

SIDE-BY-SIDE COMPARISON OF MAJOR 340B PROVISIONS

House SECURE 340B Act Draft vs. Senate 340B Drug Pricing Integrity and Affordability for Patients Act Discussion Draft

Prepared July 5, 2026 | Comparison of the top 15 operational, financial, and policy provisions

Draft-status note: This analysis compares the June 30, 2026 House SECURE 340B Act draft and the June 23, 2026 Senate discussion draft. The Senate draft contains bracketed dates, deadlines, and alternative language that remain unresolved.

Executive assessment

The House draft is more protective of covered entities on the two most consequential financial issues: it blocks immediate manufacturer-imposed rebate conversion and guarantees broad contract-pharmacy access without numerical or geographic caps. It also creates strong PBM nondiscrimination protections. Those protections are paired with substantial new obligations, including universal public reporting, biennial independent audits, patient financial-assistance requirements, hospital medical-debt restrictions, tighter child-site standards, subgrantee controls, and a new covered-entity user fee. The Senate discussion draft is more restrictive operationally and gives manufacturers greater control. It authorizes manufacturer-selected rebate systems, caps contract pharmacies for major hospital categories, imposes service-area limits, preserves restricted-distribution networks, and expands manufacturer access to claims data and audits. Its most direct patient benefit is an explicit dollar cap on out-of-pocket costs for eligible patients.

Top 15 provision comparison

#	Major provision	House - SECURE 340B Act	Senate - Integrity and Affordability Discussion Draft	Principal difference / likely effect
1	Upfront discounts versus rebates	Requires manufacturers, for an initial four-year period, to provide the 340B ceiling price as an upfront purchase-price discount rather than through retrospective rebates. Existing AIDS Drug Assistance Program rebate models are excepted. Continuation after four years depends on federal certification of clearinghouse performance. (Sec. 8; pp. 50-51)	Allows each manufacturer to select an upfront discount, retrospective rebate, or Secretary-operated claims repository. Rebate requests require standardized claims data, and undisputed claims generally must be paid within 10 days. (Sec. 2; pp. 3-13)	Largest structural difference. The House protects covered entities from immediate rebate conversion and cash-flow disruption; the Senate expressly authorizes manufacturer-selected rebates.
2	Definition of a 340B patient	Requires an outpatient service from a prescribing provider at the covered entity within 24 months. The service generally must be Medicare-reimbursable, the prescription must relate to that service, and the relationship must be supported by auditable records retained for at least five years. (Sec. 2; pp. 2-5)	Requires an outpatient service at the covered entity within two years, an auditable medical record retained for at least three years, and a prescription or order from a qualifying practitioner resulting from the service or a referral. (Sec. 4; pp. 18-20)	Both adopt a two-year lookback. The House is more prescriptive regarding reimbursable services, clinical responsibility, prescription-by-prescription qualification, and record retention.
3	Prescriptions resulting from referrals	Creates a separate referral pathway only for qualifying FQHC patient-centered medical homes, critical access hospitals, and sole community hospitals. Requires ongoing clinical involvement, extensive documentation, drug limitations, referral-volume audits, corrective action, and possible temporary loss of referral authority. (Sec. 2; pp. 5-11)	Includes prescriptions arising as a result of a referral within the general patient definition, without the House bill's special entity limitations, volume thresholds, and separate enforcement framework. (Sec. 4; pp. 18-19)	The Senate language is potentially broader for referrals. The House provides clearer authority but confines it to specified safety-net entities under extensive controls.
4	Number and location of contract pharmacies	Expressly provides that there may be no numerical or geographic limitation on contract pharmacies, although agreements must be registered, reviewed, and publicly reported. (Sec. 3; pp. 12-14)	Limits DSH hospitals, freestanding cancer hospitals, and rural referral centers to no more than five contract pharmacies, excluding mail-order pharmacies from the count. Most contract pharmacies must be within the covered entity's defined service area. (Sec. 5; pp. 23-27)	The House preserves broad networks. The Senate would materially reduce many hospital contract-pharmacy networks and localize most arrangements.

#	Major provision	House - SECURE 340B Act	Senate - Integrity and Affordability Discussion Draft	Principal difference / likely effect
5	Mail-order, specialty, and restricted-distribution drugs	Treats mail-order and specialty pharmacies as permissible contract pharmacies and prohibits manufacturers from selectively restricting distribution, refusing shipment, or demanding claims data outside the federal clearinghouse. (Sec. 3; pp. 11-14, 17-18)	Allows mail-order arrangements only under specified entity and patient-residence conditions. For drugs in exclusive specialty or restricted-distribution networks, a manufacturer satisfies its obligation by making the drug available through a network participant. (Sec. 5; pp. 27-32)	The House is more favorable to covered-entity access. The Senate preserves manufacturer control over restricted networks and narrows mail-order use.
6	Contract-pharmacy agreements and violations	Requires annual registration, submission and HHS review of agreements, standard provisions, clearinghouse participation, duplicate-discount safeguards, audits of both parties, and at least five years of records. Manufacturer refusal, shipment restrictions, and conditions on access become program violations. (Sec. 3; pp. 12-18)	Requires formal compliance procedures, registration and annual certification, submission of agreements and amendments within 30 days, and HHS modification authority. Violations trigger escalating repayment, interest, civil penalties, and potential exclusion. (Sec. 5; pp. 23-40)	Both federalize contract-pharmacy oversight. The House emphasizes enforceable manufacturer access; the Senate places greater direct financial and participation risk on pharmacies.
7	Patient affordability requirements	Requires covered entities to extend financial-assistance policies to child sites and contract pharmacies. Hospital entities must offer assistance and nominal-copayment sliding scales through at least 400% of poverty; most other entities must cover patients through at least 200%. It does not automatically make all drugs free. (Sec. 5; pp. 32-34)	Sets explicit per-drug maximums for eligible patients: \$0 below poverty; the lesser of 20% of the otherwise applicable obligation or \$35 from 100% to below 200% of poverty; and the lesser of 30% or \$50 for other applicable patients. Contract pharmacies must apply the reductions. (Sec. 7; pp. 57-63)	The House uses a broader institutional assistance model. The Senate provides clearer, enforceable point-of-sale dollar limits.
8	Hospital medical-debt protections	Prohibits hospital covered entities from selling patient debt, reporting adverse information to credit bureaus, or denying or delaying medically necessary care because of unpaid bills. Legal collection is generally barred unless the patient has income of at least 600% of poverty or assets exceeding 400% of the debt. (Sec. 5; pp. 34-37)	No comparable comprehensive medical-debt section. Affordability requirements focus on the patient's obligation for the 340B drug itself. (Sec. 7)	The House extends far beyond the pharmacy transaction and would impose significant hospital-wide debt-collection protections.
9	Hospital child-site eligibility	Requires ownership or qualifying common ownership; extensive clinical, operational, and financial integration; Medicare and Medicaid participation; provider-based compliance; and a community-need test based principally on a Community Vulnerability Score. (Sec. 4; pp. 18-31)	Requires the site to appear on the Medicare cost report, be wholly owned and provider-based, provide more than drug dispensing, be in a shortage area, and meet comparative charity-care and Medicaid/CHIP outpatient-revenue thresholds. (Sec. 8; pp. 67-80)	Both tighten eligibility. The House emphasizes integration and community vulnerability; the Senate emphasizes site-specific charity care, public-program revenue, and shortage-area performance.
10	Transparency and public reporting	Requires annual reporting by every covered entity, including all sites and pharmacy arrangements. Data include patients and prescriptions by payer, charity care, use of savings, patient demographics, government contracts, TPAs, operating costs, and pharmacy locations. HHS must publish searchable entity-specific information. (Sec. 6; pp. 37-41)	Uses a tiered reporting structure focused initially on DSH hospitals and other entities designated by HHS, with added reporting for larger entities. Emphasizes 340B margin, patient categories, charity care, and uses of margin, with public entity-specific publication. (Sec. 6; pp. 43-57)	The House is broader across the program. The Senate is more targeted but more explicitly requires calculation and disclosure of actual 340B margin.
11	Claims-data exchange and clearinghouse	Creates a federal claims clearinghouse and generally channels claims information through it rather than directly to manufacturers. The four-year upfront-discount period allows the clearinghouse to demonstrate its ability to identify duplicate discounts and diversion. (Sec. 8; pp. 50-66)	Requires standardized encounter, retail, and medical claims data as a condition of the selected discount or rebate process. Data may flow directly to a manufacturer or contractor or to a Secretary-operated repository, depending on the selected mechanism. (Sec. 2; pp. 3-13)	The House favors a centralized neutral data channel. The Senate permits manufacturer-specific processing and creates a larger recurring data-submission burden.

#	Major provision	House - SECURE 340B Act	Senate - Integrity and Affordability Discussion Draft	Principal difference / likely effect
12	Audits and general enforcement	Authorizes broad HHS audits of covered entities, child sites, contract pharmacies, and manufacturers. Each covered entity must also obtain a biennial independent audit covering itself and every child-site and pharmacy location. Eligibility failures may result in disenrollment. (Sec. 7; pp. 41-50)	Authorizes routine and for-cause audits by HHS and manufacturers, including use of manufacturer internal audit staff under federal procedures. Knowing certification or recertification misstatements may result in penalties of up to twice the discounts or rebates improperly received. (Sec. 2; pp. 13-16)	The House creates a costly recurring independent-audit obligation. The Senate gives manufacturers a more explicit and active audit role.
13	PBM discrimination and vendor compensation	Prohibits plans, insurers, and PBMs from reducing reimbursement, imposing differential fees, excluding entities from networks, requiring 340B identification outside the clearinghouse, denying coverage, or conditioning benefits on sharing savings. TPA compensation cannot be tied to 340B revenue or volume. (Sec. 9; pp. 66-70)	Does not establish a comparable broad PBM nondiscrimination regime. It limits TPA fees to flat-dollar fair-market-value payments and caps contract-pharmacy compensation at a flat amount not exceeding 125% of the pharmacy's average dispensing fee from all third-party payers. (Sec. 9; pp. 80-84)	The House protects reimbursement and network access. The Senate directly restructures TPA and contract-pharmacy economics and could eliminate many percentage-based arrangements.
14	Nonhospital entities and subgrantees	Requires nonhospital entities to be nonprofit or public and confines purchases to services and drugs within the qualifying grant's scope and duration. Parent entities are directly liable for subgrantee compliance. Detailed agreements, registration, records, Medicaid-volume tests, and in-kind contribution standards apply. (Sec. 13; pp. 78-84)	Requires specified subgrantees to document the qualifying grant and public or nonprofit status and certify that 340B revenues are consistent with the grant and that patients are primarily low-income or uninsured. A bracketed provision could exclude some in-kind-only arrangements. (Sec. 3; pp. 16-18)	The House creates the more comprehensive and operationally demanding regime. The Senate relies more on certification, with unresolved language on in-kind support.
15	Administration, funding, and implementation	Imposes an annual covered-entity user fee beginning in FY 2027 equal to 0.1% of prior-year 340B drug purchases. Funds support the clearinghouse, audits, and OPA systems; the bill also authorizes appropriations and at least 20 direct-hire positions. Most provisions technically take effect at enactment, with final rules within 180 days and generally at least a 180-day transition. (Secs. 10 and 14; pp. 70-73, 84-85)	Requires at least two prime vendors, conflict-of-interest and fee restrictions, broad HHS rights in prime-vendor data, and transfer of civil penalties to OPA. Most amendments apply one year after enactment. (Secs. 10-12; pp. 84-88)	The House directly finances a larger oversight infrastructure through covered-entity fees. The Senate relies more on penalties and prime-vendor reform and provides a longer general implementation runway.

Source documents

- House: Strengthening the Exercise of Controls and Upgrading Requirements for Efficiency in 340B Act (SECURE 340B Act), House discussion draft dated June 30, 2026.
- Senate: 340B Drug Pricing Integrity and Affordability for Patients Act, Senate discussion draft dated June 23, 2026.