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Federal policymaking is reshaping the 340B environment as health systems prepare for 2027

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What's Trending

Several converging legislative actions and proposed rules are poised to cause major disruption to the 340B environment beginning in January 2027. The impact of these changes includes reduced payments for 340B-acquired outpatient drugs, jeopardized 340B eligibility for certain hospitals, and increased administrative requirements.

- **The Centers for Medicare & Medicaid Services' (CMS's) CY 2027 Outpatient Prospective Payment System (OPPS) proposed rule includes a major Medicare payment reduction for 340B-acquired outpatient drugs.** The proposed rule would reduce the Medicare payment rate for affected 340B drugs from the current average sales price (ASP) + 6% to ASP - 33.4%, a 37.2% reduction from the current payment rate. The proposal targets separately payable drugs and biologics acquired through 340B, with exceptions including pass-through drugs.

CMS reports that the 2026 hospital drug acquisition-cost survey showed that hospitals' costs for 340B-acquired drugs were dramatically below current Medicare reimbursement. The agency estimates the proposed rule will result in \$5.7 billion in reduced total drug spending in 2027 alone—\$4.55 billion less in Original Medicare drug payments and \$1.15 billion less in beneficiary drug payments in the first year.

The net effect will vary by organization because CMS proposes redistributing the savings through higher non-drug OPPS payments. Hospitals with greater 340B drug exposure relative to non-drug outpatient volume could be disproportionately affected. If finalized, the new rates would begin January 2027.

- **Increases in the uninsured population under H.R.1 could reduce Medicaid inpatient days and jeopardize 340B eligibility for some hospitals.** Changes stemming from H.R.1 could reduce Medicaid coverage and increase uncompensated care. The Congressional Budget Office (CBO) estimates the law will ultimately reduce Medicaid enrollment by more than 11 million and increase the number of uninsured people by 7.5 million in 2034. Medicaid enrollment losses could reduce Medicaid inpatient days, which could lead to facilities dropping below the required disproportionate share hospital (DSH) adjustment percentage qualification thresholds for 340B.

Rep. Hillary Scholten recently introduced legislation that would temporarily shield certain hospitals from losing 340B eligibility if their DSH adjustment percentages did fall below the required threshold. At the time of publication, the bill had not progressed.

- **The Health Resources and Services Administration's (HRSA) new pilot replaces up-front 340B discounts with a manufacturer rebate model.** In July, HRSA announced its revised 340B Rebate Model Pilot, which is set to take effect January 1, 2027, and run for at least a year.

Under the pilot program, covered entities will no longer acquire select drugs included in the CMS Medicare Drug Price Negotiation Selected Drug List for years 2026 and 2027 target at the 340B price and will instead acquire the drug at the wholesale cost. Providers will have up to 45 days following dispensing to submit claims. Manufacturers will pay the rebate or issue a documented denial within 10 days of a completed submission. This is HRSA's second attempt at a rebate pilot after the first model was blocked in litigation.

- **The bipartisan SUSTAIN 340B Act reshapes key program requirements in an attempt to address long-running sources of confusion and ambiguity.** Introduced in August, the SUSTAIN 340B Act would establish new statutory standards for 340B contract pharmacy arrangements, the definition of a patient, manufacturer obligations, and covered entity transparency and reporting.

SUSTAIN explicitly says 340B should operate through point-of-purchase discounts rather than rebates. It would also end any rebate model pilot within one year, replacing it with a proposed third-party clearinghouse to collect claims-level data.

Why It Matters

The coinciding implementation of multiple new 340B policies leaves providers in a delicate position to plan and respond. Taken together, the changes could affect whether hospitals remain eligible for 340B, how much value they generate from the program, when they realize those savings, and what the administrative requirements are for the program. The combination will add increased pressure to already thin hospital margins, particularly for safety-net hospitals.

340B eligibility could become an enterprise-level financial risk. For hospitals relatively close to the applicable DSH threshold, losing 340B eligibility from reduced Medicaid inpatient days could create a financial effect larger than Medicaid revenue loss alone. If a facility loses its 340B eligibility, it loses its ability to buy covered drugs at the 340B price altogether and as a result, the hospital's costs increase substantially. The threat of 340B eligibility loss is more substantial for rural and mid-sized urban providers that are already vulnerable, as well as for drug-intensive service lines.

Lower Medicare drug reimbursement could compress margins for drug-intensive service lines.

Hospitals with high Medicare infusion volume and significant 340B utilization could be particularly exposed. A significant reduction in Medicare reimbursement for affected 340B-acquired outpatient drugs would substantially reduce margin on high-cost infusion medications, many of which are central to 340B savings.

Lower reimbursement could make it more difficult for health systems to sustain infusion services and diminish the financial benefit generated through the 340B program to support patient care. Increased financial pressures and reduced savings may require health systems to reassess the financial sustainability of certain service lines that especially depend on 340B savings.

The new rebate model could create substantial cash flow challenges and increase administrative burden. Hospitals are forced to finance higher acquisition costs while they wait for claims to be validated and rebates issued.

Delayed or disputed rebates could negatively affect program savings, complicate compliance efforts, and reduce the financial stability that health systems rely on to expand services for vulnerable populations. The effect could be disproportionate for organizations with limited cash reserves and for portfolios containing very expensive specialty drugs.

The changing 340B environment may cause increased data and technology burden. Several new parameters of the enacted and proposed 340B policies include more transaction-level data, more reconciliation, and more scrutiny of how an individual dispense becomes a 340B transaction. These changes expand 340B management beyond the pharmacy department into revenue cycle and finance, IT and data, and legal and compliance functions.

Implementation of new programs and policies could require significant operational changes, system enhancements, policy updates, and compliance oversight, creating both opportunities and administrative challenges for covered entities.

In response to this evolving landscape, hospitals and health systems participating in the 340B program should:

- **Evaluate the varying impact on their organizations.** The effect of these changes will be unique to each hospital, depending on their payer mix, service lines, and other key factors.

- **Consider potential downstream decisions.** These will include site-of-care strategies, infusion footprints, specialty pharmacy strategies, physician alignment, and services that currently subsidize others.
- **Explore non-340B reliant opportunities for margin enhancement and efficiency gains.** This could include AI-supported workflows, centralization and virtualization of work, pharmacy revenue cycle optimization, or inpatient drug spend reductions.

Health systems are being asked to prepare simultaneously for compounding and potentially conflicting changes to numerous policies that directly and indirectly impact 340B, among other programs.

Financial pressures will intensify as providers face growing rates of uncompensated care from Medicaid coverage loss, lower reimbursement for high-cost 340B drugs, greater workforce and administrative requirements, and potentially lower or less predictable 340B savings. Health system leaders need to understand the interconnected relationships between policies and how proposed changes will impact their specific organizations.

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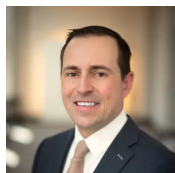
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