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340B at a Crossroads: What Health Systems Need to Know About Senator Cassidy's Reform Proposal

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On June 25, 2026, Senate HELP Committee Chairman Bill Cassidy (R-LA) released a sweeping legislative discussion draft titled the 340B Drug Pricing Integrity and Affordability for Patients Act. This proposal represents the most significant proposed overhaul of the 340B Drug Pricing Program in more than 15 years — and if enacted, it would have profound implications for every hospital, health system, and safety-net provider currently participating in the program.

At ML Strategies, we have been tracking 340B policy developments closely, and we want to make sure our health system clients understand what is in this draft, why it matters, and what steps to take now.

Background: Why 340B Reform Is on the Table

Congress created the 340B program in 1992 to help safety-net providers stretch limited federal resources by purchasing outpatient drugs at deeply discounted prices. Since the Affordable Care Act expanded eligibility, the program has grown dramatically reaching a record $81 billion in drug purchases in 2024, representing more than 16 percent of all US drug spending.

That growth has attracted scrutiny. Drug manufacturers have long argued that hospitals are exploiting statutory ambiguities to capture outsized margins without routing savings to low-income patients. Congressional investigators, including Chairman Cassidy's HELP Committee, have raised questions about whether 340B benefits are actually flowing to vulnerable populations. High-profile media reports have highlighted cases where large health systems directed 340B revenues to profitable service lines while scaling back services in underserved communities.

> *The 340B program has not been updated by Congress in 15 years. This draft signals that a statutory reckoning may finally be arriving — and health systems need to be prepared.*

Cassidy is inviting stakeholder comment on the discussion draft through August 28, 2026. While it is not yet a formal bill, this is a serious legislative vehicle built on years of investigation, and it deserves careful attention from every covered entity.

What the Discussion Draft Would Change: A Health System Perspective

1. How You Receive Your Discounts — Upfront or as a Rebate

One of the most consequential changes in the draft is the formal introduction of a manufacturer rebate model as an alternative to the traditional upfront discount. Under current practice, covered entities purchase drugs at the 340B ceiling price at the point of sale. This draft would allow manufacturers to choose to instead offer a retrospective rebate after claims data is submitted.

Notably, this legislative proposal tracks an administrative effort already underway. In July 2025, HRSA launched a voluntary 340B Rebate Model Pilot Program allowing manufacturers of drugs subject to the Medicare Drug Price Negotiation Program to deliver 340B discounts as retrospective rebates rather than upfront price reductions. Nine manufacturer plans covering ten high-utilization drugs were approved for a January 1, 2026, effective date, but the pilot never took effect because the US District Court for the District of Maine vacated the program in February 2026 after suit by the American Hospital Association and allied providers. HRSA subsequently issued a Request for Information, which closed in April 2026, and in June 2026 issued a new information collection request, signaling the agency has not abandoned the concept. Importantly, the draft does give covered entities the ability to choose their preferred mechanism — discount, rebate, or a new government-operated claims repository — provided they pass all discounts or rebates directly to their 340B patients. However, the operational and cash-flow implications of a rebate model are significant:

- Health systems would need to pay higher acquisition costs upfront and wait for reimbursement, potentially straining working capital.
- Covered entities would be required to submit standardized claims data within 30 to 90 days of dispensing — a new administrative burden with civil monetary penalties for non-compliance.
- Disputed claims processes, while outlined in the draft, add procedural complexity that could delay cash recovery.

Health systems that rely heavily on 340B revenue to fund operations should model the financial impact of a delayed-rebate scenario now, before this becomes law.

2. Contract Pharmacy Access Is Being Restricted

The draft significantly tightens the rules around contract pharmacy arrangements, which have been one of the most litigated and contested areas of the program. Key changes include:

- Hospital covered entities (DSH hospitals, free-standing cancer hospitals, and rural referral centers) would be capped at five contract pharmacies, excluding mail-order pharmacies.
- All contract pharmacies must be located within the covered entity's defined "service area," generally the Public Use Microdata Area in which the entity is located plus contiguous areas.
- Mail-order pharmacies would only be permitted for non-specified nonhospital entities, and only if the patient lives within the service area or in a non-Metropolitan Statistical Area (for certain rural hospitals).
- Contract pharmacies would face a tiered penalty structure for compliance violations — from financial liability to civil monetary penalties of $3,000 per claim to removal from the program for repeat offenders.

For health systems that have built robust contract pharmacy networks to expand patient access, these restrictions could materially reduce program revenue and patient reach. A five-pharmacy cap is a significant operational constraint for large integrated systems.

3. Tighter Standards for Child Site (Off-Campus Facility) Eligibility

The draft establishes a new, detailed eligibility framework for off-campus outpatient facilities commonly called "child sites" to participate in the 340B program. For a facility to qualify under the proposal, it must meet eleven distinct requirements, including:

- Being listed on the covered entity's Medicare cost report on a reimbursable line.
- Being wholly owned by the covered entity.
- Meeting Medicare provider-based standards under CMS regulations.
- Being located in a federally designated health professional shortage area.
- Demonstrating that its charity care spending, as a share of total patient service revenue, equals or exceeds both the main campus benchmark and the state-wide hospital average.
- Meeting Medicaid and CHIP utilization thresholds relative to the main campus and state averages.

Facilities that do not satisfy all eleven requirements would be ineligible to participate and would need to be deregistered. Health systems with large off-campus outpatient networks — which have expanded significantly under hospital outpatient department payment models — should assess whether their current child sites would meet these new standards.

> *The charity care and Medicaid utilization thresholds could disqualify suburban or specialty outpatient facilities that serve a less disadvantaged patient population relative to the parent hospital's main campus.*

4. New Transparency and Reporting Requirements

The draft imposes substantial new reporting obligations on hospital covered entities, phased by size:

- All DSH hospitals must report annual margin generated on 340B drugs — the difference between payments received and acquisition costs, net of program compliance costs.
- Hospitals with net patient revenues above $200 million must provide itemized margin reporting and submit copies of government contracts for indigent care.
- Hospitals with net patient revenues above $1 billion must report the demographic breakdown of patients receiving 340B drugs by insurance status, and detailed charity care spending.
- Non-hospital covered entities with revenues above $200 million must report how 340B margin is used across defined spending categories such as medical care, pharmaceuticals, sliding fee discounts, and community health workers.

This data would be published publicly by HHS in a searchable, electronic format. For health systems that have historically guarded 340B program economics closely, this level of public disclosure is a significant shift. It will invite external scrutiny of how 340B savings are deployed — and may be used by policymakers, journalists, and advocacy groups to make the case for further restrictions.

5. Mandatory Patient Affordability Provisions

Perhaps the most operationally demanding new requirement for hospital health systems is a mandatory sliding fee scale for all hospital covered entities. Under the draft:

- Patients with family income below the Federal Poverty Level would pay $0 out-of-pocket for 340B drugs.
- Patients with income between 100 and 200 percent FPL would pay the lesser of 20 percent of the applicable cost-sharing or $35 per drug.
- Patients with income above 200 percent FPL would pay the lesser of 30 percent or $50 per drug.

These requirements would apply at the point of sale for self-administered drugs and would extend to contract pharmacies dispensing on behalf of the covered entity. Civil monetary penalties of $2,500 per violation apply. Health systems would need to reconfigure their pharmacy billing and eligibility systems to implement income-based out-of-pocket caps across their enterprise.

6. Contracting Reforms: TPA and Contract Pharmacy Fees

The draft directly addresses what it characterizes as "predatory practices" by third-party administrators (TPAs) and contract pharmacies. Going forward:

- TPA fees must be a flat dollar amount per unit of service — not a percentage of the 340B discount or drug price.
- Contract pharmacy dispensing fees are capped at 125 percent of the pharmacy's average per-prescription fee from all third-party payors.
- Violators face civil monetary penalties equal to ten times the amount improperly received.

Many health systems have existing TPA and contract pharmacy agreements structured around a share of the 340B benefit. Those arrangements would need to be restructured, potentially reducing the financial attractiveness of contract pharmacy relationships.

7. Redefined "Patient" and New Subgrantee Standards

For the first time, the draft would codify a statutory definition of "patient." To qualify, an individual must have received an outpatient health care service from the covered entity within the previous two years, and the prescription must result from that visit or a referral. If enacted, this definition would limit 340B eligibility for individuals with only a remote or indirect connection to the covered entity.

New subgrantee eligibility requirements would also require entities to certify that 340B revenues are being used consistently with the scope of their qualifying federal grant and that their patient population is

primarily low income or uninsured.

The Bottom Line: What Health Systems Should Do Now

This discussion draft is not yet law — and it will face significant pushback from the hospital industry. 340B Health, which represents more than 1,600 participating hospitals, has already expressed serious concerns. America's Essential Hospitals has signaled engagement but cautioned against provisions that would favor manufacturers over providers.

This draft reflects a political environment in which Congress and the administration are increasingly receptive to accountability arguments about 340B.

Health systems should take the following steps now:

- **Assess your child site portfolio**. Determine which off-campus facilities would qualify under the eleven new requirements. Identify those at risk of deregistration and begin modeling the financial impact.
- **Model a rebate scenario**. Work with finance and pharmacy teams to assess cash-flow impacts if key manufacturers move to a retrospective rebate model.
- **Audit your contract pharmacy network**. Map existing pharmacy agreements against the proposed five-pharmacy cap and service area requirements. Prioritize which relationships to retain if limits are enacted.
- **Review TPA agreements**. Identify any percentage-based fee arrangements that would be prohibited under the new contracting rules and assess renegotiation timelines.
- **Engage in the comment process**. The August 28, 2026, deadline for stakeholder feedback is an opportunity to put your organization's specific concerns on the record. Comments should be data-driven and focused on patient impact.
- **Build coalitions**. Work through 340B Health, America's Essential Hospitals, and your regional hospital associations to present a unified industry response. Individual health system voices matter but coordinated advocacy is more effective.

The 340B program has been a financial lifeline for many health systems, enabling them to expand services, support uncompensated care, and invest in their communities. The Cassidy legislative discussion draft proposes real and significant constraints on how that program operates. Health systems that engage early — understanding the details, quantifying the impacts, and contributing to the policy debate — will be best positioned to protect their interests as this legislation moves forward.

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