

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-1832-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies Proposed Rule (CMS-1832-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 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. We also urge CMS to exclude Maximum Fair Price (MFP) units from Average Sales Price (ASP), and not to finalize the agency’s proposals with respect to preparatory procedures associated with cell and gene therapy.

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

MassBio appreciates CMS’s continued efforts to develop an accurate methodology for removing 340B units from rebate calculations for Part D rebatable drugs, so as to assure they are actually removed from the calculation as envisioned by Congress.

We are strongly concerned that the proposed “Prescriber-Pharmacy Methodology” will not fully accomplish this purpose, and recommend that CMS adopt improvements to it. As CMS readily acknowledges, the lists of providers and pharmacies it uses to power this estimation is necessarily missing prescribers and pharmacies. The 340B OPAIS database, like many other HRSA data sources, is incomplete—generally reflecting HRSA’s lack of oversight over the 340B program, including the 340B

statute's duplicate discount prohibition. We suggest that among the measures CMS takes to improve the data quality, CMS permit manufacturers to report errors in the prescriber-pharmacy listings, and that once corrected such errors should be fixed retroactively in CMS's monthly files.

Even with these efforts, the Prescriber-Pharmacy Methodology remains an "estimate" and falls short of accurate accounting of 340B units for purposes of exclusion from the rebate calculation. For this reason, MassBio supports CMS's proposal to establish a Medicare Part D claims data 340B repository. We agree that CMS should collect claim-level information on Part D 340B claims, and assess its usefulness for excluding units from the Part D rebate calculation. This data could also have further wide-reaching uses across the 340B, Medicare, and Medicaid programs.

For the claims repository to be valid and have maximum utility, the data it holds must be complete. Accordingly, we suggest that submission of data to the repository be mandatory, rather than voluntary, on the part of 340B-covered entities. Such a mandatory requirement could be authorized under CMS's authority to establish "a uniform system for the reporting," of "discharge and bill data" by facilities and organizations,¹ as well as CMS's other general authorities over Medicare-enrolled organizations.

Average Sales Price: Units Sold at Maximum Fair Price

MassBio objects to CMS's proposal to include units of selected drugs under the Medicare Drug Price Negotiation Program sold at Maximum Fair Price in the calculation of the manufacturer's ASP.

The ASP has long been an industry benchmark for prices of therapies. CMS may make specific use of ASP for payment under section 1847A. But it has uses across the health care industry and far beyond Medicare. Including Maximum Fair Price (MFP) discounts in the ASP will wreak havoc on these systems, by artificially depressing ASP, and making it appear that a discount available only to Medicare patients is in fact available to all. This will undermine one of the few reliable drug pricing benchmarks in the United States. This proposal also would impermissibly extend the impact of MFP for an additional two quarters after a product is removed from the selected drug list.

We urge CMS to reconsider its proposal, and to not include Maximum Fair Price sales in the ASP calculation. We believe CMS has the authority to do so. Specifically, section 1847A(b)(2)(B) of the Social Security Act authorizes CMS to determine what constitutes a "unit" for the purposes of calculating ASP. If a sale of a product is not counted as a "unit" for the purposes of ASP, it is not included in ASP calculation. CMS has used this authority to exclude units purchased through the Competitive Acquisition Program (CAP) in 2005,² and should use this authority again to exclude units of selected drug purchased at MFP. Similar to the CAP, the Inflation Reduction Act's Medicare Drug Price Negotiation Program represents an alternative system for Medicare pricing and reimbursement for Part B drugs, separate and apart from ASP-based reimbursement.

Autologous Cell-Based Immunotherapy and Gene Therapy Payment

MassBio does not support CMS's proposal that preparatory procedures for tissue procurement required for manufacturing an autologous cell-based immunotherapy or gene therapy be included in the payment of the product itself.

¹ SSA § 1121.

² 70 Fed. Reg. 70,479 ("[I]n accordance with our statutory authority, including our authority under section 1847A(b)(2)(B) of the Act to establish methods for counting units, we have decided to exclude, for the initial 3-year contract period under the CAP, units of CAP drugs that are administered to beneficiaries by participating CAP physicians.").

CMS accurately describes how these therapies have a unique and multi-stage preparation process that involves multiple parties cooperating to collect cells, alteration to create the therapy and administration. In any other context, a physician participating in this process, by collecting cells from a patient, using their professional skill and acumen to physically withdraw a specimen from a Medicare beneficiary, would be viewed as performing a physician's service for which they should be compensated under the PFS. Yet CMS chooses to categorize these services as a mere "part of the manufacturing process," and will not pay for this service separately.

Cell-based immunotherapy and gene therapies represent the forefront of medicine, with the potential for durable and even curative results. It should be CMS's goal to encourage beneficiary access to these therapies through appropriate reimbursement. That appropriate reimbursement includes sufficient payment to the health care professionals who perform the services associated with their use. Yet rather than adopt an innovative payment approach to match the innovation occurring in therapies and their administration, CMS proposes an approach whose chief justifications seems to be that it will "continue[] the current payment policies" in order to remain "consistent." We urge CMS to look beyond "consistency" and to separately compensate physicians performing preparatory procedures.

We note also that this proposed policy's corollary, that payments for cell collection services are not bona fide service fees, is confusing and may be difficult for manufacturers to interpret and comply with. Were CMS to adopt its proposed policy to not pay for cell collection, a more straightforward approach would be to treat payments for cell collection as a bona fide service fee, together with guidance from CMS and OIG on how the fair market value for these payments should be determined.

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)