SECURE 340B ACT

Executive Summary

Based on the 85-page discussion draft titled the Strengthening the Exercise of Controls and Upgrading Requirements for Efficiency in 340B Act

Executive Overview

The SECURE 340B Act would comprehensively restructure the 340B Drug Pricing Program. It combines major protections for covered entities—especially statutory protection for contract-pharmacy arrangements and a federal ban on discriminatory payer and pharmacy benefit manager practices—with extensive new eligibility, patient-assistance, reporting, audit, data-sharing, and enforcement requirements.

The legislation's central policy tradeoff is clear: covered entities would receive stronger legal protection against manufacturer, insurer, and PBM restrictions, but they would operate within a substantially more regulated, transparent, and data-intensive federal program.

Most Consequential Changes

1. Creates a statutory, prescription-specific definition of a 340B patient.

2. Protects contract-pharmacy access without numerical or geographic limits, while imposing detailed registration, contracting, reporting, and audit requirements.

3. Establishes much stricter hospital child-site eligibility standards, including a community-need test.

4. Requires expanded financial assistance and imposes new medical-debt protections.

5. Mandates public reporting of 340B utilization, savings, patient demographics, charity care, and contract-pharmacy information.

6. Requires biennial independent audits and gives HRSA broader sanction and disenrollment authority.

7. Creates a national claims-level 340B data clearinghouse.

8. Prohibits discriminatory payer and PBM practices and requires covered-entity user fees to finance expanded HRSA oversight.

1. Statutory Patient Definition and Referral Rules (Section 2)

The bill would replace the largely administrative patient-definition framework with a detailed statutory test. For each 340B prescription, the individual generally must have received an outpatient service from an eligible prescribing provider at the covered entity during the preceding 24 months. The service must be Medicare-reimbursable—or of a type that would be reimbursable—and, for grant-based entities, within the scope of the relevant federal grant or designation. The prescription must relate to that service, and the covered entity must maintain records demonstrating the provider-patient relationship and the provider's clinical responsibility for the related care.

Eligibility would be demonstrated separately for each prescription or order. Patient-relationship records would be retained for at least five years and could be audited by HRSA or the affected manufacturer, generally no more than once annually.

A prescribing provider generally must be an employee or qualifying independent contractor of the covered entity, or of an affiliated physician organization with assigned billing rights that furnishes care at covered-entity locations. The provider must have clinical responsibility for the drug-related care, be enrolled in Medicare or Medicaid, and not be excluded from federal health programs.

The practical effect could be to narrow eligible prescriptions originating from loosely affiliated physicians, outside specialists, or arrangements in which the covered entity cannot demonstrate a direct and auditable connection between its service and the prescription.

2. Limited Referral Exception

The bill would establish a referral pathway only for qualifying federally qualified health centers that are certified patient-centered medical homes, critical access hospitals, and sole community hospitals. The patient must have received direct care from the covered entity within 24 months before referral. The covered entity must make the referral, consult with the outside clinician, and provide appropriate follow-up care.

Referral arrangements would carry extensive documentation requirements. Referral prescriptions exceeding 25 percent of an entity's total 340B volume, falling within the highest quartile for the entity category, or exceeding historical category averages would trigger audits. Referral arrangements also would be audited at least every four years, with more frequent reviews for abnormal volume. A referral share above 35 percent could lead to a corrective action plan and, if not corrected, temporary loss of referral authority and monetary penalties.

3. Contract-Pharmacy Protection Coupled with Robust Oversight (Section 3)

The bill would expressly require manufacturers to offer 340B-priced drugs regardless of whether the drug is dispensed directly by the covered entity or through a contract pharmacy. Manufacturers would have to deliver—or permit delivery of—the drug to covered-entity-designated contract pharmacies and could not restrict distribution solely because a covered entity uses a contract pharmacy.

The legislation provides that there may be no numerical or geographic limitation on contract pharmacies. Manufacturers also could not require claims data to be submitted directly to them outside the new federal clearinghouse.

In exchange, covered entities would assume substantial new duties:

- Register each contract-pharmacy arrangement annually and submit the agreement to HRSA before implementation.
- Use standardized federal contract provisions covering drug ownership, patient choice, data reporting, Medicaid duplicate-discount protections, audit access, and clearinghouse participation.
- Retain auditable records for at least five years and obtain required information from contract pharmacies.
- Permit HRSA and manufacturer audits relating to diversion and duplicate discounts.
- Ensure that contract pharmacies provide all data needed for the covered entity's clearinghouse submissions.

HRSA would publicly disclose the covered entity and child sites using each pharmacy, the pharmacy's location, dispensing volume, geographic distance from the covered entity, mail-order or specialty status, and whether the pharmacy is located in a rural, urban, frontier, underserved, or provider-shortage area.

4. Much Stricter Hospital Child-Site Eligibility (Section 4)

A hospital child site would have to be owned and operated by the covered entity, registered with HRSA, clinically and financially integrated with the parent, and subject to the same patient financial-assistance policies. It generally would have to satisfy Medicare provider-based requirements or a comparable statutory integration test.

Among other requirements, a child site would have to participate in Medicare and the state Medicaid program; accept those patients without discrimination; provide a clinically meaningful range of services; integrate clinical leadership, medical records, quality oversight, finances, billing, human resources, purchasing, governance, and operations with the parent; and appear on a reimbursable line of the hospital's Medicare cost report.

CMS recognition of a site as provider-based generally would allow HRSA to deem the site compliant with many of these integration requirements. Certain jointly owned sites could qualify when the hospital owns at least 51 percent, all co-owners are nonprofit or governmental, no for-profit owner participates, and the structure was not created primarily to obtain or expand 340B eligibility.

5. New Community-Need Standard for Child Sites

A child site generally would qualify only if its ZIP Code Tabulation Area is at or above the 50th percentile nationally under the CDC Social Vulnerability Index or at or above the 40th percentile compared with other areas in the same state. New sites would be tested at registration, existing sites at recertification, and all sites periodically thereafter.

A site failing the standard could be removed from 340B without affecting the parent hospital or other qualifying sites. Exceptions would include a payor-mix test—at least 40 percent of patients are Medicaid beneficiaries, uninsured, or at or below 200 percent of poverty—and a renewable two-year safety-net exception for essential services to underserved populations when no adequate nearby alternative exists.

6. Patient Financial Assistance and Medical-Debt Protections (Section 5)

Covered entities would have to extend their financial-assistance policies to patients served through child sites and contract pharmacies, make those policies visible at the point of care, publicly report them, and maintain auditable implementation records.

Hospital covered entities generally would have to make assistance available to patients with incomes up to at least 400 percent of the federal poverty level. The bill also calls for a sliding-fee schedule for 340B drugs with nominal copayments for eligible hospital patients. Other covered entities not already governed by federal sliding-fee or grant requirements generally would provide assistance up to at least 200 percent of poverty. Plain-language notice would be required in English and, where appropriate, the community's primary language. The requirements would apply immediately to newly registered contract pharmacies and within three years to existing locations.

Hospital covered entities also would face major medical-debt restrictions. They generally could not sell patient debt, report adverse debt information to credit bureaus, deny or delay medically necessary care because of unpaid bills, require advance payment for such care, or take legal action to collect patient debt. Legal collection would be permitted only from patients demonstrating a clear ability to pay, defined as the greater of income at or above 600 percent of poverty or assets worth more than 400 percent of the outstanding debt. Violations could result in penalties of up to $5,000 per instance and referral to OIG or the IRS.

7. Public Reporting of 340B Finances and Operations (Section 6)

Beginning within one year, every covered entity would submit an annual report covering the parent entity, child sites, and contract-pharmacy arrangements. Required information would include:

- Numbers of 340B patients and prescriptions, separated by payer type.
- Charity-care levels and a description of how 340B savings are used.
- Patient income, insurance, Medicaid, CHIP, uninsured, and underserved-area demographics.
- Medication-access and financial-assistance policies.
- Government contracts supporting hospital eligibility and third-party administrator relationships.
- Medicare and Medicaid funding shortfalls, 340B operating costs, contract-pharmacy names and addresses, and service utilization by income level.

HHS would post the information publicly within 30 days in an electronic, searchable format, both in aggregate and by individual covered entity. This would expose individual hospitals' 340B margins, patient mix, assistance practices, contract-pharmacy networks, and claimed uses of savings to unprecedented public scrutiny.

8. Mandatory Independent Audits and Stronger Enforcement (Section 7)

HRSA would receive explicit authority to audit covered entities, manufacturers, child sites, and contract pharmacies for eligibility, diversion, duplicate discounts, improper contract-pharmacy practices, non-covered drugs, and inaccurate ceiling prices. Covered entities could contract only with vendors that agree to provide requested information to HRSA and auditors.

Every covered entity would have to engage an independent auditor at least once every two years to examine the covered entity, every child site, and every contract-pharmacy location. The covered entity would have

to correct violations, disclose them to HRSA, assign responsibility to a corporate officer, notify affected manufacturers, and repay improper discounts with interest when amounts exceed a federal de minimis threshold.

The bill establishes a formal corrective-action-plan process, but it also permits temporary suspension, civil monetary penalties, and disenrollment. Three audit findings in two years or five findings in five years could lead to accelerated corrective action, immediate penalties, removal from 340B, and temporary disqualification from reentry.

Private nonprofit hospitals relying on state or local government contracts would face annual verification that the contract is active, mutually binding, and expressly requires services for low-income individuals ineligible for both Medicare and Medicaid. HRSA also would verify nonprofit status against IRS or CMS information.

9. National Claims-Level 340B Data Clearinghouse (Section 8)

The bill would create an independent national clearinghouse for claims-level 340B data. For the first four years, manufacturers would have to provide the 340B ceiling price as an up-front purchase-price reduction rather than through retrospective rebates, except for qualifying AIDS Drug Assistance Program arrangements.

Continuation of that protection after four years would depend on the clearinghouse meeting performance benchmarks: processing all required claims, identifying at least 90 percent of claim value as free from duplicate discounts, timely adjudication of at least 90 percent of claim value, and complete and accurate initial data for at least 95 percent of claim value. If those benchmarks are not certified, the bill's continuing restriction on alternative manufacturer discount mechanisms would end.

Clearinghouse Data and Compliance Consequences

Covered entities would submit extensive pharmacy- and medical-claim information, including service dates, NDCs, prescription and claim identifiers, provider and pharmacy identifiers, health-plan information, wholesaler accounts, invoices, quantities, and covered-entity identification numbers. Historical claims generally could not be reclassified from non-340B to 340B more than six months after the drug was furnished.

The clearinghouse would retain data for ten years. Covered entities would be responsible for data maintained by contract pharmacies and third-party administrators. After notice, failure to correct incomplete or late submissions within 30 days could permit the affected manufacturer to suspend some or all 340B discounts until the failure is cured.

Manufacturers, plans, and PBMs could use clearinghouse data only for permitted program-integrity purposes—not pricing or marketing—and misuse would be subject to monetary penalties. The bill also would establish repayment, with interest, for duplicate discounts or diversion caused by a covered entity or an improper state Medicaid rebate request.

10. Federal Ban on Payer and PBM Discrimination (Section 9)

Group health plans, insurers, and PBMs could not discriminate against covered entities or contract pharmacies because they dispense 340B drugs. Prohibited conduct would include:

- Lower reimbursement than paid to similarly situated non-340B pharmacies or providers.
- Differential fees, clawbacks, chargebacks, dispensing fees, audit requirements, or network conditions.
- Interference with patient pharmacy choice or mail delivery.
- Requiring identification of 340B claims outside the federal clearinghouse.
- Refusing to contract because of 340B status or denying coverage because a drug was purchased through 340B.

Plans and PBMs also could not require a covered entity to share its 340B discount or savings as a condition of network participation, formulary placement, claim routing, or another benefit. PBM violations could result in civil penalties of up to $5,000 per violation per day.

Third-party administrators would have to be compensated through bona fide service fees. Compensation could not be calculated as a percentage of 340B revenue, another revenue-based measure, or the volume of 340B drugs dispensed.

11. User Fees and Expanded HRSA Capacity (Section 10)

Beginning in fiscal year 2027, covered entities would pay an annual user fee generally equal to 0.1 percent of the amount paid for 340B drugs during the prior year. Payment would become a condition of participation. The funds would support the clearinghouse, information systems, audits, compliance tools, and other program-integrity activities. The Secretary could establish exceptions for certain entities.

The legislation would authorize $3 million annually for fiscal years 2027 through 2031 for audits and enforcement, $9 million annually for fiscal years 2028 through 2031 for broader implementation, and direct-hire authority for at least 20 permanent HRSA oversight employees.

12. Nonhospital Covered Entities and Subgrantees (Section 13)

Nonhospital covered entities would have to be nonprofit or public and could use 340B only for patients, services, and drugs within the scope and duration of the federal grant, project, or authorizing statute supporting eligibility. They would be directly responsible for subgrantee compliance and would have to execute enforceable written agreements covering every subgrantee site.

Subgrantees would have to register each location, document receipt of qualifying federal funds or in-kind contributions, remain within grant scope, and disenroll when the underlying funding or eligibility ends. Certain in-kind arrangements would require a value exceeding $25,000 annually, written implementation and termination plans, and, in specified circumstances, a Medicaid patient percentage greater than the statewide percentage.

Effective Date and Bottom-Line Assessment

Most amendments would take effect upon enactment. HHS would be directed to issue final implementing regulations within 180 days and establish transition periods of at least 180 days for substantive new covered-entity or manufacturer obligations, unless the legislation specifies another timeline.

For covered entities, the bill offers two major benefits: a clear federal right to use contract pharmacies without manufacturer-imposed geographic or numerical restrictions, and broad protection against discriminatory PBM and insurer practices. Those benefits come with substantial operational costs and potential eligibility reductions.

Hospitals would need to reevaluate every child site against ownership, provider-based, integration, cost-reporting, payer-participation, and community-vulnerability requirements. Every covered entity would need prescription-level patient documentation, expanded financial assistance, public financial reporting, regular independent audits, and comprehensive claims-data transmission.

Overall, the SECURE 340B Act would preserve and protect the basic 340B discount and contract-pharmacy model, but convert the program into a considerably more regulated, transparent, data-intensive, and enforceable federal program. The greatest risk would fall on entities with marginal child sites, expansive referral arrangements, weak patient-assistance policies, or complex contract-pharmacy and third-party administrator structures.