340B at an Inflection Point: Preparing for CY 2027 Payment and Operational Changes

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Today, few topics demand as much strategic attention in healthcare government reimbursement as the 340B Drug Pricing Program. The 340B program is a critical financial lifeline for safety-net providers, but it is currently facing unprecedented operational, legal, and legislative pressures. Below, we break down the history of the program, the most pressing structural threats, and a sweeping new regulatory proposal from CMS that could fundamentally impact your bottom line.

A Brief History: From Protection to Rapid Expansion

The 340B program was created by Congress in 1992 under Section 340B of the Public Health Service Act. Its original purpose was straightforward: to shield safety-net providers from the unintended consequences of the newly created Medicaid Drug Rebate Program, which had inadvertently caused drug prices to spike for clinics serving vulnerable communities.

By requiring pharmaceutical manufacturers to provide steep upfront discounts (typically 20% to 50%) on outpatient drugs as a condition of having their drugs covered by Medicaid and Medicare Part B, Congress enabled "covered entities" to stretch scarce federal resources.

However, the modern 340B landscape looks vastly different due to two major catalysts:

1. **The 2010 Expansion:** The Affordable Care Act (ACA) significantly expanded the types of hospitals eligible to participate. Around the same time, federal regulators permitted covered entities to contract with an unlimited number of external, commercial pharmacies (contract pharmacies) to dispense these discounted drugs.
2. **Exponential Growth:** What began as a targeted program for select public health clinics has grown into the second-largest federal drug program behind Medicare Part D, processing tens of billions of dollars in discounted drug sales annually.

Regulatory Flashpoint: The CY 2027 Proposed Rules

The public comment window for the CY 2027 Outpatient Prospective Payment System (OPPS) Proposed Rule closed on August 31, 2026, while the comment period for the CY 2027 Physician Fee Schedule (PFS) Proposed Rule closed on September 14, 2026. With the public comment phase now concluded, federal agencies are reviewing stakeholder input ahead of final rules slated to take effect on January 1, 2027. The financial impact will vary by organization based on Medicare Part B drug utilization, payer mix, and the extent to which individual drugs are separately reimbursed under OPPS. Hospitals should begin modeling the potential impact using their own historical claims and drug utilization data rather than relying solely on CMS's aggregate estimate.

The structural changes driving these individualized financial impacts are concentrated on three major regulatory pressure points:

Proposed Medicare Payment Reduction:

CMS proposes reducing Medicare Part B payments for separately payable 340B-acquired drugs under the OPPS to average sales price (ASP) minus 33.4%, compared with the current general rate of ASP plus 6%. CMS is relying on a 2026 hospital acquisition-cost survey to support the proposed payment methodology following the Supreme Court's 2022 decision.

New Mandatory Part D Repository:

Under the proposed PFS rule, CMS intends to establish a mandatory Medicare Part D Claims Data 340B Repository. Following a voluntary soft-launch period opening on October 1, 2026, covered entities would be required to submit claim-level data for applicable Part D 340B claims beginning with dates of service on or after January 1, 2027, generally on a quarterly basis.

Accelerated Remedy Recoupment:

To pay for the multi-billion-dollar settlement mandated by the courts for those historical 340B underpayments, CMS is proposing to accelerate its budget-neutral recoupment from providers. CMS proposes increasing the annual OPPS conversion-factor offset from 0.5% to 3% beginning in 2027, which CMS estimates would complete the recovery by 2029. Although the proposal is intended to be budget-neutral across OPPS, it would not necessarily be budget-neutral for an individual hospital. The net impact would depend on the organization's 340B drug volume, mix of separately payable drugs, and share of non-drug OPPS services.

The proposal would not affect every provider or drug claim in the same manner. Certain hospital categories would be exempt, and CMS is proposing revised modifier requirements to identify whether separately payable drugs were acquired through the 340B program.

Ongoing Operational Challenges

In addition to the impending CMS rule, providers must still navigate a highly fractured operating environment:



The Shift Toward a Rebate Model:

Historically, 340B has operated as an upfront discount. However, some pharmaceutical manufacturers are pursuing a shift to a back-end rebate model where providers must buy drugs at full cost and wait for reimbursement. HRSA has established a limited rebate-model pilot under which qualifying manufacturers may seek approval to provide the 340B ceiling price through a rebate rather than an upfront discount for selected drugs. For affected covered entities, the model could create new cashflow, data-submission, reconciliation, and operational considerations.

Contract Pharmacy Restrictions and Legal Battles:

Drug manufacturers continue to restrict 340B pricing for medications shipped to external contract pharmacies. Litigation remains ongoing, leaving providers to navigate increasingly complex data submission and administrative requirements, including the use of third-party clearinghouses to preserve their discounts.

Sweeping Modernization Bills:

Bipartisan momentum is being built on Capitol Hill. High-profile legislation, like the SECURE 340B Act and the 340B Drug Pricing Integrity and Affordability for Patients Act, aims to explicitly redefine patient eligibility, mandate standardized hospital financial assistance policies, and force strict reporting on how 340B savings are spent.

The Growing Intersection Between 340B and Worksheet S-10

As policymakers consider greater transparency and accountability within the 340B program, hospital charity care, uncompensated care, and the use of 340B savings are receiving increased scrutiny. Medicare Cost Report Worksheet S-10 is an important, auditable source of hospital uncompensated-care data and directly affects the distribution of Medicare DSH uncompensated-care payments.

Recent bipartisan reform proposals contemplate expanded reporting, financial-assistance requirements, patient-affordability protections, and greater transparency regarding how covered entities use 340B savings. Although these proposals have not been finalized, they reinforce the importance of maintaining consistent and supportable data across a hospital's Financial Assistance Policy, patient-account practices, community-benefit reporting, Worksheet S-10, and broader 340B governance. Hospitals with incomplete or inconsistent documentation could face increased audit, reimbursement, and reputational risk as these policy discussions move forward.

What Hospitals Should Do Now

While the CY 2027 policies remain proposed, hospitals should begin evaluating their potential financial and operational exposure. Key priorities include:

- Model the ASP-minus-33.4% proposal using actual separately payable Part B drug claims.
- Separate the direct drug-payment impact from the potential increase in non-drug OPPS reimbursement.
- Assess exposure to the accelerated OPPS conversion-factor reduction.
- Evaluate cashflow and reconciliation readiness for the rebate pilot.
- Validate alignment among 340B governance, Financial Assistance Policies, charity-care practices, public reporting, and Worksheet S-10 documentation.

At Meduit, our Government Reimbursement Services combine specialized expertise with proprietary data analytics to help hospitals strengthen the accuracy, alignment, and audit readiness of their uncompensated care reporting. We cross-examine Financial Assistance Policies, bad debt files, account-level practices, and supporting workflows to develop accurate and defensible Worksheet S-10 submissions. As the 340B program transitions into its next era, proactive compliance modeling will remain the defining line between structural financial strain and organizational resilience.

Sources

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