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March 16, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: Medicare Prescription Payment Plan Guidance– Part Two
Baltimore, MD 21244–1810

Re: Medicare Prescription Payment Plan: Draft Part Two Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments

Dear Administrator Brooks-LaSure:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Center for Medicare and Medicaid Services' (CMS's/the Agency's) Medicare Prescription Payment Plan: Draft Part Two Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO membership includes biologics and vaccine manufacturers and developers who have worked closely with stakeholders across the spectrum, including the public health and advocacy communities, to support policies that help ensure access to innovative and life-saving medicines and vaccines for all individuals.

BIO's member companies work to discover transformative therapies that provide a significant, durable benefit and value for patient health outcomes, delivery of care, and overall health care spending. These novel, disruptive therapies are aimed at serious and rare diseases where patients often have limited treatment options. Taken together, our companies offer hope for cures and treatments where there was none, help reduce health care costs, and ensure a better quality of life.

General Comments

BIO thanks CMS for its continued efforts to implement the Medicare Prescription Payment Plan (MPPP) through this Draft Part 2 Guidance, the recently released Final Part 1 Guidance, and the recent ICR opportunity on the draft MPPP model materials. As we have stated in previous comments, BIO strongly supports the development of the MPPP which will make healthcare expenses more manageable for enrollees and reduce the immediate financial strain of significant out-of-pocket (OOP) costs. The timely implementation of the MPPP is essential as patients continue to struggle with substantial cost-sharing, which may lead them to delay or

forego necessary care. Many enrollees will benefit from the flexibility of spreading out payments over time, making it easier for them to manage their financial situation and access the care they need.

As CMS develops ways to facilitate education and outreach of the MPPP to enrollees, we encourage CMS to minimize the potential for enrollee confusion and develop model tools and resources necessary for enrollees to benefit from the program. Even though Part D sponsors play an important role in coordinating the MPPP, solely leaving many aspects of the MPPP up to plan discretion may create challenges and confusion for enrollees. Accordingly, CMS should ensure that plan-developed materials are clear, consistent, simple to understand, and easily accessible to enrollees. In addition, while we appreciate CMS' release of the draft MPPP model documents, we also request that CMS prioritize the development of a calculator-tool and other educational materials that will help enrollees understand their monthly cost-sharing obligations. As CMS develops its upcoming educational materials, the Agency should again allow for stakeholder input so that patients and other parties can be involved in the development of outreach and education materials and ensure that the materials are patient-centered and user-friendly. Our more detailed comments on the guidance are below.

30.1 General Outreach and Education

CMS proposes that Part D sponsors will educate enrollees about the MPPP using membership ID cards, Evidence of Coverage (EOC), Annual Notice of Change (ANOC), Explanation of Benefits (EOB), and their Part D sponsor website.

BIO thanks CMS for its guidance and willingness to prioritize MPPP outreach and education. We are supportive of widespread educational efforts on the MPPP and applaud CMS for its efforts in making the MPP available for all Part D enrollees in 2025. Educational materials on the MPPP not only will help encourage participation into the program but can also be used as an educational tool for beneficiaries to improve their health literacy. We greatly appreciate CMS' willingness to continue to actively work with stakeholders to develop easy-to-use educational tools that will minimize potential enrollee confusion regarding participation in the MPPP. However, we remain concerned that the level of discretion granted to Part D sponsors to operationalize the program may create further confusion and complexity for many enrollees.

For instance, while Part D sponsors are "encouraged" to provide enrollees with information on their estimated monthly payments before they enroll, they are not required to do so. Therefore, if the Part D sponsor chooses to not provide that level of specificity in their enrollment materials, a beneficiary may not understand how the MPPP could change their monthly payment obligations. As CMS confirms in the draft ICR draft model materials, "your payments might change every month, so you might not know what your exact bill will be ahead of time." This lack of information is particularly problematic for Medicare beneficiaries on fixed incomes who need to budget in advance so they can allocate funds for their prescriptions. Due to the high stakes of beneficiaries delaying prescription refills or abandoning them at the pharmacy, it is critical that Part D sponsors provide beneficiaries with estimated monthly payments under the MPPP. Both current and prospective enrollees need to be able to view their estimated monthly prescription OOP costs under the program so they can make informed decisions to assist with financial planning and make timely payments to prevent lapses in coverage.

BIO appreciates that CMS has included EOB within the required outreach and communication documents. As BIO has previously commented, enrollees will need to receive routine communication throughout the plan year regarding their cost sharing obligations under the MPPP; accordingly, the EOB will be an essential part of this reoccurring communication. As CMS develops the final EOB for CY 2025, we encourage CMS to include model language on how plans may provide beneficiaries with a projection of their cost sharing obligations, both with and without participation into the MPPP, to help beneficiaries determine whether they should opt-into the program.

As Part D sponsors send outreach and communication documents to Medicare beneficiaries, BIO also recommends that CMS consider taking the opportunity to remind beneficiaries about other important cost sharing support. For example, many Medicare beneficiaries are unaware that the IRA eliminated enrollee cost-sharing for recommended vaccines under Medicare Part D. CMS should also include explanations on the \$35 monthly cap on covered insulin products, restructuring of Part D benefit, and the expansion of eligibility for Extra Help (the Medicare Part D Low-Income Subsidy Program). Reminding beneficiaries within the outreach and communication documents would ensure that beneficiaries are informed of these important benefits and also encourage the uptake of important vaccines. Likewise, as Part D Sponsors are also required to provide materials to pharmacies to distribute at POS, CMS should also require these POS materials to be updated with information on the IRA vaccine cost-sharing benefit. Ensuring that beneficiaries are informed at pharmacy POS is critical as many beneficiaries receive vaccines on site at retail pharmacies. We encourage CMS to remind plans that they are required to cover all commercially viable vaccines under the IRA without utilization management and to adequately inform beneficiaries of these critical benefits.

BIO recognizes that the need for widespread beneficiary outreach should be balanced by the need for tailored and scenario-based tools that are adapted to the unique needs of enrollees. As CMS develops its educational products, we encourage the Agency to include a way for patients to receive tailored information on their monthly cost-share obligations, such as developing a scenario-planning calculator tool mentioned in the draft Part One guidance. A calculator tool is essential for beneficiaries to be well-informed about their specific cost-sharing obligations and how the MPPP may impact their final pay amount. The calculator tool should be developed with beneficiary feedback to ensure that it clearly and effectively explains the MPPP in a way that resonates with beneficiaries. CMS should develop this calculator tool as soon as feasible, with sufficient time for enrollees to use and comprehend the tool ahead of the Annual Election Period.

30.2 Targeted Outreach and Education Requirements for Part D Sponsors

CMS proposes a standardized framework for the “Likely to Benefit Notice” based on their analysis of historic Prescription Drug Event (PDE) records.

BIO supports requiring Part D sponsors to use the targeted outreach and education requirements for enrollees who are identified as likely to benefit, prior to and during the plan year. We also applaud CMS for requiring Part D sponsors to report information related to the MPPP through PDE records and submit beneficiary and contract Plan Benefit Package (PBP) level data related to program participation. As CMS monitors and collects data around MPPP participation, we request that CMS provide greater transparency around how the Agency will review MPPP information and report participation data so that stakeholders may be able to collaborate on offering a comprehensive support system to benefit enrollees. The ongoing

monitoring and assessment of MPPP implementation should be a collaborative and patient-centered approach so all parties can identify areas for improvement and enhance the effectiveness of the program. Outreach and education materials related to the MPPP should not create further beneficiary confusion but rather empower patients to understand their personal prescription drug costs.

As BIO has previously commented, beneficiaries may have very different OOP situations and each beneficiary's ability to benefit from the program may not be captured by a single prescription POS threshold. BIO is concerned with CMS' decision to finalize a \$600 single prescription POS threshold to identify enrollees likely to benefit, as this will likely exclude a large group of beneficiaries who could have otherwise benefited from the program. For instance, the threshold may exclude beneficiaries who take multiple prescription medications where each prescription falls under the \$600 threshold but the cumulative cost-sharing would be burdensome for the beneficiary. It is critical that this threshold does not overshadow a broader necessity of ensuring that the entire spectrum of Medicare enrollees receive choice and access to information about the MPPP. CMS should not only emphasize outreach and education materials for those beneficiaries who fit the "likely to benefit" criteria, but instead provide widespread outreach to the wider Medicare population so that all beneficiaries are able to make an informed decision on whether they would like to participate.

BIO supports the POS notification requirement which will allow for proactive and timely notification to beneficiaries. Similarly, BIO supports notification requirement that the Part D sponsor must provide the "Likely to Benefit Notice" if there are prior authorization or other utilization management edits that would result in OOP costs above the pharmacy POS notification threshold. As this is a minimum requirement, BIO recommends that this can be further strengthened by requiring additional identification criteria as CMS continues to assess and monitor MPPP participation. While we appreciate the requirement that additional identification criteria be uniformly applied to all enrollees, future guidance would be helpful to clarify and respond to beneficiary needs as the program is implemented, particularly for those beneficiaries that may not trigger the pharmacy POS notification threshold but may nonetheless benefit from the program.

In order to facilitate understanding between Part D sponsors, contracted providers, and network pharmacies on MPPP requirements, BIO requests that CMS provide educational materials on the MPPP as a part of CMS' existing provider communications. CMS could also explore additional materials to contracted pharmacies and providers to identify eligible patients in real-time and assist in the POS notification process.

30.3 Communications with Program Participants and Model Materials Requirements for Part D Sponsors

BIO appreciates CMS' release of the MPPP Model Documents and the opportunity to provide further comments through the ICR. While BIO will be providing more detailed comments on the model documents through the ICR process, in the meantime, we urge CMS to provide additional guidance to effectively operationalize some of the procedures outlined in the model materials. For instance, to supplement the "Notification of Termination of Participation," we urge CMS to develop a uniform process and timeline around reinstatements. Importantly, beneficiaries who experience temporary financial challenges should be given the opportunity to be reinstated into the MPPP after paying overdue amounts. While we greatly appreciate CMS' provisions in Final Part 1 Guidance that requires Part D sponsors to reinstate individuals who

demonstrate good cause for failure to pay and pays all overdue amounts billed, the Final Part 1 guidance gives Part D sponsors full discretion to reinstate those individuals within a “reasonable timeframe.” BIO remains concerned about the lack of a concrete timeline given that beneficiaries in vulnerable financial situations may need timely reinstatement in the MPPP option. A delayed reinstatement could cause beneficiaries to accrue significant OOP costs later in the calendar year where they may no longer have an option to distribute OOP costs within that calendar year. Accordingly, it is evident that CMS should clarify the definition of “reasonable timeframe” and provide additional guidance to protect beneficiaries’ rights to reinstatement into the MPPP.

BIO also requests that CMS develop further guidance and clarify how beneficiaries will be notified throughout the good cause and reinstatement process. As it currently stands, a beneficiary who demonstrates good cause and pay all overdue amounts may not receive any communication from the Part D sponsor regarding their eligibility for reinstatement in the subsequent plan year after they pay all overdue amounts. Absent any requirement for Part D sponsors to notify beneficiaries, beneficiaries may not understand or be aware of their two-month grace period, the opportunity to demonstrate good cause, their rights to be reinstated into the MPPP, and their need to proactively opt-in again if interested in the subsequent year. It is clear that CMS should actively ensure that Part D sponsors notify beneficiaries of the good cause determination opportunity and reinstatement rights, as well as develop a uniform process to clarify the role and responsibilities of Part D sponsors, beneficiaries, and any other parties around reinstatement. CMS should also ensure that beneficiaries are informed of their rights to appeal a Part D sponsor’s rejection of the good cause determination.

In addition, BIO urges CMS to develop greater protections for beneficiaries who fall into situations not specifically listed under the good cause criteria in the Final Part 1 Guidance. BIO remains concerned by the level of discretion given to Part D sponsors to reinstate those beneficiaries in the absence of clear and uniform procedures to assess a beneficiary’s unique circumstances that may have caused beneficiaries to miss payments in the past. Given the diverse medical needs and financial situations of Medicare beneficiaries, it is important that all beneficiaries be protected from unjust terminations and be given the opportunity to participate again after paying overdue amounts. BIO strongly believes that missed payments should not exclude beneficiaries from future participation in the MPPP, particularly after they have paid back overdue amounts. BIO urges CMS to develop protections for beneficiaries who may be inadvertently disenrolled after missed payments and provide opportunities for these beneficiaries to be reinstated if they so choose.

As BIO has previously commented, we continue to request that CMS explicitly require Part D sponsors to publicly report information on enrollees who are terminated from the MPPP and denied reentry into the MPPP in subsequent years. Part D sponsors could report this data through their existing obligation to report data elements related to the MPPP through the MARx System and HPMS, as expressed in the Final Part 1 Guidance. Information around terminations will greatly enhance accountability and transparency to ensure that enrollees are not unjustly terminated or prevented from participating.

40 CMS Part D Enrollee Education and Outreach

CMS proposes to develop an educational product for Part D enrollees on the Medicare.gov website and through other communication channels. CMS states that it will make appropriate

modifications to CMS-provided Medicare Part D documents, which may include the Medicare & You Handbook, Medicare.gov, and Medicare Plan Finder, among others.

BIO appreciates CMS' willingness to develop comprehensive educational resources on the MPPP in light of the inherent need to raise awareness of this important payment option. Ensuring the timely release of these educational resources ahead of the Annual Election Period will be critical to empower beneficiaries to participate in the MPPP and provide an opportunity for various stakeholders to collaborate on widespread outreach of the program. As CMS continues to develop and update these educational materials, additional clarity would be appreciated to help stakeholders understand their roles and responsibilities in assisting beneficiaries to make informed healthcare decisions. CMS should actively involve stakeholders in the drafting and development of these educational materials and ensure that such materials are patient-centered and provide clear, actionable, and accessible information to all parties.

Conclusion

BIO appreciates CMS' efforts to implement this payment option and looks forward to partnering with CMS to finalize operational details and drive patient access into the MPPP. Should you have any questions, please contact us at 202-962-9200.

Sincerely,

/s/

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/s/

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