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September 3, 2024

Submitted electronically to Regulations.gov

William N. Parham, III
Director
Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS-10849
Room C4–26–05
7500 Security Boulevard Baltimore, Maryland 21244–1850

RE: Information Collection Request Form for Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under Sections 11001 and 11002 (CMS-10849, OMB 0938-1452)

Dear Mr. Parnham:

The Massachusetts Biotechnology Council ("MassBio") appreciates this opportunity to submit comments on the above-referenced Information Collection Request (ICR).

MassBio represents the premier global life sciences and healthcare hub of Massachusetts, which has a vibrant biomedical research and development community that is a global leader for medical discovery and innovation. MassBio's 1,700+ member organizations are dedicated to preventing, treating, and curing diseases through transformative science and technology that brings value and hope to patients. MassBio's mission is to advance Massachusetts' leadership in the life sciences to grow the industry, add value to the healthcare system, and improve patient lives.

MassBio remains concerned about the impact the Medicare Drug Price Negotiation Program (the "Negotiation Program") will have on the future development of innovative and life-saving therapies, as well as on the world-leading small and emerging biotech companies based in Massachusetts. The data collected through the ICR will be the foundation of the Negotiation Program's activities for IPAY 2027. Therefore the ICR should be carefully constructed to mitigate these potential harms. In that light, we wish to raise two issues for CMS's consideration in design of the ICR.

1. With respect to the manufacturer-specific factors, in many cases CMS is proposing to collect data from manufacturers that CMS already has. This data collection will burden manufacturers and sap resources needed elsewhere.

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2. The instructions for public input should clearly describe how CMS will use public comments in the negotiation process, so the public can tailor their comments to CMS's needs.

CMS Should Not Collect Data Already in the Agency's Possession

Several of the categories of data CMS is proposing to collect from manufacturers describe information that CMS already has in its ready possession, or data that CMS could easily obtain from other federal agencies. For example, the collection and maintenance of Medicaid Best Price data and Part D Net price information is the responsibility of CMS, and CMS could use its own data sources for negotiation. The Federal Supply Schedule and Big Four prices could likewise be obtained through a request to colleagues across the federal government.

Nonetheless, CMS is proposing that manufacturers themselves collect and submit this data on CMS's behalf. The purpose of the Paperwork Reduction Act is to "minimize the paperwork burden for individuals, small businesses . . . and other persons resulting from the collection of information by or for the Federal Government." Accordingly, the very purpose of PRA's notice requirements is to impose upon CMS the duty to "evaluate whether the proposed collection of information is necessary," and to "minimize the burden of the collection of information on those who are to respond."[1] Certainly, the federal government re-collecting data from the public that it already collects is an unnecessary exercise. And CMS could easily reduce that burden by removing the duplication.

To the extent CMS has concerns about the accuracy of data, CMS could adopt procedures like it has done for other data elements like NDCs: pre-populate information compiled by CMS and make it available for manufacturers to review and confirm, or correct, CMS's sources.

Public Participation in the Negotiation Program

We appreciate that CMS has taken steps above and beyond those required under the Inflation Reduction Act to allow for public participation. The written submissions and listening sessions will provide an important opportunity for patients and others to have a meaningful voice in the Negotiation Program.

Recognizing the importance of public input, we urge CMS to structure the input process in a way that will maximize the usefulness of patient comments. As currently proposed, the instructions for public commentary do not detail how CMS will make use of information submitted, if at all. Patients are being asked to submit a lengthy and burdensome response, with no assurances or guidance on how CMS will take account of their views, if at all. This makes it difficult for the public to appropriately tailor their submissions to meet CMS's needs. And the lack of information my discourage the public from submitting comments altogether, if it feels that comments are not appreciated or useful. To help prevent this, CMS should add additional detail to the instructions making clear how public comments will be

[1] 44 U.S.C. § 3501, 3506.

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used and, ideally, take steps to conduct outreach to affected stakeholder groups to ensure their robust participation.

MassBio thanks CMS for your consideration of our comments. Please don't hesitate to contact me at (617)-674-5148 or kendalle.oconnell@massbio.org if you have any questions or would like any additional information to consider our comments.

Sincerely,

Kendalle Burlin O'Connell
CEO & President