MASSBIO

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September 3, 2024

Submitted electronically to Regulations.gov

Dr. Meena Seshamani, M.D., Ph.D.,
CMS Deputy Administrator & Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
Attention: CMS-1807-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CY 2025 Payment Policies Under the Physician Fee Schedule Proposed Rule (CMS-1807-P)

Dear Dr. Seshamani:

The Massachusetts Biotechnology Council ("MassBio") appreciates this opportunity to submit comments on the above-referenced Proposed Rule. Our comments are specifically focused on the codification of regulations for the Medicare Prescription Drug Inflation Rebate Program.

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.

We write to urge CMS not to estimate the number of 340B units of Part D rebatable drugs based on data from the Health Resources and Services Administration (HRSA), and instead to take an active role in identifying the actual number of such units.

Exclusion of 340B Acquired Units From Part D Rebatable Drug Requirements

MassBio objects to CMS's proposal to adopt an "estimation methodology" to remove 340B units from rebate calculations for Part D rebatable drugs. Instead, CMS should fulfill its statutory duty and actively identify units acquired through the 340B program so as to assure they are actually removed from the calculation as envisioned by Congress.

Our objection stems, in part, from CMS's proposal to use data from HRSA's Prime Vendor Program as the source of the estimate. MassBio members have long been frustrated by HRSA's lack of oversight the 340B program, including the 340B statute's duplicate discount prohibition. Without such oversight,

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covered entities have little motivation to avert the occurrence of double discounts, particularly since doing so is not in the covered entities' financial interest because it can result in their loss of 340B discounts. This gives little confidence that data supplied by HRSA for purposes of estimating 340B units of a Part D rebatable drug will be complete and accurate.

In order to ensure that inflation rebates for Part D drugs are not overstated, CMS should not engage in estimations, particularly based on potentially flawed data. Instead, CMS must take an active role in identifying units acquired through the 340B program and ensure the agency's own compliance with the statutory requirements to remove duplicate claims.

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