

September 12, 2025

Submitted electronically to Regulations.gov

Chris Klomp
CMS Deputy Administrator & Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
Attention: CMS-1834-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CY 2026 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Proposed Rule (CMS-1834-P)

Dear Mr. Klomp:

The Massachusetts Biotechnology Council (“MassBio”) appreciates this opportunity to submit comments on the above-referenced Proposed Rule.

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 life sciences to grow the industry, add value to the healthcare system, and improve patient lives.

We write to encourage CMS to use its forthcoming Drug Acquisition Cost Survey to help ensure patients can benefit from reduced cost sharing for drugs purchased via the 340B program.

In the Proposed Rule, CMS announced that it will launch a survey of the acquisition costs for each separately payable drug acquired by all hospitals paid under the OPPI. Based on recent statements made by the White House, MassBio understands the intent of this survey will be to lower Medicare payments under the Outpatient Prospective Payment System for 340B drugs.

The 340B program has grown tremendously in just the past few years, far eclipsing any possible expectations of its size. In 2023, 340B covered entities purchased \$66.3 billion in covered outpatient drugs under the 340B Program.¹ That number is a significant jump even from the year prior, during which covered entities bought a still-remarkable \$53.7 billion in covered outpatient

¹ <https://www.hrsa.gov/opa/updates/2023-340b-covered-entity-purchases>.

drugs.² This scope and scale is entirely inconsistent with how Congress originally conceived the program. The number of qualifying and participating covered entities has surged by over 600% since 2000, with more than 60,000 covered entities and over 33,000 contract pharmacies participating nationally in 2023.³

The proposed acquisition cost survey is an important step in the federal government's efforts to fully comprehend the size of this program, and begin to take action to remedy its ill effects. In particular, this growth has occurred in the absence of basic guardrails to ensure that patients, rather than supply chain intermediaries, fully benefit from the program's intended savings. For example, even though covered entities acquire drugs at a significant markdown, Medicare beneficiaries do not share in those benefits: When purchasing Part B-covered drugs from these covered entities they pay percentage-based cost sharing on the ordinary Medicare payment amount, typically 20 percent of ASP+6 percent. This turns the logic of the 340B program on its head, asking the most vulnerable patients to pay full price for a product that the covered entities acquire at a discount.

CMS has an historic opportunity to remedy these imbalances. Surveying providers to understand their acquisition costs can help CMS and the federal government gain full understanding of this program and how it has gone astray. We commend CMS for initiating this survey and look forward to commenting on the policies CMS proposes to implement its results.

MassBio thanks CMS for your consideration of our comments. Please don't hesitate to contact me at (617)-674-5100 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
President & CEO
Massachusetts Biotechnology Council (MassBio)

² Id.

³ U.S. Senate Committee on Health, Education, Labor & Pensions. Congress Must Act to Bring Needed Reforms to the 340B Drug Pricing Program: Majority Staff Report. April 2025. https://www.help.senate.gov/imo/media/doc/final_340b_majority_staff_reportpdf1.pdf.