SUSTAIN 340B ACT

Detailed Summary of Legislative Provisions

Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of 340B Act

Based on the 97-page Senate legislative text supplied for review

Prepared August 5, 2026

Note: The uploaded text contains a blank Senate bill number and blank introduction and committee dates. This summary therefore identifies the legislation by its stated short title.

Executive Summary

The SUSTAIN 340B Act would comprehensively rewrite the statutory framework governing the 340B Drug Pricing Program. It would expressly protect the use of contract pharmacies and prohibit manufacturers from restricting delivery of 340B-priced drugs to those pharmacies, while simultaneously imposing extensive new registration, contracting, audit, data-reporting, patient-eligibility, child-site, financial-assistance, and user-fee requirements on covered entities.

The legislation also would create a national claims-data clearinghouse to identify duplicate discounts, establish new nondiscrimination requirements for commercial plans, insurers, pharmacy benefit managers (PBMs), Medicare prescription drug plans, and Medicare Advantage prescription drug plans, and authorize substantial new federal oversight and enforcement resources. In practical terms, the bill exchanges clearer statutory access to 340B pricing and stronger protections against manufacturer and payer restrictions for a much more prescriptive and auditable compliance system.

- Contract pharmacies would receive explicit statutory protection. Manufacturers would be required to offer and deliver covered outpatient drugs at or below the 340B ceiling price regardless of whether the covered entity dispenses the drug directly or through a contract pharmacy. Manufacturer-imposed distribution limits and direct claims-data demands generally would be prohibited.
- Covered entities would face mandatory contract-pharmacy registration, annual recertification, standardized contract provisions, public disclosures, independent audits, records retention, and enhanced federal and manufacturer audit exposure.
- A statutory patient definition would use a two-year lookback, require an auditable medical record and a qualifying prescription nexus, exclude drug-administration-only and infusion-only encounters, and authorize carefully regulated prescriptions resulting from referrals to non-340B providers.
- Hospital child sites would have to be wholly owned and operationally, clinically, financially, administratively, and publicly integrated with the parent covered entity. Newly acquired sites generally would face a three-year delay before 340B participation.
- Every covered entity would submit annual public transparency data concerning 340B volume, payer mix, charity care, use of savings, patient demographics, government contracts, third-party administrators, funding shortfalls, outpatient volume, and program operating costs.
- A national independent clearinghouse would receive claims-level data to prevent duplicate discounts and diversion. Covered entities, State Medicaid agencies, manufacturers, plans, and PBMs would have defined data-use, repayment, and cooperation obligations.
- Covered entities would have to adopt transparent financial-assistance policies that generally reach patients at or below 200 percent of the Federal poverty level and include a sliding fee scale for 340B drugs, subject to a delayed application at child sites and contract pharmacies.
- Plans, insurers, and PBMs would be prohibited from paying less, imposing differential fees or network terms, requiring identification of 340B claims, denying coverage, steering patients, or otherwise discriminating based on 340B status. Violations could generate penalties of up to $5,000 per violation per day.
- Beginning in fiscal year 2031, covered entities collectively would pay $50 million annually in user fees, indexed in later years and allocated principally according to each entity’s share of total 340B prescription volume.
- Although the Act generally would take effect upon enactment, many operational requirements depend on later HHS rulemaking, systems development, reports, and phased implementation deadlines.

Source pages: 1-97.

Legislative Overview

The uploaded Senate text lists Senators Moran, Baldwin, Capito, Kaine, Boozman, and Hickenlooper as sponsors. Its stated purpose is to amend the Public Health Service Act with respect to the 340B drug discount program and for other purposes. The bill contains 16 sections.

The structure of the bill reflects two parallel policy objectives: (1) preserving covered-entity access to 340B pricing, contract pharmacies, patient choice, and nondiscriminatory reimbursement; and (2) establishing substantially stronger federal standards for program eligibility, reporting, audits, duplicate-discount prevention, use of savings, and patient financial assistance.

Source pages: 1-2.

Detailed Section-by-Section Summary

Section 1 - Short Title and Table of Contents

The bill may be cited as the "Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of 340B Act," or the "SUSTAIN 340B Act." The section also provides the table of contents for the legislation.

Source pages: 1-2.

Section 2 - Sense of Congress

Congress declares that the purpose of the 340B program is to stretch scarce federal resources and help safety-net providers maintain, improve, and expand patient access to health care. The statement characterizes the program as requiring manufacturers, as a condition of participation in Medicaid and Medicare Part B, to provide point-of-purchase discounts to covered entities serving disproportionate numbers of low-income, underserved, or medically vulnerable patients.

This provision is nonbinding, but it provides an express statement of statutory purpose that could guide HHS rulemaking, enforcement, and judicial interpretation of the amendments that follow.

Source pages: 2.

Section 3 - Contract Pharmacies

Section 3 creates an express statutory framework for covered-entity use of wholly owned and contract pharmacies. It simultaneously establishes new covered-entity compliance duties and manufacturer obligations.

A. Covered-entity authority and inactive pharmacy limits

- A covered entity may use one or more wholly owned pharmacies and one or more contract pharmacies to acquire and dispense 340B covered outpatient drugs to its patients.
- A covered entity generally must cancel a contract with a pharmacy that has not dispensed any 340B drugs to its patients during the most recent 12-month period.
- Cancellation is not required when inactivity results from an ownership change requiring a replacement contract, a change in the covered entity's service area, emergency or contingency access needs, or other circumstances approved by the Secretary.
- The Secretary may establish a non-overly-burdensome process for increased auditing of covered entities that use a "high number" of contract pharmacies, with the threshold left to HHS.

B. Registration, recertification, and contract review

- Each contract-pharmacy arrangement must be registered with HHS and annually recertified.

- The covered entity must submit the written agreement and register the arrangement before it is implemented, and must attest to compliance with 340B requirements.
- HHS must establish a process to review written agreements for compliance.

C. Mandatory written-agreement provisions

HHS must promulgate regulations requiring written agreements that are signed and effective before dispensing begins, identify each contract-pharmacy location, and contain standard provisions. Those standard terms must address at least the following:

  - The contract pharmacy must provide pharmacy services and data needed for the covered entity's clearinghouse submissions.
  - Neither party may require a patient to use a particular pharmacy, obtain a prescription from the covered entity, or otherwise interfere with pharmacy choice, subject to the bill's specified exception.
  - Optional services may include home care, delivery, or reimbursement support, but 340B drugs remain restricted to patients of the covered entity.
  - The contract pharmacy must provide customary operational and financial information requested by the covered entity, including billing, collection, receiving, and dispensing records.
  - The parties must maintain a patient-eligibility verification system and safeguards against diversion.
  - Medicaid prescriptions may not be filled with 340B drugs unless the covered entity, pharmacy, and State Medicaid agency have an arrangement to prevent duplicate discounts and report it to HHS.
  - The contract pharmacy must accept an annual independent audit commissioned by the covered entity.
  - Both the covered entity and pharmacy must be subject to HHS and manufacturer audits of records relevant to diversion and duplicate-discount compliance.
- HHS must issue oversight guidance and require retention of relevant auditable records for at least three years.

D. Manufacturer obligations and prohibited restrictions

- Manufacturers must offer covered outpatient drugs at or below the ceiling price regardless of whether the drug is dispensed directly or through a contract pharmacy.
- Manufacturers must deliver, or permit delivery of, 340B-priced drugs to locations requested by the covered entity in accordance with its contract-pharmacy arrangements.
- Manufacturers may not impose distribution restrictions that uniquely target 340B drugs, covered entities, or contract pharmacies.
- Manufacturers may not require claims data to be submitted directly to them, except through the independent clearinghouse established in Section 9.
- HHS may prohibit additional manufacturer conditions through notice-and-comment rulemaking.

The bill expands manufacturer civil monetary penalty exposure to intentional refusals to offer or deliver drugs at or below the ceiling price and to intentional conditions placed on a covered entity's ability to buy at or below that price.

E. Public transparency and audits

For every registered contract-pharmacy arrangement, the covered entity must submit information for HHS publication identifying the covered entity and child sites, pharmacy name and address, effective

date, last year of 340B dispensing, annual number of 340B drugs dispensed, and whether the pharmacy is mail-order or payer-mandated.

HHS and manufacturers may audit relevant records at their own expense. A manufacturer must first present credible allegations, document good-faith written outreach, and allow the covered entity 30 days to resolve the concern before requesting HHS authorization. A corporate officer is made responsible for correcting audit findings. HHS must establish the credible-allegation standard, decision timeline, and permissible number, scope, and duration of audits by rule.

Source pages: 2-17.

Section 4 - Patient Definition and Referral Prescriptions

Section 4 creates a detailed statutory patient standard, establishes mandatory audits and sanctions, and authorizes certain prescriptions written by non-340B referral providers.

A. General patient definition

An individual is a patient of a covered entity only if all of the following are satisfied:

- The individual received an outpatient health care service from the covered entity within the preceding two years.
- The covered entity maintains an auditable medical record, consistent with federal and State law, demonstrating the patient relationship for each prescription or order. The record must be retained for at least three years, or longer if another law requires.
- The individual received the prescription or order from a qualifying practitioner as a result of the covered entity outpatient service, or through a qualifying referral under the new referral-prescription provisions.
- An individual registered in an AIDS Drug Assistance Program covered entity is deemed a patient for 340B purposes.
- For a State or political subdivision receiving section 318 funding, an individual receiving a drug for the funded disease or condition is treated exclusively as that governmental entity's patient for purposes of qualifying the prescription.
- An individual is not a 340B patient when the only service received is drug administration, dispensing for later self- or home administration, or infusion. This exclusion could materially narrow 340B eligibility for infusion-only or drug-only encounters.
- A discharge prescription resulting from an emergency-department or inpatient stay at any covered entity category listed in section 340B(a)(4)(A)-(O) is deemed to satisfy the patient requirements.

B. Outpatient service and practitioner standards

A qualifying outpatient health care service must be furnished under a valid documented written order or referral and must either be reimbursable under Medicare or Medicaid, identifiable through a CPT or HCPCS code, or - for grant-based covered entities in subparagraphs (A)-(K) - fall within the scope of the applicable grant or designation.

A qualifying practitioner generally must be an employee or independent contractor for whose services the covered entity bills and remains responsible, or must serve under an ongoing contractual, cooperative, or permitted medical-staff relationship under which the covered entity retains clinical responsibility. The practitioner also may not be excluded from Medicare or a State health care program.

C. Audits and sanctions for patient-status violations

- Covered entities must permit HHS and manufacturers to audit patient-status and referral-prescription records at the auditor's expense.
- HHS must audit patient-status records at least once every three years and audit high-risk and high-volume covered entities more frequently, using definitions established by HHS.
- Manufacturers may request referral-specific audits based on a credible allegation, subject to a required good-faith resolution process and disclosure to the covered entity of the materials provided to HHS.
- A noncompliant covered entity must implement an HHS-approved corrective action plan. Failure to correct may result in program exclusion for up to three years and civil monetary penalties covering drugs purchased during the period of noncompliance.

The section also makes registration with HHS and listing in the 340B Office of Pharmacy Affairs Information System a statutory condition of participation.

D. Referral prescriptions written by non-340B providers

An eligible covered entity may treat a drug prescribed by a non-340B referral provider as a 340B covered outpatient drug when the prescription is written within 12 months after the covered entity's referral. Eligible entities include covered entities in subparagraphs (A)-(K) and (N), plus sole community hospitals described in subparagraph (O).

The covered entity must document its patient relationship, the care furnished by both providers, consultation with the prescribing provider, the referral, and the prescription. The prescription must be filled at the covered entity's wholly owned or contract pharmacy; records must be retained for at least three years; and 340B savings may not be shared with the referring prescriber.

Infused, clinician-administered, and other clinician-administered drugs generally are excluded from the referral pathway. Exceptions apply for certain section 330 entities already furnishing infusion services on enactment and for entities receiving HHS approval based on inadequate local access for low-income, medically underserved residents.

E. Referral-volume monitoring and enforcement

- HHS must audit an eligible covered entity when its annual volume of drugs prescribed by non-covered referral providers exceeds the lesser of 20 percent of its total 340B drug volume or its own average annual referral-prescription percentage during the most recent three-year period.
- HHS must create a hardship exception for medical need, workforce shortages, or similar circumstances.
- Covered entities must annually report the percentage of 340B revenue and the percentage of 340B drug volume attributable to referral prescriptions. HHS must publish only aggregate, non-entity-identifying information.
- Violations require a corrective action plan. Failure to comply within 180 days may suspend referral-prescription authority for up to three years, and HHS may impose civil monetary penalties for discounts associated with noncompliant referral prescriptions.

The HHS Inspector General must conduct annual studies over a 12-year period and report to Congress beginning no later than two years after enactment and annually for the next ten years.

Source pages: 17-35.

Section 5 - Sunset of the 340B Rebate Model Pilot Program

HHS must conclude the 340B Rebate Model Pilot Program, or any substantially similar HHS program, no later than one year after enactment. The pilot may not be expanded. At the one-year

point, HHS must discontinue the pilot and transition to the national 340B Drug Discount Program Data Clearinghouse established by Section 9.

The provision therefore preserves a point-of-purchase discount structure as the default and substitutes a centralized duplicate-discount data system for the rebate pilot.

Source pages: 35-36.

Section 6 - Child Sites

Section 6 establishes detailed statutory eligibility standards for child sites owned and operated by hospital covered entities described in subparagraphs (L)-(O). The parent must annually document and recertify that each child site is wholly owned, clinically and financially integrated, and operating consistently with parent policies.

A. Core eligibility standards

A child site must satisfy the following principal requirements:

- Apply the same patient financial-assistance policy as the parent covered entity.
- Ensure that professionals ordering or dispensing 340B drugs retain clinical responsibility for the health services that produce the prescription or order.
- Provide a clinically meaningful range of services appropriate to the qualifications of the professionals furnishing care at the site.
- Operate under the same license as the parent unless State law requires or necessitates a separate license; a State rate-setting agency determination that the site is not part of the covered entity makes the site ineligible.
- Demonstrate clinical integration through shared privileges, equivalent monitoring, medical-director reporting, parent professional-committee responsibility, integrated or readily accessible medical records, and coordinated access to parent inpatient and outpatient services.
- Demonstrate full financial integration through shared income and expenses, cost reporting in the parent's cost centers, and identification in the parent's trial balance.
- Hold the site out to the public as part of the covered entity.
- Maintain 100-percent parent ownership, the same governing body and organizational documents, and parent final control over administration, contracts, personnel, policies, and medical-staff appointments.
- Maintain the same frequency, intensity, supervision, and accountability as other parent departments.
- Integrate billing, records, human resources, payroll, benefits, compensation structure, and purchasing, either directly or through parent-managed contracts.
- List the site on a reimbursable line of the parent's most recent Medicare cost report and show costs and charges for outpatient-department services, or submit equivalent certifications if no Medicare cost report is filed.

B. CMS provider-based deeming and registration

When CMS has determined that a site qualifies as provider-based and complies with 42 C.F.R. § 413.65, HHS must deem the site to satisfy the statutory child-site criteria. HHS must establish a registration process for sites qualifying under either the detailed statutory criteria or CMS provider-based deeming.

C. Newly acquired and newly constructed sites

- A newly acquired site that was not already 340B-eligible generally may not participate until three years after acquisition.
- HHS may grant a case-specific hardship exception and approve participation on a date within 180 days after acquisition.
- A newly constructed site beginning operations after enactment may participate only after meeting all statutory requirements; the bill does not impose the same fixed three-year delay on a newly constructed site.

HHS must establish, through rulemaking, a process for determining the status of legacy sites that were previously treated as child sites but do not satisfy the new criteria. The deadline is tied to the first covered-entity recertification after enactment: the process must be established within 180 days after that recertification.

D. Reports and records

- GAO must report within three years on child-site program-integrity issues.
- HHS must report within two years and every two years thereafter on the number, geography, payer mix, and type of child sites, the effects of eligibility delays, and needed policy changes.
- GAO must report within one year on best practices for using child-site savings to improve access to care and health-related benefits.
- Covered entities must retain child-site compliance records for at least three years and submit to HHS audits.

Source pages: 36-53.

Section 7 - Transparency

Beginning no later than one year after enactment and annually thereafter, every covered entity must report extensive information covering the parent entity, all child sites, and all contract-pharmacy arrangements for the preceding year.

A. Required annual data

- Total number of individuals who received 340B drugs.
- Total number of 340B prescriptions or administrations billed to insurance, categorized by Medicare, Medicaid, CHIP, individual or group coverage, group health plan, and uninsured status, as specified by HHS.
- For Medicare cost-reporting entities, charity care as a ratio of worksheet S-10 charity care to total operating cost; for other entities, a qualitative charity-care description tailored to the grant or designation and designed not to be overly burdensome.
- Optional information concerning under-reimbursed care.
- A standardized description of how 340B savings were used for health services or health-related benefits, categorized by services, benefits, populations, and assistance to underserved, uninsured, or medically vulnerable patients and communities.
- An attestation by the chief executive officer, chief financial officer, or chief operating officer that savings benefited the patients and communities served.
- Patient financial demographics, including eligibility for assistance or sliding-scale programs, residence in shortage or underserved areas, membership in underserved populations, uninsured status, Medicaid coverage, and CHIP coverage.
- Policies promoting medication access and adherence.
- For nongovernmental hospitals, State and local government contracts and modifications.

- Identification of third-party administrators used for 340B administration.
- The Medicare and Medicaid service funding shortfall reported on IRS Form 990.
- Outpatient patient volume and 340B program operating costs.

B. Publication, retention, and audit

Covered entities must retain the supporting records for at least three years. HHS must publish the reported information within 90 days of receipt in an electronic, searchable format, both in the aggregate and by covered-entity type. Proprietary information in submitted government contracts must be redacted before publication.

HHS must establish a direct electronic submission process within one year and report the collected information to Congress annually. Covered entities must permit HHS to audit the records used in the reporting, including records showing how 340B discounts were used.

Source pages: 53-60.

Section 8 - Enhancing Program Integrity

A. Expanded audits

HHS may conduct additional audits of covered entities, child sites, contract pharmacies, and manufacturers. Covered-entity audits may address eligibility, diversion, duplicate discounts, contract pharmacies, and improper discounts on drugs that are not covered outpatient drugs. Manufacturer audits may address inaccurate ceiling prices.

- Audit standards and protocols must be publicly available.
- An audit may not be closed before a required corrective action plan has been fully implemented.
- Covered entities may contract only with 340B vendors that agree to provide data to HHS and independent auditors and respond to audit requests on time.
- When an entity failed eligibility requirements for the full audit period, or a manufacturer failed its obligations for the full period, consequences must be consistent with the violation and may not treat the failure as retroactively curable.
- HHS must issue audit and reporting rules within one year.

B. Corrective action, repeat audits, and disenrollment

The section expands sanctions for knowing and intentional failure to implement a corrective action plan within 180 days after HHS notice, subject to additional time allowed by HHS. HHS must increase audit frequency for previously noncompliant entities and assign correction responsibility to a corporate officer.

HHS must create a formal notice and corrective-action process and disenroll a covered entity that fails to implement a corrective action plan within 180 days after a final audit report involving eligibility, diversion, duplicate discounts, contract-pharmacy requirements, non-covered-outpatient-drug claims, certain ADAP rebate claims, or required reporting and use of program savings.

C. Private nonprofit hospital contracts with government

For private nonprofit hospitals relying on a State or local government contract to qualify under hospital categories (L)-(O), HHS must obtain, review, verify, and document that the contract:

- Is a mutually binding exchange requiring health services or supplies in return for something of value.
- Identifies the hospital and governmental party and is signed and dated by appropriate officials.

- States an effective date and remains active and unexpired during registration, recertification, or the entire audit period.
- Explicitly requires services for individuals who are both low-income and ineligible for Medicare and Medicaid.

HHS must verify existing contracts within one year and may not register or recertify a hospital whose contract fails these standards. A qualifying private nonprofit hospital also must annually verify an active government contract and its nonprofit status.

Source pages: 60-70.

Section 9 - Preventing Duplicate Discounts

A. National 340B data clearinghouse

Within one year, HHS must contract with an independent, conflict-free third party to operate a national clearinghouse. The initial contract is for four years and may be renewed after a new bidding or competitive process.

For 340B drugs furnished to Medicare, Medicaid, CHIP, or health-plan enrollees, the clearinghouse must:

- Request and receive claims-level Medicaid rebate data from States, claims-level data from covered entities, and other data specified by HHS.
- Maintain data confidentially, validate covered-entity submissions, and obtain corrections when submissions are incomplete or inaccurate.
- Notify covered entities, HHS, State Medicaid agencies, and manufacturers of identified violations to allow remediation.
- Provide manufacturers with covered-entity claims data so manufacturers can identify units that may generate another rebate or discount, including voluntary commercial arrangements.
- Where feasible, share timely data with covered entities, HHS, States, and manufacturers for the statutory prevention purposes identified in the bill.
- Calculate total 340B sales for purposes of allocating user fees.
- Permit grant-based covered entities in subparagraphs (A)-(K) with patient volume in the lowest decile to submit aggregated retrospective data.

HHS may grant a case-specific hardship exemption allowing aggregate rather than claims-level submissions when claims-level reporting is not feasible.

B. Data restrictions and covered-entity duties

- The clearinghouse contractor may have no direct contractual involvement with participating covered entities, payers, or manufacturers; may disclose data only as necessary for statutory and program-integrity purposes; may not sell or license the data; and may not collect non-340B drug-pricing information from covered entities.
- Covered entities must participate in data transmission, including data available through contract pharmacies.
- Manufacturers, plans, third-party administrators, and PBMs may use clearinghouse data only to prevent duplicate discounts and diversion. Use for pricing, marketing, or another unauthorized purpose may trigger civil monetary penalties.
- All exchanges must comply with HIPAA privacy, security, and breach-notification regulations.

C. Repayment and definitions

HHS must require resolution with affected manufacturers when duplicate discounts are identified. Repayment may be made by the covered entity for its noncompliance, by a State Medicaid program for rebates it improperly requested, or by a State when the financial benefit accrued to the State, including under managed care.

The bill defines "diversion" as resale or transfer of a 340B drug to a person who is not a patient under the new statutory patient definition. It defines "duplicate discount" as a Medicaid payment for a 340B drug that is also subject to a Medicaid drug rebate.

D. Plan and PBM noninterference

Group health plans, health insurers, and PBMs may not interfere with the ability of covered entities, contract pharmacies, or manufacturers to prevent or recover duplicate discounts. HHS must impose civil monetary penalties for violations. Within one year, CMS and HRSA must report to Congress on coordinated federal efforts to address duplicate discounts. HHS may issue implementing regulations.

Source pages: 70-79.

Section 10 - Patient Financial Assistance

Each covered entity must make its financial-assistance policy transparent at the point of care and publicly available, apply the policy to patients served by child sites and contract pharmacies, and provide the policy to HHS upon request. Implementation and enforcement records must be retained for at least three years.

A qualifying policy generally consists of a written financial-assistance policy meeting Internal Revenue Code section 501(r)(4)(A), available at least to patients with income at or below 200 percent of the Federal poverty level, plus an applicable sliding fee scale for 340B covered outpatient drugs. HHS may approve a different policy for a specific covered entity.

The policy must be written in plain language and made available to patients of the parent entity, child sites, and contract pharmacies. Compliance is expressly protected from being treated as a prohibited remuneration or referral act under the cited civil monetary penalty, anti-kickback, and physician self-referral statutes.

The requirements as applied to child sites and contract pharmacies are delayed until three years after enactment. GAO must study and report on the effect of the requirements on patient access to 340B drugs.

Source pages: 79-81.

Section 11 - Equitable Treatment of Covered Entities and 340B Pharmacies

A. Commercial plan, insurer, and PBM nondiscrimination

A group health plan, individual or group health insurer, or PBM may not impose requirements, exclusions, reimbursement terms, or other conditions that differ because an entity or pharmacy participates in 340B or dispenses 340B drugs.

The bill specifically prohibits:

- Paying a covered entity or 340B pharmacy less than a similarly situated non-340B entity or pharmacy for the same quantity of a drug.
- Applying differential fees, chargebacks, clawbacks, adjustments, professional dispensing fees, network requirements, audit requirements, inventory requirements, or other restrictions that interfere with the value of the 340B discount.

- Interfering with a patient's choice to obtain a 340B drug in person, by direct delivery, by mail, or through another shipment method.
- Requiring a covered entity or pharmacy, directly or through a third party, to identify 340B drugs.
- Refusing to contract based on 340B status or covered-entity category.
- Denying coverage of a drug because it is a 340B drug.
- Requiring use of a 340B pharmacy in a manner inconsistent with statutory contract-pharmacy requirements or patient need and access.
- Failing to permit point-of-sale differentiation between private and State Medicaid plans sponsored by the same payer, including through appropriate BIN/PCN identifiers.

HHS must impose civil monetary penalties not exceeding $5,000 per violation per day. Proposed regulations are due within 180 days and final regulations within one year. These penalties may be imposed in addition to other available enforcement actions.

B. Medicare Part D and MA-PD protections

A Medicare prescription drug plan sponsor or Medicare Advantage organization offering an MA-PD plan may not require a covered entity to use a 340B pharmacy in a manner that violates 340B contract-pharmacy requirements or is inconsistent with patient need and access.

Source pages: 82-88.

Section 12 - User Fee Program

A. Fee amount and allocation

Beginning in fiscal year 2031, HHS must assess and collect quarterly user fees from every covered entity. The total fee pool is $50 million in fiscal year 2031. Beginning in fiscal year 2032, the amount is indexed to the annual percentage change in the specified Washington-Arlington-Alexandria Consumer Price Index through the preceding June 30.

Each covered entity's share is based on its proportion of total 340B covered-outpatient-drug prescription volume. HHS must notify entities of the annual assessment no later than December 31 of the applicable fiscal year, and payment is made in four equal quarterly installments during the calendar year following notification. The bill also describes collection across the last three quarters of the fiscal year and the first quarter of the next fiscal year, leaving implementation details for HHS administration and possible rulemaking.

B. Permitted uses

- A web-based fee collection system.
- Operation and maintenance of the national data clearinghouse.
- Improvements to the security, searchability, reliability, and integrity of the 340B Office of Pharmacy Affairs Information System.
- Improvements to manufacturer and covered-entity compliance tools.
- Covered-entity and manufacturer audits.
- Other program-integrity uses approved by HHS.

Fee revenue must supplement, not replace, appropriated funds. HHS may create exceptions to the otherwise applicable fee amount for certain covered entities through rulemaking. Payment of the assessed user fee becomes a statutory condition of covered-entity eligibility.

The HHS Inspector General must review the program annually for its first five years and report to Congress by September 30 of each review year.

Source pages: 88-94.

Section 13 - Studies and Reports

- GAO must report within two years on hospital debt-collection practices, including practices of hospital covered entities in categories (L)-(O).
- HHS must study reasonable dispensing fees for the 340B program and report to Congress within two years.
- The HHS Assistant Secretary for Planning and Evaluation must study interactions between the new 340B clearinghouse and the other federal drug-discount data systems cited in the bill, and recommend ways to streamline operations and reduce duplicative discounts. The section does not specify a deadline for the ASPE study.

Source pages: 94-95.

Section 14 - Additional Resources

The bill authorizes $3 million annually for fiscal years 2027 through 2031 for the HHS Inspector General to conduct 340B audits, investigations, oversight, and enforcement. It separately authorizes $9 million annually for fiscal years 2027 through 2030 to implement the Act. In total, these provisions authorize up to $51 million over the stated periods, but authorization does not itself provide an appropriation.

HRSA receives authority to hire additional staff as needed. HHS must use notice-and-comment rulemaking, as appropriate, to implement the amended 340B statute.

Source pages: 95-96.

Section 15 - Definitions

- “Child site” means a site wholly owned and operated by a covered entity.
- “Contract pharmacy” means a pharmacy under contract with a covered entity to dispense covered outpatient drugs on the covered entity’s behalf, whether distributed in person or by mail.

Source pages: 96-97.

Section 16 - Effective Date

The Act and all amendments generally take effect on the date of enactment. That immediate effective-date clause is subject to the many specific transition periods, reporting deadlines, rulemaking deadlines, delayed applications, and fiscal-year start dates contained throughout the bill.

Source pages: 97.

Implementation Timeline

The following table consolidates the principal deadlines stated in the bill. Deadlines measured from enactment would depend on the actual enactment date.

Deadline / Period	Principal Requirement	Responsible Party
Date of enactment	General effective date; contract-pharmacy protections, patient definition, core compliance provisions, parent-level financial-assistance requirements, and other amendments take legal effect unless a specific delay applies.	HHS and regulated parties
Within 180 days	Proposed regulations for payer/PBM civil monetary penalties. A separate child-site process is due within 180 days after the first covered-entity recertification following enactment.	HHS

Deadline / Period	Principal Requirement	Responsible Party
Within 1 year	End rebate pilot and transition to clearinghouse; contract with clearinghouse operator; establish transparency submission system; begin annual transparency reporting; verify existing nonprofit-hospital government contracts; issue audit procedures; GAO child-site best-practices report; CMS/HRSA duplicate-discount coordination report; final payer/PBM penalty rules.	HHS, GAO, CMS, HRSA
Within 2 years	First HHS child-site report; first OIG referral-prescription report; GAO hospital debt-collection report; HHS dispensing-fee report.	HHS, OIG, GAO
Every 2 years after first child-site report	Continued HHS reporting on child sites.	HHS
At least every 3 years	Patient-status audits of covered entities, with more frequent audits for high-risk and high-volume entities.	HHS
3 years after enactment	Financial-assistance requirements apply to child sites and contract pharmacies; newly acquired child sites generally become eligible after a three-year delay; GAO child-site integrity report due.	Covered entities, HHS, GAO
12-year study period	OIG annual study of referral prescriptions, with reports beginning by year two and continuing for the next ten years.	HHS OIG
FY 2027-2031	$3 million per year authorized for OIG oversight and enforcement.	Congress / HHS OIG
FY 2027-2030	$9 million per year authorized for general implementation.	Congress / HHS
FY 2031	Covered-entity user fee program begins with a $50 million total annual assessment.	HHS / covered entities
FY 2032 and later	User fee pool indexed annually to the specified CPI measure.	HHS

Principal Stakeholder Effects

Covered entities

Covered entities would gain clear statutory rights to use contract pharmacies, receive delivery of 340B-priced drugs at those locations, resist discriminatory payer/PBM terms, and use a defined referral-prescription pathway. In return, they would assume extensive new obligations: contract registration and standard clauses; annual contract-pharmacy audits; three-year record retention; patient-status audits at least every three years; strict child-site integration standards; annual public reporting; financial-assistance policies; claims-level clearinghouse submissions; corrective-action exposure; and user fees beginning in fiscal year 2031.

Drug manufacturers

Manufacturers would be prohibited from limiting contract-pharmacy delivery, imposing special 340B distribution restrictions, or requiring direct submission of claims data outside the clearinghouse. They would gain structured access to clearinghouse data, expanded authority to request audits based on credible allegations, repayment mechanisms for identified duplicate discounts, and stronger covered-entity compliance standards.

Health plans, insurers, and PBMs

Plans, issuers, and PBMs would become directly regulated under federal 340B nondiscrimination provisions. They could not use lower reimbursement, differential fees, network limits, steering, 340B claim-identification requirements, coverage exclusions, or other special terms based on 340B status. They also would be required to cooperate with duplicate-discount prevention and could face daily civil monetary penalties.

Patients

Patients would receive explicit protections for pharmacy choice and transparent financial assistance, including a general 200-percent-of-poverty eligibility floor and sliding drug fees. Discharge prescriptions and qualifying referral prescriptions would receive statutory recognition. At the same time, the narrower patient definition, infusion-only exclusion, referral-volume audits, and three-year delays affecting newly acquired child sites could restrict some current 340B utilization depending on HHS implementation.

HHS, HRSA, CMS, OIG, and GAO

Federal agencies would undertake a major implementation program involving multiple notice-and-comment rules, a national claims clearinghouse, expanded audit and enforcement capacity, public data systems, recurring reports, contract verification, user-fee collection, and new staffing. The bill authorizes funding and user fees, but the scope and timing of implementation would depend heavily on appropriations, procurement, systems readiness, and regulatory decisions.

Major Issues Left to HHS Rulemaking or Administrative Judgment

- What constitutes a high number of contract pharmacies, a high-risk or high-volume covered entity, and the permissible number, scope, and duration of manufacturer audits.
- The standard mandatory terms for contract-pharmacy agreements and the registration and recertification procedures.
- The credible-allegation standards and pre-audit resolution procedures for contract-pharmacy, patient-status, and referral-prescription audits.
- The criteria for child-site hardship exceptions, treatment of noncompliant legacy child sites, and provider-based deeming administration.
- The reporting form, data definitions, payer categories, publication format, redaction standards, and audit approach for annual transparency reports.
- Claims-data specifications, privacy controls, hardship exemptions, and operating rules for the national clearinghouse.
- Alternative financial-assistance policies for covered entities not readily fitting the statutory 501(r) model.
- The meaning of “similarly situated” for payer/PBM nondiscrimination, additional prohibited practices, and penalty administration.
- Exceptions from user-fee assessments and the detailed timing and mechanics of fee collection.

Source Document

SUSTAIN 340B Act, 119th Congress, 2nd Session, Senate legislative text, 97 pages, document identifier TAM26924 18S S.L.C. The uploaded draft does not display an assigned bill number or completed introduction and committee information.