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**RE: Solicitation for Feedback on CY 2025 IRA Part D Redesign**

Dear Deputy Administrator Seshamani:

The Massachusetts Biotechnology Council (MassBio) appreciates the opportunity to submit comments on the Centers for Medicare & Medicaid Services (CMS) solicitation for feedback on the Inflation Reduction Act (IRA) Part D Redesign for CY 2025 and beyond. 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 commends the Administration and Congress for including policies in the IRA's Part D Redesign that will further the Part D program's goal of ensuring access to lifesaving medications by providing strong protections for beneficiaries. The Part D Redesign will, for the first time in the history of the Part D program, place a cap on out-of-pocket (OOP) spending for Medicare Part D enrollees at \$2,000 starting in 2025. It also requires Part D plans to provide enrollees with the option to "smooth" their OOP costs below the cap into more manageable monthly payments over the course of the plan year, and places a cap on the yearly increase in beneficiary premiums. Furthermore, the Part D Redesign also simplifies the Part D benefit by eliminating the "coverage gap."

MassBio believes that the IRA's Part D Redesign includes important and much needed changes to the Part D benefit to increase access to life-saving medicines for America's seniors. However, successful implementation of the Part D Redesign will be crucial to realizing this underlying policy goal. In this letter, we provide the agency with our recommendations regarding two key aspects of the Part D Redesign. Our recommendations, which are explained in more detail below, can be summarized as follows:

- CMS' implementation of the "smoothing" provision should prioritize beneficiary education and facilitate flexible enrollment.

- CMS should maintain and enforce existing beneficiary protections and consider strengthening certain protections to address potential access barriers resulting from the Part D Redesign’s implementation.

### **1) CMS’ Implementation of the “Smoothing” Provision Should Prioritize Beneficiary Education and Facilitate Enrollment.**

The IRA requires Part D plans to provide beneficiaries the option to “smooth” their OOP payments over the course of the plan year. This will allow beneficiaries to spread their annual OOP responsibility throughout the year with manageable monthly payments, as opposed to the current framework under which beneficiaries can be faced with frontloaded OOP costs that ultimately can serve as a barrier to medication access and adherence. Given the importance of the new smoothing program to fulfilling the underlying goals of the Part D Redesign, it is essential that beneficiaries are educated regarding the program and do not face barriers to enrollment.

For example, CMS should ensure that messaging regarding the smoothing option is clear and consistent, and provided well in advance of CY 2025. Smoothing program messaging should be provided in promotional and educational materials at several different points of contact with the beneficiary, including at the pharmacy counter, CMS/Medicare Plan Finder websites, and on social media. CMS should also require Part D plans to include smoothing program educational materials in Part D plan materials beneficiaries are accustomed to receiving, such as such as the Annual Notice of Change (ANOC), the Evidence of Coverage (EOC), and the monthly Explanation of Benefits (EOB). Furthermore, as it does for other plan materials, CMS should establish standards and develop model materials specific to smoothing program education. Such standards should encompass language access, type face and other relevant standards to ensure these educational materials can be reasonably understood by all beneficiaries.

CMS should also establish a flexible enrollment process that ensures beneficiaries are not deprived of the statutorily designated option to enroll in a smoothing program because of technical or administrative barriers created by Part D plans. As such, CMS should utilize an approach that requires “passive enrollment,” for example, allowing an enrollee to “elect” the smoothing program by paying the lower, smoothed amount, as opposed to the full amount without smoothing. Beneficiaries should also be given the option to opt in to the smoothing program on an ongoing basis, including upon enrollment and at the pharmacy counter.

Last, CMS should establish guardrails on a plan’s ability to remove a beneficiary from its smoothing program for failure to make a payment. For example, CMS should establish a grace period that allows beneficiaries additional time to make a payment, so that slight delays in payment do not result in immediate removal from the plan’s smoothing program. Furthermore, CMS should provide for an appeals process that allows beneficiaries to challenge a Part D plan’s decision to remove the beneficiary from its smoothing program. Here, CMS could clarify that the existing right to appeal a Part D plan’s coverage determination regarding “the amount of cost sharing for a drug”<sup>1</sup> will also encompass a smoothing program removal appeal. Alternatively, CMS could establish a separate and distinct appeals process specifically applicable to Part D plan’s decision to remove a beneficiary from its smoothing program.

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<sup>1</sup> See 42 C.F.R. § 423.566(b).

## **2) CMS Should Maintain and Enforce Existing Beneficiary Protections and Consider Strengthening Certain Protections.**

The IRA's Part D Resign represents a transformation to the Part D program that will significantly alter the current framework of financial responsibilities for Part D plans. MassBio is concerned that this may, in turn, create unforeseen incentives for Part D plan sponsors to greater control costs through increased use of inappropriate utilization management. As such, in its implementation of the Part D Redesign, it will be imperative for CMS to ensure there are no unintended negative consequences on beneficiary access as a result of the Part D Redesign. Specifically, CMS should maintain and enforce existing protections for Part D beneficiaries outlined in regulations and guidance. The Part D program currently includes several important policies intended to protect vulnerable beneficiary access to medications. These policies include, but are not limited to, the six "protected" classes, beneficiary notification requirements, standards for convenient access to network pharmacies, formulary oversight and utilization management policy review. CMS should closely monitor Part D plan behavior during implementation of the Part D Redesign and strongly enforce these existing protections.

Furthermore, CMS should preemptively address the potential for new access barriers created by Part D plans as a result of the Part D Redesign by *strengthening* certain beneficiary protections. For example, CMS can strengthen existing formulary oversight and utilization management policy review mechanisms by departing from oversight standards that rely on generalized "standard industry" or "existing best" practices, and instead adopt a specific, widely accepted rigorous set of standards to guide the agency's review in these areas. This will help ensure that plans are not discriminating against certain beneficiaries by using formularies that discourage their enrollment, or using utilization management policies that restrict access to medically necessary medications. CMS can also provide stakeholders with additional guidance on when the agency will require coverage of more than two drugs for particular categories or classes in cases where the additional drugs present unique and important therapeutic advantages in terms of safety and efficacy, and their absence from the sponsor's formulary would substantially discourage enrollment by beneficiaries with disease states, for example among beneficiaries with rare disease.

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MassBio appreciates the opportunity to comment on this solicitation, and looks forward to continuing this dialogue with CMS as it proceeds with implementation of different aspects of the IRA, including Part D Redesign.

Sincerely,

Kendalle Burlin O'Connell  
President & CEO