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April 19, 2024

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

Re: The Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents (CMS-10882)

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) Information Collection Request (ICR) on the Part C and Part D Medicare Prescription Payment Plan (MPPP) Model Documents.

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.

As BIO has commented previously through the proposed Part 1 and Part 2 MPPP Guidance, the MPPP will be a critical benefit for patients to help them reduce the immediate financial strain of out-of-pocket costs. We appreciate CMS' development of the MPPP Model Documents and support CMS' ongoing efforts to facilitate education and outreach of the MPPP. As CMS continues to finalize guidance and develop resources on the MPPP, it is important that a robust toolkit of patient-centered materials be available to all Medicare beneficiaries so that any Medicare beneficiary as a potential enrollee can understand and utilize the MPPP. To that end, BIO offers the following suggestions to the Model Documents to ensure that the documents are clear, consistent, patient-centered, simple to understand, easily accessible, and minimize the potential for enrollee confusion.

Part D Sponsor Notice to Acknowledge Acceptance of Election in the Medicare Prescription Payment Plan

CMS' proposed Model Documents includes the following description: "Your payments may change every month, so you might not know what your exact bill will be ahead of time." BIO remains concerned that this language will create further beneficiary confusion. Patients may

interpret this language as a sign that they may receive surprise medical bills after participating in the MPPP or that their monthly bills will be irregular if they participate. As a result, patients may be less willing to enroll in the program. Although a Part D sponsor's projection of a patient's bill may vary from the actual bill, patients should feel empowered that they can use plan projections of a patient's monthly bills under the MPPP to spread out their financial obligations and plan for future months. Accordingly, the language in the Model Documents should reflect the resources available for enrollees to receive a projected breakdown of their monthly bill, including any potential calculator tools and/or other CMS or plan materials. Instead of the current language above, BIO proposes that the language instead be replaced with the following: "a projected breakdown of your monthly bills can be found at <insert link as appropriate>."

In addition, we encourage CMS to add the following language under "What Other Benefits Can I Utilize with my Medicare Part D Plan?" in order to remind enrollees of other important cost-savings that can be utilized.

BIO's proposed language is underlined below:

What Other Benefits Can I Utilize with my Medicare Part D Plan?
Starting 2024, Medicare Part D plans now offer the following:

- Removal of copays for recommended vaccines
 - CDC-recommended adult vaccines are now free for individuals with Medicare Part D.
- \$35 monthly cap on covered insulin products
 - Cost-sharing for insulin products is limited to no more than \$35 per month for people with Medicare Part D. No deductibles apply.
- Reduction in coinsurance
 - Individuals with Medicare Part D who reach the catastrophic phase of coverage will no longer have any out-of-pocket responsibility for covered drugs for the remainder of the year.

We also encourage CMS to add the following qualifier to the section under "Extra Help" so that individuals who may not have qualified for Extra Help in the past can be reminded that they now may qualify for the program, due to the expansion of eligibility of Extra Help under the IRA.

BIO's proposed language is underlined below:

Extra Help: A Medicare program that helps pay your Medicare drug costs if you have limited income and resources. Starting 2024, Extra Help has been expanded to provide more assistance to eligible individuals. Visit secure.ssa.gov/i1020/start to find out if you qualify and apply. You can also apply with your state's Medicaid office. Visit [Medicare.gov/basics/costs/help/drug-costs](https://www.Medicare.gov/basics/costs/help/drug-costs) to learn more.

Part D Sponsor Initial Notice for Failure to Make Payments under the Medicare Prescription Payment Plan

CMS' proposed Model Document includes the following description: "Like any other debt, you're required to pay the amount you owe." Enrollees may interpret this language incorrectly to infer that they may receive late fees similar to other debts owed. However, as CMS has

stated in guidance, enrollees will not be penalized with any late fees from missing payments under the MPPP. Accordingly, we believe that a qualifier should be added as follows: While you won't receive any late fees like with some other debts, you are still required to pay the amount you owe.

Part D Sponsor Notice for Failure to Make Payments under Medicare Prescription Payment Plan - Notification of Termination of Participation in the Medicare Prescription Payment Plan

BIO remains concerned that the current Model Document does not mention the opportunity for beneficiaries to demonstrate good cause and to be reinstated into the MPPP if they pay back overdue amounts. It is critical that patients who fall behind on payments be given the opportunity to reenroll in the program after paying back overdue amounts. As it currently stands, beneficiaries may not be aware of their reinstatement rights. Beneficiaries may also not be aware of the need to proactively opt-in again if they have been terminated from the MPPP but are interested in enrolling in a subsequent year. Accordingly, BIO proposes the following language underlined below:

Can I use this payment option in the future?

After paying back the total amount owed, you may contact your plan sponsor to be reinstated into the MPPP in the current plan year. Your plan sponsor may ask you to provide information to demonstrate good cause for nonpayment, like an emergency or unexpected situation.

In addition, we encourage CMS to include a new section within the Model Document, which may be titled "Important Information About Your Reinstatement Rights" to include more detailed information regarding enrollee rights for reinstatement. For instance, it is important that enrollees are aware of their right to appeal a Part D sponsor's rejection of the good cause determination. CMS can also use this section to inform enrollees of their ability to be reinstated in a subsequent plan year.

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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Healthcare Policy and Research

/s/

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