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April 10, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244–1850

RE: Medicare Part D Manufacturer Discount Program Agreement: HPMS Information to Execute MDP Agreements and to Determine Which Manufacturers Qualify as a Specified Manufacturer or Specified Small Manufacturer for Phased-in Discounts under 1860D-14C(g)(4) of the Social Security Act (CMS-10846)[1]

Dear Administrator Brooks-LaSure:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the proposed Information Collection Request (ICR) on the Medicare Part D Manufacturer Discount Program Agreement (CMS-10846), issued by the Centers for Medicare & Medicaid Services (CMS) on February 7, 2023. Information collected from manufacturers via this ICR is needed for CMS to execute Manufacturer Discount Program (MDP) agreements and to determine which manufacturers qualify as a specified manufacturer or a specified small manufacturer. We note this ICR shares many concepts with the recent Small Biotech Exception ICR (CMS-10844). To that end, many of our comments below reflect the comments we submitted on March 27, 2023 regarding the ICR on the Small Biotech Exception, particularly an emphasis on predictability and transparency and ensuring that eligibles companies qualify for this important provision.

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. As a result, 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 that have worked closely with stakeholders across the spectrum, including the

[1] FR, Vol 88, No. 25, P. 7976, February 7, 2023.

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public health and patient advocacy communities, to support policies that help ensure access to innovative and life-saving medicines and vaccines for all individuals.

Introduction

Small biotech manufacturers are at the forefront of America's innovation ecosystem. At BIO, we represent hundreds of biopharmaceutical manufacturers, with the vast majority of our members being small manufacturers who are working on some of the most important and cutting-edge scientific and medical research. Emerging biotech manufacturers are exceptionally productive, taking into account their lower market capitalization, and are responsible for nearly 80 percent of clinical drugs in the pipeline. Many of these companies have yet to achieve a revenue stream and rely on private capital and outside investment to fund their clinical trials and research. Ensuring that these manufacturers benefit from the small biotech provisions in the Inflation Reduction Act (IRA) is critical as America seeks to maintain its global competitiveness in this strategically important growth sector. Even more important is ensuring that these small manufacturers have the policy and regulatory environment they need to bring the next generation of medicines to the patients whose lives can be transformed by breakthroughs in new treatments and therapies. We look forward to working with you to ensure small biotech manufacturers benefit from these provisions in a manner that is consistent with Congressional intent.

BIO Comments

Determining Which Manufacturers Qualify as a Specified Manufacturer or Specified Small Manufacturer for Phased-in Discounts under 1860D-14C(g)(4) of the Social Security Act.

In the Supporting Statement, CMS notes the following:

> "MDP discounts are phased in for "specified manufacturers," defined at section 1860D14C(g)(4)(B) of the Act, and "specified small manufacturers," defined at section 1860D14C(g)(4)(C) of the Act. In order to implement the MDP, CMS will identify which participating manufacturers qualify for the phased-in discounts using Medicare claims data and ownership information submitted by manufacturers as part of this information collection, pursuant to the requirements at section 1860D-14C(g)(4) of the Act. When submitting comments on this collection, CMS requests that interested parties give particular attention to the new data fields included in Appendix A that are being added for this purpose."

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CMS also notes it will be releasing draft MDP guidance in mid-2023. BIO looks forward to the opportunity to comment on such guidance. In the interim, we would like to share our high level comments on this ICR (CMS-10846).

CMS does not address how or when it will notify manufacturers regarding its determination of whether a manufacturer, based on the information the manufacturer submits through the proposed ICR, qualifies for phased-in discounts as a specified manufacturer or specified small manufacturer. To that end, our comments that follow focus on ensuring predictability and transparency. This includes the following process attributes:

- Clear process (i.e., who submits, what to submit, when to submit) for qualifying for the phased-in discounts.
- Appropriate and fair timelines to submit information to qualify.
- Consistency and clear criteria in evaluating submissions for the phased-in discounts.
- Proper and timely notification regarding qualification if the manufacturer does or does not meet the requirements for the phased-in discounts, as well as a clear dispute process for appeal of such decision and fair timelines for appeal.
- Clarity regarding the form and manner that CMS will use to notify companies if they meet – or do not meet – the criteria for the phased-in discounts.

We note that the qualifications for "specified manufacturer and specified small manufacturer" for both phased-in discounts and the Small Biotech Exception from negotiation are similar and urge CMS to carry out parallel actions for implementing these protections, using the same approach and terminology, where relevant, for both (but recognizing that there will need to be separate forms for the Small Biotech Exception and the Part D phase-in, since the statutory requirements do differ in some respects). We note that while the February 7 ICR for the Medicare Part D Manufacturer Discount Program Agreement references Appendix A for HPMS, the Small Biotech Exception ICR of January 24 does not.

Moreover, as we have previously stated in our response to the January 24 ICR for the Small Biotech Exception, BIO encourages the Agency to provide further clarity on the process by which manufacturers can apply for and be evaluated for the specified manufacturer or specified small manufacturer phase-ins.

Specifically, we urge CMS to concentrate further on the following areas:

- *Clarity on Data Source for 2021 Drug Spending and Availability of Data for Manufacturers.* CMS should clarify what data source it will use for identifying 2021 total expenditures, as the agency has stated that the drug spending dashboard data published at *cms.gov* is not being used for the specified manufacturer and specified small manufacturer phased-in discount provisions; we also understand CMS is

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considering use of Prescription Drug Event (PDE) data. We recommend that CMS provide the data it will be using for 2021 to manufacturers so that this data can be validated by manufacturers that apply for (or will apply for) the specified manufacturer and specified small manufacturer phased-in discounts.

- *Clarity on Process and CMS Response to Manufacturer.* In the supporting statement, CMS notes that in order to participate in the MDP in 2025, manufacturers must provide the required information and enter into agreements with the agency no later than March 1, 2024. CMS should specify not only the timeline for when the submission of information by the specified manufacturer and specified small manufacturer is due, but also the timeline for CMS review and response to the manufacturer, in situations where CMS grants the phase-in as well as situations where CMS does not. To promote certainty for manufacturers, CMS should commit to responding to each manufacturer as far in advance of January 1, 2025, as possible.

- *CMS Response and Justification for Decision.* CMS should provide clarity on the form and content of its expected response and notification to manufacturers applying for the phase-in, specifically whether the response will be by letter, email, or other form of official communication. Further, if CMS determines that it does not agree that a manufacturer qualifies for the specified manufacturer or specified small manufacturer phase-in, CMS's response should outline in sufficient detail how such a determination was made, including on which expenditure data the agency relied and other information, as relevant, that led to a negative determination.

- *Dispute Resolution.* CMS should provide a dispute resolution process where applicants for the specified manufacturer or specified small manufacturer phase-in can respond to and appeal a negative determination by CMS. Specifically, manufacturers should have the opportunity to provide additional data or information to the agency to support its application for the specified manufacturer or specified small manufacturer phased-in discount.

- *Flexibility.* We agree with CMS' stated approach to require that manufacturers apply only once at the start of the program for the specified manufacturer or specified small manufacturer phase-in. Given that this is a new program and process, however, we recommend that the agency allow for a flexible approach. For example, if CMS determines that information submitted by the manufacturer is incomplete or unclear, we urge CMS to engage in a dialogue with the manufacturer to resolve any outstanding issues to complete their submission. Further, we encourage CMS to allow a manufacturer to submit information after the information submission

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deadline, such as in good faith circumstances where a manufacturer may later realize that it should qualify for the phased-in discount.

- *Clear Definition of Acquired.* The draft data fields in Appendix A to the ICR include the question "Was the submitting Manufacturer acquired by another Manufacturer after December 31, 2021?" To provide clarity to manufacturers, it is important that CMS define what it means to be "acquired" pursuant to Sec. 1860D–14C(g)(4)(B)(ii)(III) and 1860D–14C(g)(4)(C)(ii)(III). This may be a complex determination, particularly for manufacturers that are part of a controlled group. Accordingly, we ask that CMS solicit comments from stakeholders in the upcoming draft MDP guidance regarding the definition of "acquired" and consider those comments in formulating a final definition.

- *Confidentiality of Proprietary Information, Publication of Manufacturers Qualifying for Specified Manufacturer and Specified Small Manufacturer Phase-In.* CMS should fully protect the confidentiality of all proprietary information submitted in relation to this ICR. At the same time, CMS should outline its approach for sharing with the public information regarding the specified manufacturers and specified small manufacturers the agency determines qualify for the phase-in. Such information will be important for understanding the impact of this IRA provision and provide further certainty to specified manufacturers and specified small manufacturers.

- *Clear Direction as to Which Manufacturer Within a Controlled Group Should Submit the Specified Manufacturer and Specified Small Manufacturer Phase-In Form*. It is critical that manufacturers know the appropriate entity that should submit the form for the specified manufacturer and specified small manufacturer phase-in. This is particularly important in circumstances where multiple companies are part of a controlled group. Manufacturers can qualify for the phase-in for all of their applicable drugs and thus multiple members of a controlled group may market applicable drugs that qualify as specified drugs or specified small manufacturer drugs based on the status of the controlled group. To streamline the application process, CMS should clarify that only one member of a controlled group should submit the specified manufacturer and specified small manufacturer phase-in form on behalf of the controlled group. For controlled groups seeking to qualify as a specified small manufacturer, the labeler of the specified small manufacturer drug that constitutes 80 percent or more of the Part D total expenditures for all specified small manufacturer drugs of the controlled group should submit the form. For controlled groups seeking to qualify as specified manufacturers, any member of the controlled group should be permitted to submit the form on behalf of the controlled group.

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Process of Health Plan Management System (HPMS) Submission: In the supporting statement, CMS states that it plans to enhance the existing HPMS functionality in place for the Coverage Gap Discount Program to support the new requirements for the MDP, including for manufacturers to submit information needed to determine eligibility for the specified manufacturer or specified small manufacturer phase-in form. We look forward to engaging with CMS as it provides these updates to ensure their workability for all parties.

Conclusion: BIO looks forward to working with the Agency on IRA implementation and many other issues. Should you have any questions, please do not hesitate to contact either of us at 202-962-9200.

Sincerely,

/s/
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/s/
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