NATIONAL ASSOCIATION OF SPECIALTY PHARMACY

September 14, 2026

Submitted electronically via www.regulations.gov
The Honorable Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1848–P
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: CMS–1848–P — CY 2027 Physician Fee Schedule Proposed Rule; Medicare Prescription Drug Inflation Rebate Program — Mandatory Reporting to the Medicare Part D Claims Data 340B Repository (Proposed 42 C.F.R. §§ 424.516(f)(4), 424.535(a)(10), and 428.203(c))

Dear Dr. Oz:

The National Association of Specialty Pharmacy (NASP) appreciates the opportunity to comment on the CY 2027 Physician Fee Schedule proposed rule.[1] 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-touch and often high-cost 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.

NASP member pharmacies serve as contract pharmacies for 340B covered entities, and the operational consequences of the 340B proposals included in the proposed rule would have direct implications on them. These comments are limited to the proposal to convert voluntary reporting to the Medicare Part D Claims Data 340B Repository into a mandatory Medicare enrollment obligation. Specialty pharmacy will be disproportionately affected as CMS itself notes evidence that specialty medications are more than 20 times more likely to be dispensed

[1] Medicare and Medicaid Programs; CY 2027 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program, 91 FR 43842 (July 16, 2026). https://www.govinfo.gov/content/pkg/FR-2026-07-16/pdf/2026-14327.pdf

through the 340B Program than other drugs. NASP supports accurate identification of 340B units and the statutory goal of preventing duplicate discounts. Our recommendations are directed at making the requirement operationally achievable without disrupting patient access.

Summary of Recommendations

- **Retain quarterly reporting.** Do not adopt a more frequent cadence.
- **Phase in the mandate** and treat 2027 as a transition year, with a good-faith compliance standard and an express opportunity to correct errors.
- **Do not expand the data elements** absent a demonstrated programmatic need.
- **Issue operational guidance before January 1, 2027,** on responsibility for submission across covered entities, contract pharmacies, and third- party administrators (TPAs), and on the treatment of claims identified as 340B-eligible only after adjudication.
- **Adopt a graduated compliance pathway** to include education, notice, and corrective action plans before any targeted Medicare enrollment sanction.
- **Revisit the burden estimate** which understates the technology and staffing investment required, particularly for smaller covered entities and their pharmacy partners.

I. The Proposed Quarterly Submission Cadence Is Reasonable and Should Be Retained

NASP supports the proposal at § 428.203(c)(3) requiring quarterly submission within one calendar quarter following the close of the relevant quarter. A quarterly cadence aligns reasonably well with the reconciliation cycles that already govern 340B contract pharmacy arrangements.

NASP urges CMS not to adopt a more frequent cadence, whether monthly or claim-by-claim. More frequent reporting would create significant administrative burden without improving data quality. Because contract pharmacy models rely on retrospective replenishment and complex claims reconciliation, data submitted on a shorter cycle would be materially less complete and would generate a higher volume of downstream corrections, increasing burden for submitters and for CMS while degrading the reliability of the very dataset the agency intends to evaluate.

II. Converting a Voluntary Process into a Condition of Enrollment Requires a Phased Implementation and a Realistic Burden Estimate

The shift from voluntary to mandatory reporting is not a marginal change in an existing workflow; for many participants it requires building a reporting function that does not exist today. Covered entities, contract pharmacies, and TPAs will need new data extracts, validation

logic, reconciliation controls, secure transmission pathways, certification workflows, and trained personnel to operate them.

CMS estimates approximately 14,000 responding 340B providers, 56,000 annual submissions, eight hours of labor per submission, and an aggregate annual burden of 462,000 hours and roughly $52.4 million.[2] In NASP's view, that is likely a gross underestimation that fails to account for the work that precedes development of the submission, including system development and integration, TPA contracting and data-use amendments, ongoing validation across multiple pharmacy partners, and the compliance oversight necessary to support a certification of completeness and accuracy. The estimate also assumes a level of automation that likely will not exist in year one across the board.

NASP members' practical reference point is the experience with OASIS-style federal data collection: a laborious process requiring dedicated submission software and specialized staff. Where a new federal reporting channel demands its own software and specialized personnel, the constraint is typically staffing related. Large health systems have departments dedicated to 340B compliance. Smaller covered entities — rural hospitals, grantees, community clinics, and the pharmacies that serve them, often do not. NASP is concerned smaller entities, and contract pharmacies will be unable to fund the necessary systems and staffing under the proposed timeline.

NASP recommends that CMS: phase in the requirement, designating 2027 as a transition period in which submissions are required but assessed under a good-faith compliance standard; publish file specifications, testing tools, and a validation environment well in advance of the first mandatory reporting period; and confirm that submitters may correct identified errors without penalty. CMS should also consider a targeted accommodation, such as an extended first-year timeline or a phased entity submission pathway for low-volume covered entities.

III. The Proposed Data Elements Are Appropriate and Should Not Be Expanded

The five claim-level elements proposed at § 428.203(c)(1): date of service, prescription or service reference number, fill number, dispensing pharmacy NPI, and NDC–11, together with the covered entity's 340B ID and OPAIS name, appear sufficient to identify and match claims to PDE records. NASP appreciates that CMS aligned the mandatory elements with those already specified for voluntary submission, which preserves the value of 2026 testing work.

Collecting, validating, and transmitting these elements consistently across thousands of covered entities, tens of thousands of contract pharmacy relationships, and multiple TPA

[2] 91 FR 44223 (ICR regarding Sec. 428.203(c), OMB control number 0938-1485 (CMS-10930)). https://www.govinfo.gov/content/pkg/FR-2026-07-16/pdf/2026-14327.pdf

platforms will require significant system development and sustained oversight. NASP therefore urges CMS not to add data fields, including patient-level, prescriber-level, pricing, or claim-financial data, unless the agency first demonstrates a clear programmatic need and provides a notice and comment opportunity to receive stakeholder feedback.

IV. Operational Readiness and Retrospective Replenishment Are the Central Implementation Challenges

CMS correctly recognizes that the requirement reaches claims dispensed by contract pharmacies and identified as 340B-eligible through retrospective replenishment models. In specialty pharmacy practice, 340B eligibility is typically determined days or weeks after dispensing, following prescriber-affiliation and patient-eligibility review by the covered entity or its TPA. A claim's 340B status is therefore a moving determination, and a meaningful share of eligible claims are identified after initial adjudication, in some cases after the quarterly submission deadline has passed.

NASP appreciates that CMS has proposed a resubmission mechanism at § 428.203(c)(4) and has acknowledged that TPAs and other vendors may submit on a 340B provider's behalf. Those provisions are necessary but not yet sufficient, because the operative details are deferred to future guidance. NASP recommends that CMS, before the first mandatory reporting period:

- Publish the corrections process and its timing, including the window for adding claims later determined to be 340B-eligible and for correcting previously submitted claims, and confirm that a timely, good-faith submission followed by a later correction would be considered compliant.
- Recognize that contract pharmacies and TPAs hold the transactional data but are not the enrolled parties subject to § 424.516(f)(4). CMS should confirm in the final rule that the reporting obligation and the certification rest with the covered entity and that a contract pharmacy is not independently exposed to Medicare enrollment action for a covered entity's reporting failure, and that a covered entity may rely in good faith on data furnished by its contract pharmacies and TPAs.
- Ensure the certification attests to completeness and accuracy as of the date of submission, based on the eligibility determinations then available. This is consistent with the retrospective nature of replenishment and with CMS's own recognition that 340B status is generally not known at the point of sale.
- Confirm the technical channel and data use terms early, including file format, transmission method, volume limits, testing availability, and the contractual and privacy terms that allow TPAs and pharmacies to transmit data on a covered entity's behalf.

V. Medicare Enrollment Revocation Is Disproportionate for Reporting Deficiencies

CMS proposes to enforce the requirement through § 424.516(f)(4), reserving the right to revoke Medicare enrollment under existing § 424.535(a)(10) for noncompliance.[3] Revocation is a serious decision. Applying it to a data-submission deficiency — particularly a late, incomplete, or subsequently corrected submission during the first years of a brand-new reporting channel — is disproportionate to the conduct and to the programmatic interest at stake, especially because CMS has stated it will not use repository data to calculate rebates under this proposal.

The consequences of this severe sanction would fall on patients. Revoking a covered entity's Medicare enrollment interrupts care for beneficiaries with cancer, transplant, and other complex conditions, and destabilizes the specialty pharmacy relationships that sustain that care — and would be a risk concentrated significantly among entities most pressed to build compliant reporting infrastructure quickly.

NASP recommends that CMS adopt a graduated compliance approach in the final rule: (1) education and technical assistance; (2) written notice of a deficiency with a defined cure period; (3) a corrective action plan; and (4) enrollment action reserved for persistent, willful, or egregious noncompliance after those steps have failed. CMS should also state expressly that it will not pursue enrollment action for reporting deficiencies during the transition period.

VI. Confidentiality and Scope Commitments Should Be Preserved in the Final Rule

NASP supports CMS's statements that repository data will not be made available to external parties, including manufacturers and Part D plan sponsors, and that any future use of repository data to remove 340B units from rebate calculations would proceed through notice and comment rulemaking. NASP urges CMS to restate both commitments in the final rule, and to confirm that repository data will not be repurposed for other 340B oversight, audit, or enforcement activities without separate rulemaking.

Conclusion

NASP shares CMS's objective of identifying 340B units accurately and protecting against duplicate discounts. A quarterly cadence, a stable and limited data set, a workable corrections pathway, clear allocation of responsibility across covered entities and their pharmacy partners, and a graduated compliance approach will produce better data than an accelerated mandate enforced by the threat

[3] 91 FR 44012. https://www.govinfo.gov/content/pkg/FR-2026-07-16/pdf/2026-14327.pdf

of revocation. NASP appreciates your consideration of these comments. Please contact us with any questions.

Respectfully submitted,

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President & CEO

National Association of Specialty Pharmacy