Biotechnology Innovation Organization
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July 14, 2025 **VIA ELECTRONIC DELIVERY**

The Honorable Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244–1850

RE: Negotiation Program Drug Selection for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request Forms (CMS-10844, OMB 0938-1443)

Dear Administrator Oz:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Drug Selection for Initial Price Applicability Year (IPAY) 2028 Information Collection Request (ICR) Forms, consisting of the Small Biotech Exception ICR Form, the Biosimilar Delay ICR Form, and the Identification and Selection of Renegotiation-Eligible Drugs ICR Form (altogether hereafter referred to as the Drug Selection ICR).

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.

Small Biotech Exception

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 patients whose lives can be transformed by breakthroughs in new treatments and therapies.

Importantly, the Small Biotech Exception recognizes that small biotech manufacturers with a single product that represents most of their Medicare revenue would be disproportionately impacted by

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Medicare "negotiation," which could have an immediate and tangible impact on the ability of such manufacturers to invest in future R&D – and in areas that predominantly affect the Medicare population. Our specific recommendations follow.

NDA Submissions. For the IPAY 2028 Form under the Part B track, CMS requests that manufacturers must "list the NDA(s) and/or BLA(s) that were held as of December 31, 2021, by the entity that held the NDA(s) or BLA(s) on December 31, 2021, for the qualifying single source drug for which the Submitting Manufacturer seeks the Small Biotech Exception (i.e., the entity identified in Question 6b). List all NDA(s) and/or BLA(s), including for drugs and biological products other than the qualifying single source drug for which the Submitting Manufacturer seeks the Small Biotech Exception."

BIO remains concerned that CMS' request for additional information related to BLAs and NDAs for which manufacturers are not seeking the Small Biotech Exception is unnecessary and burdensome. This language is also contrary to the reporting under Part D, which allowed manufacturers to list only those NDAs/BLAs tied to the active moiety or ingredient of the qualifying single source drug. BIO requests that CMS maintain consistency between the Part D and Part B and streamline the requirement so that manufacturers only need to submit the NDAs/BLAs for which they are seeking the Small Biotech Exception.

Paperwork Burden Estimate. For the IPAY 2028 Forms, CMS changed the paperwork burden estimate to 9.75 hours for all Submitting Manufacturers, constituting a large reduction in estimated hours for many manufacturers compared to previous years' estimates. BIO is concerned that this change underestimates the true reporting burden that manufacturers face in completing these forms, understating the time and effort needed to secure the Small Biotech Exception and ensure compliance for small biotech manufacturers.

Biosimilar Delay

High Likelihood Determination. BIO strongly believes that biosimilar manufacturers should be granted a meaningful opportunity to request a delay in the selection of a reference product for negotiation. As BIO has stated in our comments on the IPAY 2028 Draft Guidance, it is critical that the "high likelihood" determination is accurate and relies on all of the most recent available information that bears on the likelihood of market entry within the requisite time period.

Identification and Selection of Renegotiation-Eligible Drugs

As BIO has stated in our IPAY 2028 Draft Guidance comments, we request that CMS provide greater transparency into how CMS will utilize data submissions from this form to identify drugs selected for renegotiation. Clear insight into the rationale and methodologies for applying the proposed 15% MFP change threshold – and CMS's rationale for the 15% threshold itself – would help manufacturers better understand and prepare for potential renegotiation.

Thank you for your consideration of these comments.
Sincerely,

Melody Calkins
Director, Health Policy
Biotechnology Innovation Organization