Biotechnology Innovation Organization
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August 4, 2023

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

RE: Information Collection Request 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 July 7, 2023. As noted by the Agency, 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.

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

[1] FR, Vol 88, No. 129, P. 43355, July 7, 2023.

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BIO Comments

As we have noted in previous comments to the Agency, 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 – including the phase-in of Part D discounts enacted as part of 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.

One of these critical provisions for small biotech companies is the phase-in of Part D discounts for certain drugs for "specified manufacturers" and "specified small manufacturers" (IRA section 1860D-14C(g)(4)). In related draft guidance released by CMS on May 12, 2023, the Agency states it will identify which manufacturers qualify for these phase-ins by analyzing Medicare Parts B and D claims data. CMS further stated that prior to releasing the revised HPMS Discount Program module in late 2023, the agency will release additional information explaining the methodology used to identify manufacturers eligible for phase-ins.

Clarity on Methodology. We strongly support CMS's release of information explaining the methodology it plans to use to identify manufacturers eligible for the phase-ins and urge the agency to release such information as soon as possible. In addition, we urge CMS to provide manufacturers access to the claims data it will use so the data can be validated by manufacturers who believe they qualify for the specified manufacturer and specified small manufacturer phased-in discounts.

Clarity on Timelines. We urge CMS to clarify as soon as possible the timeline for when ownership information should be submitted and the date in advance of March 1, 2024, by which CMS expects to confirm eligibility for the phase-in.

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Clarity on Form and Manner of Eligibility Determination. CMS should provide clarity on the form and manner for how it will provide an eligibility determination to manufacturers that submit and attest to the required ownership information. Further, if CMS determines that a manufacturer does not qualify for the specified manufacturer or specified small manufacturer phase-in, CMS should provide sufficient detail to the manufacturer regarding 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 those manufacturers determined by CMS to be ineligible for the specified manufacturer or specified small manufacturer phase-in can respond to and request a review of CMS's decision.

Flexibility. Given that this is a new program and process we recommend that the agency allow for a flexible approach. For example, if CMS determines that information submitted by the manufacturer regarding ownership information 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 deadline, such as in good faith circumstances where a manufacturer may later realize that it should qualify for the phased-in discount.

Confidentiality of Proprietary Information. CMS should fully protect the confidentiality of all proprietary information submitted in relation to qualification for the phase-ins.

Publication of Manufacturers Qualifying for Phase-Ins. We understand that CMS will provide a list of manufacturers qualifying for phase-ins to assist Part D sponsors. We recommend that CMS specify where and in what manner this information will be published, who will have access to this information, and what additional information (if any) CMS plans to provide along with the list of qualifying manufacturers.

Phase-Ins of Manufacturer Discounts and Beneficiary Access. As we have noted in previous comments to the Agency, CMS has not addressed whether Medicare or plans will be required to pick up the Part D liability from manufacturers that qualify for the phase-ins. We urge CMS to consider the impact of this issue on patient access and innovation. Increased liability for Part D plans may incentivize them to place additional formulary restrictions on manufacturer drugs qualifying for the phase-ins which could impact patient access to these drugs. The intent of the phase-ins is to drive innovation by supporting the ability of small manufacturers to recoup their investment in new potentially life-enhancing therapies.[2] If

[2] Chairman Ron Wyden, Principles for Drug Pricing Reform (June 2021), *available at* https://www.finance.senate.gov/imo/media/doc/062221%20SFC%20Drug%20Pricing%20Principles.pdf (drug

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additional access restrictions are placed on drugs developed by small/specified small manufacturers this may negatively impact future investment and innovation.

BIO looks forward to continuing engagement with the Agency on IRA implementation and many other issues. Should you have any questions, please do not hesitate to contact me at 202-962-9200.

Sincerely,

/s/
Crystal Kuntz
Senior Vice President
Healthcare Policy & Research
BIO

pricing reforms should be "tailored to the scale of [small biotechnology] companies, as well as other factors that affect their access to capital," which "take on a disproportionate share of the risk of R&D").