results in the earliest disenrollment if the plan is unable to obtain the beneficiary's desired disenrollment effective date.

Maintaining beneficiary protections through IRA implementation

While not within the context of this proposed rule, CMS' approach for IRA implementation will be important for protecting access and minimizing affordability challenges for beneficiaries. To that end, we thought it might be helpful to share some of our primary concerns with implementation moving forward.

In September, MAPRx appreciated the opportunity to comment on how CMS intends to implement the Medicare Prescription Payment Plan. When advocating for Congress to enact a true out-of-pocket (OOP) cap in Medicare, MAPRx was consistently a strong proponent of this type of program. Given the critical role this program will play in alleviating financial burdens for beneficiaries, we want to ensure that it is effective in smoothing payments and that CMS is effective in its outreach to beneficiaries who could benefit from the program. Specifically, MAPRx offered the following suggestions for adaptations to the first round of guidance:

- Display a column for patient OOP costs incurred and monthly OOP costs in the monthly billing statement to minimize confusion for program participants.
- Highlight the most important information (eg, total non-itemized OOP costs, OOP costs expected on a monthly basis for the remainder of the plan year) only on the first page of the participant's billing statement.
- Remove the threshold for conducting targeted outreach (from the likely $400 per OOP fill) given congressional intent was focused on making outreach a broad application.
- Reconsider requiring plans and pharmacies to offer real-time or POS enrollment for 2025 as the agency already has reviewed a few feasible ideas.
- Devise and launch a comprehensive educational program to inform prospective participants about this new benefit, specifically for the agency to include information on the program not only in plan marketing materials but also in materials created by the agency (eg, Medicare & You handbook and the Medicare website).

In addition to the Medicare Prescription Payment Program, MAPRx has also offered suggestions to changes in the Medicare Drug Price Negotiation Program (MDPNP), specifically that the agency focus on the following:

- Patient organizations have ample opportunity and ability to provide feedback on the negotiation process,
- CMS is transparent into how the agency factors external data into its final decisions (including the methodology deployed by the agency),
- The agency maintains access to a wide range of drugs within Part D and looks to minimize affordability and access challenges (including on utilization management of negotiated drugs), and
- The agency establishes appropriate guardrails and ongoing oversight processes to continually evaluate the program for the purposes of refining when needed.

Conclusion

Thank you for your consideration of our comments on CY 2025 MA and Part D proposed rule. The undersigned members of MAPRx appreciate your leadership to improve beneficiaries' access and affordability in MA and Medicare Part D. For questions related to MAPRx or the above comments, please contact Bonnie Hogue Duffy, Convener, MAPRx Coalition, at (202) 540-1070 or bduffy@nvgllc.com.

AiArthritis
Allergy & Asthma Network
ALS Association
American Kidney Fund
Foundation for Sarcoidosis Research
HealthyWomen
LUNGevity Foundation
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Muscular Dystrophy Association
National Health Council
National Kidney Foundation
National Multiple Sclerosis Society
The AIDS Institute
The Leukemia & Lymphoma Society
Tourette Association of America
Triage Cancer
United Spinal Association