

September 19, 2023

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Comment on Maximum Monthly Cap on Cost-Sharing Payments Program Draft Part One Guidance

Dear Dr. Seshamani:

The Massachusetts Biotechnology Council (MassBio) appreciates the opportunity to submit these comments to the Centers for Medicare & Medicaid Services (CMS) in response to the Draft Part One Guidance (the “Draft Guidance”) on the “Maximum Monthly Cap on Cost-Sharing Payments Program” established by section 11202 of the Inflation Reduction Act (IRA)¹ (the “Medicare Prescription Payment Plan” or the “Program”).²

MassBio represents the premier global life sciences and healthcare hub of Massachusetts, which has a vibrant biomedical research and development community that is a global leader for medical discovery and innovation. MassBio’s 1,600+ member organizations are dedicated to preventing, treating, and curing diseases through transformative science and technology that brings value and hope to patients. MassBio’s mission is to advance Massachusetts’ leadership in the life sciences to grow the industry, add value to the healthcare system, and improve patient lives.

MassBio supports the proposed implementation of the Medicare Prescription Payment Plan. In particular, we appreciate that CMS is proposing to implement the Program in a manner designed to facilitate enrollees’ timely access to needed therapies. In accordance with these goals, MassBio submits the following recommendations to ensure CMS: (1) supports a patient-friendly approach; (2) effectuates the smoothing of patient cost-sharing at the pharmacy point of sale (POS); and (3) ensures adherence to Program requirements by plans. We also outline priorities for beneficiary outreach materials to aid CMS in drafting Part Two of the Program guidance.

¹ Pub. L. No. 117-169.

² CMS, Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments (Aug. 21, 2023), available at: <https://www.cms.gov/files/document/medicare-prescription-payment-plan-part-1-guidance.pdf> (“Draft Guidance”).

I. MassBio Appreciates that CMS is Proposing to Implement the Program in a Manner Designed to Facilitate Enrollees' Timely Access to Needed Therapies.

A. CMS Should Support a Patient-Friendly Approach.

MassBio encourages CMS to use a patient-friendly approach to address enrollees' cashflow problems and, thereby, improve access to needed medications. Because the Program centers on improving enrollee access to critical therapies, implementation should minimize burdens placed on enrollees. For example, MassBio supports CMS's proposed patient-friendly approach that offers enrollees increased flexibility in choice of payment method. Implementing a patient-friendly approach will allow enrollees, who may not have access to specific methods of payment, to successfully comply with the Program's payment requirements.

We are concerned, however, that CMS merely “**encourages** Part D sponsors to offer multiple means of payment, such as an electronic fund transfer mechanism (including automatic charges of an account at a financial institution or credit or debit card account) and payment by cash or check.”³ We encourage CMS to reframe this policy as an obligation on Part D sponsors. Otherwise, Part D sponsors that strictly offer limited payment options may end up discouraging enrollees from participating in the Program if the limited payment options are not available to them.

B. CMS Should Effectuate Smoothing at the Pharmacy Point of Sale (POS).

To best ensure enrollees have timely access to their medications, an election to participate in the Program at the POS must be processed immediately such that enrollees can opt into the Program at the pharmacy and collect their prescriptions in the same pharmacy transaction. Otherwise the enrollee, who may be suddenly facing high out-of-pocket costs for a new therapy, may elect to leave the pharmacy empty handed. Notably, patients battling complex diseases may not be able to wait 24 hours for their medications. Unnecessary delays in obtaining life-saving medications may exacerbate a patient's medical condition.

We are therefore concerned that CMS' Draft Guidance would not require Part D sponsors to process an enrollee's request to participate in the Program immediately until 2026, giving Part D sponsors 24 hours to process such requests during 2025. While MassBio acknowledges that CMS instituted this requirement to promote the timely processing of requests, we urge CMS to avoid permitting a 24-hour waiting period. Such a policy can result in unnecessary delays and, ultimately prescription abandonment. For these reasons, MassBio urges CMS to work with Part D sponsors to identify a means for processing an enrollee's election at the POS beginning in 2025.

C. CMS Should Recommend Ensuring Plans Adhere to Draft Guidance via Oversight.

MassBio encourages CMS to implement oversight strategies to closely supervise Part D sponsors and ensure their adherence to all provisions in the Draft Guidance. To operationalize this initiative, CMS

³ Draft Guidance at 13 (emphasis added).

should institute reporting requirements and develop reporting templates while collaboratively engaging with Part D sponsors. CMS plays an integral role in ensuring Part D sponsors adhere to the requirements of the Program. CMS monitoring and oversight will facilitate Program compliance, ensuring that enrollees can continue to enjoy timely access to needed therapies.

II. CMS Should Outline Priorities for Beneficiary Outreach Materials for Part Two of the Guidance.

In response to CMS' request for specific feedback on how to best educate Part D enrollees about the Program⁴, MassBio believes that CMS should outline key priorities for Draft Part Two Guidance's beneficiary outreach materials. Specifically, CMS should offer more detailed guidance that outlines how it will effectively educate Part D enrollees about the Program. In this effort, MassBio supports implementing the program in a manner that facilitates a method of outreach that best meets enrollees' needs. Beneficiary outreach materials should be standardized, clear, and tailored to the circumstance. One way to achieve this objective is by requiring the Program to use various communication methods (e.g., text, email, or paper notices) to effectively reach the enrollees and maximize their use of the Program. Standardized, clear, and tailored outreach materials will help ensure all enrollees understand the Program.

MassBio thanks CMS for consideration of our comments and remains available to meet with CMS to discuss these comments and other related issues of interest to our members. We would be more than happy to answer any questions you may have regarding these comments or to provide any additional information.

Sincerely,



Kendalle Burlin O'Connell, Esq.
CEO & President
MassBio

⁴ CMS, Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance (Aug. 21, 2023), p. 5.