August 31, 2026

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
ATTN: CMS-1850-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; and Quality Reporting Programs, 91 Fed. Reg. 41734 (July 7, 2026) — File Code CMS-1850-P; 340B Drug Payment Policy, 340B Remedy Offset, and Billing Modifier Proposals[1]

Dear Administrator Oz:

The National Association of Specialty Pharmacy (NASP) appreciates the opportunity to comment on the CY 2027 OPPS/ASC proposed rule. NASP is the only national association representing all stakeholders in the specialty pharmacy industry, with more than 200 corporate members and 3500 total members, including independent and health-system specialty pharmacies, integrated delivery networks and hospitals, manufacturers, distributors, pharmacy benefit managers, group purchasing organizations, data and technology vendors, logistics providers, patient advocacy organizations, and practicing pharmacists, nurses, and pharmacy technicians. NASP's members dispense and manage the high-cost, high-touch therapies that patients with cancer, autoimmune disease, HIV, hemophilia, and other complex conditions depend on, along with the clinical management, adherence support, benefits navigation, and financial assistance coordination needed to support patients on these therapies.

These comments are limited to the 340B-related provisions of the proposed rule: the proposed payment rate adjustments, the reliability of the underlying Outpatient Drug Acquisition Cost Survey (ODACS), the proposed acceleration of the 340B remedy offset, the absence of an add-on payment for overhead and handling, and the JG/TB/XX billing modifier framework.

Summary of NASP's Comments

NASP has serious concerns about the proposed reduction in Medicare payment for 340B-acquired drugs and urges CMS not to finalize it. Specifically, NASP recommends that CMS:

[1]Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; and Quality Reporting Programs, 91 Fed. Reg. 41734 (July 7, 2026) (File Code CMS-1850-P). https://www.federalregister.gov/documents/2026/07/07/2026-13656/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment

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- Withdraw the proposal to pay for 340B-acquired drugs at ASP minus 33.4 percent nor the alternative rate of ASP minus 28.0 percent. These proposed reductions rely on a survey that a large majority of 340B hospitals did not answer, and a reduction of this magnitude would seriously undermine the purpose for which Congress established the 340B Program.
- Release the underlying ODACS data and provide an additional comment period before advancing any acquisition-cost-based payment change.
- Acquisition cost alone does not reflect the cost of a compliant 340B program, and CMS must undertake an effort to recognize the full costs needed to operate a 340B program.

I. Significant Payment Reductions Would Undercut the Goals of the 340B Program

CMS proposes to pay for 340B-acquired drugs at ASP minus 33.4 percent beginning January 1, 2027 — by CMS' own calculation, a payment level 37.2 percent below the general OPPS rate of ASP plus 6 percent.[2]

Congress created the 340B Program so that covered entities could stretch scarce federal resources to reach more eligible patients and provide more comprehensive services. Savings realized on Medicare outpatient drug claims are the mechanism through which that purpose is achieved. The proposed reduction removes those resources from the entities Congress intended to receive them to support patients and redistributes them, to providers that do not serve the role intended by Congress. NASP shares the concerns expressed across the hospital community that the proposed cut will make drugs less affordable for America's most vulnerable patients.

From a specialty pharmacy perspective, the consequences are patient-facing. The clinical infrastructure that supports specialty therapies at 340B covered entities and their contract pharmacy partners, including prior authorization and benefits navigation, adherence monitoring, financial assistance coordination, and ongoing care management, is essential to ensuring patients can access, initiate, and remain on complex therapies. These resource-intensive services cannot simply be scaled back without consequences for patient care. NASP is also concerned that a reduction of this magnitude could undermine the financial viability of contract pharmacy arrangements, potentially reducing patients' access to specialty pharmacy services and limiting their ability to receive care from the specialty pharmacy of their choice, that best meets their needs.

[2]Id. at 41887.

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II. The ODACS Data Does Not Support a Payment Reduction of This Magnitude

CMS solicited comment on its evaluation of the ODACS data. NASP does not believe the survey data collected supports the conclusions drawn from it and urges CMS to reconsider whether section 1833(t)(14)(D)(iii) of the Act requiring "a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug" has been satisfied.

- **Participation was low, and lowest among the hospitals most affected.** Of 4,494 survey-eligible entities, 1,958 (43.6 percent) submitted any response and only 1,338 (29.8 percent) reported acquiring a surveyed drug. Among 340B hospitals, 537 of 1,957 (27.4 percent) responded and 453 (23.1 percent) reported acquisitions. Even after CMS' population refinements, the 340B response rate is 28.6 percent.[3]
- **More than seven in ten affected hospitals did not report 340B acquisition costs.** CMS' sample includes data from less than a third of the 340B hospitals that would ultimately be subject to the proposed massive reimbursement cuts.
- **Exclusion of above-ceiling observations biases the estimate downward.** CMS excluded 4,667 records in which reported per-unit 340B acquisition cost exceeded the applicable ceiling price. Costs above ceiling do occur — in shortage conditions, in pricing disputes, and where reported costs include storage or handling components. Removing the highest reported values deflates the estimated average acquisition cost and inflates the apparent discount relative to ASP.[4]

Before finalizing any acquisition-cost-based methodology, NASP urges CMS to release the underlying survey data and provide an additional comment period to allow for additional insight on the data being considered.

III. Acquisition Cost Alone Does Not Reflect the Cost of a Compliant 340B Program

CMS proposes no add-on payment for overhead and handling, reasoning that a "prudent" estimate of acquisition cost may already account for overhead and that hospitals will likely negotiate additional discounts.[5] NASP disagrees, and notes that section 1833(t)(14)(E) of the Act expressly

[3]CMS, 2026 OPPS Drug Acquisition Cost Survey Technical Report, https://www.cms.gov/files/document/opps-drug-acquisition-cost-survey-technical-report.pdf.
[4]AHA Comment Letter, supra note 8 (describing exclusion of 4,667 records reporting per-unit 340B acquisition costs above the applicable ceiling price; removing the highest reported acquisition costs deflates the estimated average acquisition cost).
[5]91 Fed. Reg. at 41889; section 1833(t)(14)(E) of the Act authorizes an adjustment for overhead and related expenses, such as pharmacy services and handling costs.

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authorizes an adjustment for overhead and related expenses, including pharmacy services and handling costs.

Acquisition cost measures what an entity paid for a unit of drug, not what it costs to dispense that drug safely and in compliance with program requirements. Those costs are substantial and are borne by specialty pharmacies and covered entities:

- Compliance oversight, including patient definition and eligibility determinations, internal auditing, corrective action, and HRSA audit preparation;
- Diversion and duplicate discount prevention, including Medicaid exclusion file management;
- Contract pharmacy administration, contracting, monitoring, and reporting; and
- Cold chain and hazardous drug handling, secure storage, and the pharmacist and staffing labor required for clinical review, counseling, and adherence monitoring.

CMS' assumption that entities will negotiate further discounts to absorb these costs is not a substitute for measuring them. Setting payment at an aggregate acquisition cost proxy with no recognition of dispensing and compliance overhead understates the true cost of furnishing these drugs. CMS should collect data on 340B overhead, dispensing, and compliance costs before concluding that no adjustment is warranted.

IV. Conclusion

NASP urges CMS not to finalize the proposed reduction in payment for 340B-acquired drugs, in its proposal or proposed alternative. The survey evidence underlying the proposal is incomplete and insufficient, fails to account for the operational costs of maintaining a compliant 340B program, and does not provide an adequate basis for a policy change with such significant potential consequences for patients who depend on specialty therapies.

Thank you for considering these comments. Please contact me at sheila.arquette@naspnet.org with any questions.

Respectfully submitted,

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President & Chief Executive Officer

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