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Summary of the 340B for Patients Act and SECURE 340B Act

Following the passage of pharmacy benefit manager (PBM) reform legislation in early 2026, federal policymakers have shifted their attention towards new opportunities to lower the cost of health care. That includes the 340B drug discount program, which enables eligible hospitals and care facilities to stretch scarce federal resources in support of low-income or uninsured patients. While the 340B program was created by Congress with the intention of bolstering medication access for underserved patients, critics argue that it has quickly grown into a federal subsidy for well-to-do hospitals and lacks safeguards to significantly lower the cost of care. Supporters of the discount program fear that new manufacturer rebating practices, or burdensome statutory requirements on covered entities, may be detrimental to precariously funded hospitals and sites of care, leading to a death spiral of facility closures and reduced access for underserved patients. Congress has not implemented a substantial statutory change to the program since passage of the Affordable Care Act in 2010. From 2018 to 2025, 340B purchases nearly tripled in size, at a rate far outpacing all other U.S. drug markets. In 2025 alone, 340B covered entities purchased more than $100 billion in outpatient drugs. For more information on the creation, intended purpose, and current challenges with the 340B program, visit AMCP's Legislative and Regulatory Position Statement on the 340B Drug Pricing Program.

On June 29, Senate Health, Education, Labor and Pensions (HELP) Committee Chair Bill Cassidy (R-LA) unveiled a discussion draft of the 340B Drug Pricing Integrity and Accountability for Patients Act. Referred to as the 340B for Patients Act (and not to be confused with the 340B PATIENTS Act (H.R. 4581/S. 2372)), release of the draft text follows an earlier report and investigation completed by Chair Cassidy into the use of 340B savings by covered entities. On July 6, Reps. Scott Peters (D-CA) and John Joyce (R-PA) introduced a similar 340B reform package, known as the Strengthening the Exercise of Controls and Upgrading Requirements for Efficiency in (SECURE) 340B Act (H.R. 9599). While the two legislative packages share several similarities in terms of establishing "340B patient" definitions, imposing new requirements on contract pharmacies and 340B child sites, and increasing data reporting and transparency into program activities, significant differences emerge in how the proposals consider manufacturer rebates, the collection and sharing of 340B claims and savings data by the federal government, and the use of user fees to fund program activities. This recent uptick in 340B activity from Congress follows a series of developments on both the regulatory and judicial fronts, including the promulgation and later rescindment of a 340B rebate model pilot by HRSA, and legal battles between manufacturers and 340B covered entities over access to discounts. Additionally, President Trump's Fiscal Year (FY) 2027 Department of Health and Human Services (HHS) budget request proposes shifting oversight of the 340B program from the Health Resources and Services Administration (HRSA) to the Centers for Medicare and Medicaid Services (CMS), while the two bills in question keep program oversight within HRSA. A section-by-section summary of the 340B for Patients Act discussion draft and SECURE 340B Act are included below.

340B Drug Pricing Integrity and Accountability for Patients Act (*340B for Patients Act,* Discussion Draft)

Chair Cassidy's prior investigation centered on the use of 340B revenue by covered entities, fees paid to third-party administrators including the 340B Prime Vendor, and the level of affordable care provided to patients of 340B entities. These findings provide insight into the intended outcomes of the 340B for Patients discussion draft, which aims to mandate the use of 340B savings for charity care through the use of a sliding fee scale; delink the fees paid to third parties from the price of covered outpatient drugs; limit the allowable number of contract pharmacies; and boost transparency into the actions of program participants. Of note, the 340B for Patients draft would allow for manufacturers to provide savings through the use of retrospective rebates, drawing the ire of covered entities who fear a delay in their access to savings. While other 340B proposals outline the creation of a central, comprehensive data clearinghouse to prevent duplicate discounts with other federal drug affordability programs, the 340B for Patients Act discussion draft is less prescriptive and grants HHS more authority in developing the repository. Sec. 1 of the discussion draft simply establishes a short title and table of contents.

- Sec. 2 – Rebate conditions

Under current law, manufacturers may only implement rebate models with the permission of HHS. Sec. 2 would permit manufacturers to offer 340B ceiling prices through discounts *or* a rebate at their own discretion. A manufacturer may elect to provide upfront discounts to covered entities at the time of sale, as long as the covered entity maintains a physically segregated inventory system of covered and noncovered outpatient drugs, establishes a procedure for identifying 340B patients (as defined in Sec. 4 of the bill) at the time of dispensing, submits standardized claims information to manufacturers within 30 days after the drug is dispensed, and documents compliance to HHS and the applicable manufacturer annually. A manufacturer may also choose to provide discounts after the covered entity submits standardized claims data to a "standardized claims repository," to be developed and managed by HHS.

Sec. 2 would also allow manufacturers to make 340B drugs available through a retrospective rebate, provided that a covered entity files a request for a rebate, complete with standardized claims information, within 90 days of the date a drug is dispensed. A manufacturer would be required to pay rebates for undisputed 340B claims within 10 days of receiving the request. For denied 340B claims, manufacturers must justify the denial to covered entities, allow covered entities to dispute the denial or request review by HHS, and reconsider the denial should HHS determine a review to be appropriate.

While manufacturers would be granted the authority to determine how 340B prices are offered under this section, covered entities may choose how to receive discounts if they agree to pass the entirety of the discounted price, plus a nominal dispensing fee to be determined by HHS, through to patients.

For the purposes of this bill, 'standardized claims information' includes data already collected by covered entities on a regular basis, such as Healthcare Encounter Data; RX Identifiers for retail claims, Unique Transaction ID and NDC11 for medical claims; ordering physician NPI; date and location of service; etc.

Sec. 2 also requires covered entities to allow audits by HHS or manufacturers at the expense of HHS or the applicable manufacturer. Covered entities that knowingly submit false information would be subject to a civil monetary penalty for each covered drug unlawfully purchased.

- Sec. 3 – Amendments to the eligibility of subgrantees

Under the Public Health Service Act, federal grantees may pass a portion of their award to other entities, or subgrantees, to accomplish the objectives of the award. Such subgrantees are considered covered entities under the 340B program. Sec. 3 would amend the certification and recertification processes for covered entities who qualify for the 340B program due to their status as subgrantees under Title XXVI (Ryan White HIV/AIDS Program) or Sec. 318 (relating to the treatment of sexually transmitted diseases) of the Public Health Service Act by requiring such entities to attest additional information to HHS. This includes details regarding the grant parameters itself, information on the entity's public or nonprofit status, certification that revenues generated by 340B participation are consistent with the scope of the grant as described, and verification of a patient population that is primarily low-income or uninsured. Subgrantees are prohibited from participating in the 340B program if they only receive in-kind contributions from Title XXVI or Sec. 318 grantees.

- Sec. 4 – Additional definitions

The 340B statute does not currently define a 340B-eligible patient, while prior court rulings have significantly expanded the patient definition established previously by HRSA through guidance. Under Sec. 4 of the 340B for Patients Act, a 340B-eligible patient would be defined as an individual who:

1. Received an outpatient health care service at a covered entity within the last two years;
2. Has a relationship with the covered entity in which the covered entity has generated and maintains an auditable medical record;
3. Received a prescription for the covered outpatient drug "as a result" of an outpatient health care service or referral; or
4. Is registered in a state-operated AIDS drug purchasing assistance program.

The 340B for Patients discussion draft does not require "a patient" to receive a service reimbursed under Medicare, allowing for telehealth services to be considered applicable. Sec. 4 also provides definitions for "outpatient health care services," "practitioners," "specified non-hospital covered entities," "affiliates," and "control."

- Sec. 5 – Contract pharmacies

Sec. 5 pertains to the use of contract pharmacy arrangements by 340B covered entities. The bill would allow for covered entities to continue to contract with pharmacies to provide 340B drugs, clarifying that manufacturers must ship the drugs to the contract pharmacy. In order for a covered entity to enter into a contract pharmacy arrangement, the covered entity must ensure that drugs purchased fall within the scope of the entity's qualifying federal grant or statute, develop and maintain procedures to ensure compliance with the prohibition on duplicate discounts, and register and annually recertify the contract pharmacy through HHS' standardized identification system.

The bill would also limit certain covered entities, including subsection (d) hospitals (Disproportionate Share Hospitals), free-standing cancer hospitals, and rural referral centers, to a maximum of five

contract pharmacies. This limitation does not apply to contracts with mail-order pharmacies. A contract pharmacy that enters into an agreement with a covered entity must also be located within the service area of the covered entity. A service area is defined as a nonoverlapping statistical geographic area defined by the Census (Public Use Microdata Area) in which such covered entity is located, as well as all contiguous Public Use Microdata Areas to the covered entity. The bill would permit the use of contracted mail-order pharmacies only for 340B grantees dispensing to patients within their service areas, or for sole community hospitals and critical access hospitals dispensing to rural patients. Comprehensive hemophilia diagnostic treatment centers are exempt from the mail order service area restriction, while specified nonhospital covered entities, as defined in Sec. 4 of the discussion raft, are not permitted to use mail-order pharmacies.

Covered entities must submit written agreements with contract pharmacies to HHS within 30 days of entering into an agreement. Written agreements must include binding obligations on the contract pharmacy to comply with 340B discount duplication and diversion restrictions. Penalties for contract pharmacy violations of this section include civil monetary penalties, liabilities to manufacturers, and removal from the 340B program. Within 180 days of enactment, HHS would be required to issue guidance on covered entity and contract pharmacy compliance.

- Sec. 6 – Transparency

Sec. 6 establishes transparency and reporting requirements for certain covered entities, dependent on annual net revenues. Disproportionate Share Hospitals and other covered entities as determined by HHS, earning less than $200,000,000 in net annual revenue, are required to submit reports on the profit margin generated by 340B drug savings for the covered entity and each child site. Disproportionate Share Hospitals, and other covered entities as specified by HHS, earning over $200,000,000 in annual net revenue, must report the 340B margin—including for child sites—broken down by component. Disproportionate Share Hospitals earning over $1,000,000,000 annually in net revenues must report the total number of patients who received 340B drugs in the preceding year and the share of all patients treated who received 340B drugs, broken down by payer type. Such entities earning over $1,000,000,000 must also report on costs incurred for charity care for each covered entity and child site. Federal grantees earning over $200,000,000 in net annual revenues must report on the use of 340B margins on specified categories of care: medical care, dental care, mental health, pharmaceuticals, sliding fee discounts, case management, transportation, patient and community education, community health workers, outreach, eligibility assistance, and nutritional assessment. All metrics would be adjusted annually for inflation.

Covered entities are required to submit reports annually, starting 14 months after the enactment of this section. HHS must publish data reported under this section annually and must promulgate regulations to carry out this section within 180 days of enactment.

- Sec. 7 – Ensuring affordability

Sec. 7 would establish patient affordability requirements for 340B covered entities. 340B hospitals, including Disproportionate Share Hospitals, children's hospitals, free-standing cancer hospitals, critical access hospitals, and rural referral centers, would be required to establish a sliding fee scale, to be posted publicly, of cost-sharing rates for 340B drugs. Under the bill's proposed maximum out-of-pocket (OOP) obligations, patients earning less than the federal poverty level (FPL) would have an OOP maximum of $0. The OOP maximum for patients earning above the FPL but less than 200% of

the FPL would be the lesser of 20% of the otherwise applicable obligation or $35, while the OOP maximum for patients earning above 200% of the FPL would be the lesser of 30% of the otherwise applicable obligation or $50. All metrics would be adjusted annually for inflation. Each covered entity would be required to submit their sliding fee scale to HHS within a time and manner as determined by HHS.

Certain nonhospital covered entities, that are required to provide affordability assistance as a condition of their grant, would be required to establish a discount policy that ensures patients are not denied access to 340B drugs.

All affordability protections described in this section must also be made available at contract pharmacies. HHS would be required to promulgate regulations within 90 days of enactment, while the HHS Inspector General would be required to publish annual reports on covered entity and contract pharmacy practices related to this section.

- Sec. 8 – Hospital Child sites

Sec. 8 of the 340B for Patients Act narrows the eligibility of potential 340B child sites. It would allow for hospital covered entities to register off-campus outpatient facilities as child sites, as long as the facility:

1. Is listed on the covered entity's Medicare cost report on a line that is reimbursable under Medicare;
    a. Cost reports must demonstrate that services provided are associated with Medicare outpatient hospital department services;
2. Is wholly owned by the covered entity;
3. Meets Medicare provider standards;
4. Provides outpatient care services in addition to drug dispensing or administration;
5. Is subject to the charity care and sliding fee policies applicable to the covered entity under Sec. 7 of the discussion draft;
6. Is located in a health service shortage area as designated by HHS' medically underserved population criteria;
7. Provides charity care that is greater than or equal to:
    a. The total cost of charity care incurred at the parent facility; or
    b. The average cost of charity care across all hospitals in the state;
8. Earns Medicaid revenue that is greater than or equal to:
    a. The total Medicaid revenue earned at the parent facility; or
    b. The average Medicaid revenue earned across all hospitals in the state; and
9. Is annually recertified by the covered entity as compliant with the requirements under this section.

Facilities previously registered as child sites of 340B covered entities, that no longer meet the requirements of this section following enactment of the bill, would be required to self-disclose their status and any improper purchases to HHS, in addition to deregistering from the 340B program. Covered entities and child sites knowingly operating in violation of this section would be subject to civil monetary penalties of $2,500 for each violation. HHS would be required to publish annual reports that list compliant 340B child sites. This section would take effect 120 days after enactment. 60 days

after enactment, HHS would be required to issue program instructions for covered entities to register child sites.

- Sec. 9 – Contracting reform

Sec. 9 pertains to restrictions on third-party administrator and contract pharmacy fees. Third-party administrative service fees for 340B-related services are limited to flat-dollar amounts, delinked from the price of covered outpatient drugs, consistent with the fair market value of the applicable service, and in compliance with state and federal law.

Contract pharmacies' fees are also restricted to flat-dollar amounts, delinked from the price of 340B drugs, but may not exceed 125% of the average per-prescription dispensing fee paid to the pharmacy by all third-party payers in the preceding year. Covered entities must maintain auditable records of agreements with third-party administrators and contract pharmacies, to be made available to HHS upon request. HHS may impose civil monetary penalties on third-party administrators and contract pharmacies equal to ten times the amount such entity received for their services.

- Sec. 10 – Prime vendor program

The 340B prime vendor program currently allows covered entities and manufacturers to contract with a single vendor for 340B-related services. Sec. 10 would amend the 340B prime vendor program to allow for covered entities to choose between two separate prime vendors, no later than one year after the bill is enacted. This section also imposes conflict of interest and conditional requirements on prime vendor contracts, with prime vendors restricted from charging for enrollment fees or educational services. Prime vendors are also prohibited from negotiating procurement contracts for non-340B covered drugs. HHS would be granted unlimited rights to data generated under 340B prime vendor contracts.

- Sec. 11 – Transfer of civil penalty amounts collected

Sec. 11 requires the Department of the Treasury to transfer the amount of all civil monetary penalties collected for violations of this bill in a calendar year to HRSA's Office of Pharmacy Affairs.

- Sec. 12 – Application; regulations and guidance

Except where otherwise noted, all provisions of this bill would take effect one year after enactment. HHS would be granted the authority to promulgate any regulations or guidance necessary to implement this bill.

Strengthening the Exercise of Controls and Upgrading Requirements for Efficiency in 340B Act (*SECURE 340B Act,* H.R. 9599)

The SECURE 340B Act, introduced in the House of Representatives on July 6, echoes much of the sentiment found in the 340B for Patients discussion draft in its treatment of covered entities. The SECURE 340B Act implements additional transparency and reporting requirements for covered entities, child sites, and contract pharmacies, but is less stringent on the number of or use of contracted pharmacies. And while provisions of the 340B for Patients are primarily geared towards oversight of 340B covered entities and child sites, the SECURE 340B Act also touches on manufacturer

behavior by effectively banning the use of retrospective rebates. The bill's rebate ban would remain in place for at least four years while HHS contracts with a new, nationwide 340B Drug Discount Program Data Clearinghouse and evaluates its performance. The third-party clearinghouse, whose role and responsibilities are explicitly outlined in the bill text, would be responsible for the secure exchange of 340B information between covered entities, manufacturers, state Medicaid programs, and the federal government in an effort to reduce duplicate discounts and discount diversion while also facilitating the repayment of duplicate discounts where necessary.

While similar to the 340B for Patients discussion draft in some fashion, the SECURE 340B bill is more reflective of the policies found in prior discussion drafts of the SUSTAIN 340B Act. Similarities include the implementation of a 340B user fee program—designed to both supplement funding for HRSA oversight and to reduce the incentive for sites to register as covered entities when unnecessary—and the use of a nationwide data clearinghouse to prevent duplicate discounts. The "Bipartisan Senate Working Group" that introduced prior versions of the SUSTAIN Act was reformed in May of 2025, but has yet to take significant action on 340B legislation this Congress. The summary of Rep. Peters' SECURE 340B Act continues below.

- Sec. 2 – Establishing a clear patient definition

Like the 340B for Patients Act draft, the SECURE 340B Act would also establish a statutory definition of a 340B patient. The bill would define a 340B patient as an individual who:

1. Has received an outpatient health service from a covered entity within the previous two years,
    a. The 340B prescription drug must be "related to" the outpatient service provided,
    b. The service must be reimbursable under Medicare, meaning that current Medicare telehealth restrictions would apply;
2. For services furnished by 340B grantees, receives a service from the grantee within the scope of the grant or designation;
3. Has a relationship with the covered entity in which the covered entity maintains an auditable health care record.

Covered entities must maintain 340B patient health records for a period of time to be determined by HHS through notice and comment rulemaking, which differs from the 340B for Patients Act's requirement that records be maintained for at least three years. The SECURE bill also provides a definition for a 340B "prescribing providers," which would refer to a health care provider who:

1. Is employed by or is an independent contractor of the covered entity and is billed by the covered entity for services; or
    a. Is an employee or independent contractor of a physician organization affiliate of the covered entity;
2. Has provided a signature demonstrating clinical responsibility over the prescription;
3. Is enrolled as a provider under Medicare or Medicaid;
4. Is not excluded by HHS from participation in Medicare or state health programs.

Sec. 2 also includes significant parameters for the referral of 340B patients by covered entities to non-covered entities. For 340B patients who are referred to non-covered entities by 340B providers, the eligible covered entity is permitted to furnish a covered outpatient drug if the patient is prescribed

the drug within two years of receiving the original referral. Under this section, covered entities with referral qualifications include federally qualified health centers, critical access hospitals, or sole community hospitals. Orphan designated drugs, and drugs prescribed by federally qualified health centers that are infused or administered by a clinician (except for entities already providing infusions as of the date of enactment) are excluded from these referral qualifications. A referred patient's medical record must include documentation of the referral and service provided and must be retained for at least five years or as required by state law. HHS is granted auditing authority of covered entities if their referral prescriptions reflect 25% or more of their 340B-furnished prescriptions, are in the 75th percentile of all covered entities, or exceed the average annual percentage over a three-year period. HHS shall make aggregate information on covered entities publicly available and may revoke referral authorization for covered entities whose 340B referrals exceed 35% of all 340B drugs furnished in the most recent year.

- Sec. 3 – Allowable use and robust oversight of contract pharmacies

Sec. 3 of the SECURE 340B Act places additional requirements on the use of contract pharmacies for both covered entities and manufacturers, but does not include the same limitations on the number of contract pharmacies permitted, location of contract pharmacies, or use of mail order as found in the 340B for Patients discussion draft. The SECURE bill would prohibit manufacturers from imposing restrictions on the applicable ceiling price, delivery, or data-sharing requirements for 340B drugs distributed to contract pharmacies or to dispensing covered entities.

Under the bill, covered entities are required to register all contract pharmacy agreements with HHS in a timely manner, prior to implementing them. Covered entities must annually attest compliance with this section to HHS. HHS is granted the authority to develop a contract pharmacy agreement review process through notice-and-comment rulemaking, must publish information on registered contract pharmacy agreements publicly, and could issue civil monetary penalties on manufacturers that refuse to dispense or place conditions on the dispensing of covered outpatient drugs. HHS is also granted rulemaking authority to promulgate additional requirements on contract pharmacy agreements, such as information disclosures, use of the 340B data clearinghouse described in Sec. 7, patient choice of pharmacy provider, and the prevention of duplicate discounts and diversion.

- Sec. 4 – Eligibility for child sites

The SECURE 340B Act also includes new parameters for eligible child sites of 340B entities, such as ownership requirements, compliance with Medicaid and Medicare provider standards, listing on the Medicare cost report, and compliance with the financial assistance and charity policies required of the parent entity. Covered entities are also required to register and annually recertify that child sites are clinically and financially integrated, while child sites must provide a clinically meaningful range of services within employed providers' scope of practice.

While the 340B for Patients discussion draft requires child sites to be "wholly owned" by the covered entity, child sites permissible under the SECURE 340B Act may be "majority owned" by the covered entity if the other owners are 501(c)(3) tax-exempt organizations or state or local government entities. Co-owners must demonstrate a commitment to providing care to low-income and uninsured patients and may not be created for the purpose of qualifying as an eligible co-owner under this section.

Under this bill, the child sites will be considered to have met community need standards if they reside within a qualifying ZIP Code Tabulation area, which is defined as Zip Code Tabulation Area ranked as more vulnerable than 50% of all Zip Code Tabulation areas nationally, or more vulnerable than 40% of all Zip Code Tabulation areas in a state. If a potential child site does not fall within a qualifying ZIP Code Tabulation Area, it is still certified if 40% or more of its patients served are covered by Medicaid, are uninsured, or have a household income no greater than 200% of the FPL during the preceding calendar year. HHS may also grant temporary exemptions from the community need standard if a covered entity demonstrates that the child site provides safety-net care primarily to low-income or uninsured individuals, and that there is no alternative provider within a reasonable distance. Covered entities may also demonstrate that removal of the child site would drastically reduce access for the patient population. HHS is required to promulgate rulemaking to implement this section within six months of enactment, while child site eligibility redeterminations will be made during the annual covered entity recertification process.

- Sec. 5 – Improving patient affordability and protections

Sec. 5 would establish patient affordability program requirements and protections for 340B covered entities. As with the 340B for Patients discussion draft, such requirements would also apply to child sites. The SECURE 340B Act requires patient assistance programs to be made available to patients of hospital covered entities earning up to 400% of the FPL, or to patients of all other covered entities earning up to 200% of the FPL. Hospital covered entities must implement a sliding fee scale for patients earning up to 400% of the FPL, with "nominal" copays. HHS is granted the authority to establish a separate sliding fee scale policy for all other covered entities through notice and comment rulemaking. Covered entities must make their assistance programs publicly available through plain language summaries. Such assistance policies must be applied to contract pharmacies prospectively for all new pharmacies after enactment, or within three years of enactment for existing contract pharmacies.

This proposal also differs from the 340B for Patients discussion draft in prohibiting 340B hospitals from selling a patient's medical debt or denying a patient medically necessary care due to nonpayment for one or more bills. 340B hospitals are also prohibited from collecting a patient's medical debt, unless a patient earns more than 600% of the FPL or retains assets that exceed 400% of the patients' outstanding medical debt. Covered hospitals may not charge interest on a patient's medical debt in excess of the percentage allowable by state law. HHS is required to begin annual compliance review within 180 days of enactment and is permitted to enforce civil monetary penalties or refer covered entities to the HHS Inspector General or Internal Revenue Service for further action. The Comptroller General, Government Accountability Office, and HHS Inspector General are directed to develop reports and studies on compliance and the effects of this section.

- Sec. 6 – Data reporting for transparency

Sec. 6 designates annual reporting requirement for both covered entities and HHS. While the covered entity reporting requirements in the 340B for Patients discussion draft differ depending on the type of covered entity and annual revenue earned, the SECURE 340B Act's reporting requirements apply to all covered entities. Specifically, covered entities are required to include data on the total number of patients receiving 340B drugs; the total number of 340B prescriptions filled, broken down by payer type; costs incurred for charity care; a description of the use of 340B savings in a manner that benefits

patients; and the percentage of patients served who are eligible for financial assistance programs, reside in health professional shortage areas, and receive Medicaid or CHIP benefits. Covered entities are also required to report identifying information on contract pharmacies and third party administrators; operating costs related to carrying out the 340B program; and overall number of patients using outpatient services in their annual reporting to HHS. Covered entities are required to report this information within one year of enactment, and annually each year after. HHS is required to publish such information publicly within 30 days of receipt, in an electronic format defining both aggregate data and individual data by covered entity. Within a year of enactment, HHS must compile all reported data into an annual report to Congress.

- Sec. 7 – Enhancing program integrity

Sec. 7 seeks to enhance the integrity of the 340B program by granting HHS additional auditing and sanctioning authority over covered entities. HHS is granted the power to audit covered entities, including contract pharmacies and child sites, to assess compliance and identify statutory violations. Audits, which cannot be closed until a corrective action plan is implemented by the covered entity, must be conducted in accordance with "generally accepted standards." HHS may determine the consequences for failed audits, including disenrollment from the 340B program. Covered entities are also required to conduct independent, biennial audits of their facilities, contract pharmacies, and child sites. Independent auditors may not have any financial connection to the covered entity, while covered entities must submit the independent auditors' findings, methodology, and any corrective action plans as necessary to HHS. If necessary, violating covered entities must also disclose to applicable manufacturers and repay savings generated if the aggregate amount exceeds a de minimis threshold to be established by HHS. Within one year of enactment, HHS must promulgate rules and regulations to carry out these sections. Existing sanctioning authority would be amended to allow for HHS to sanction covered entities that knowingly fail to implement corrective action plans within six months of receiving notification to do so. This section establishes processes for HHS to notify covered entities of violations and for covered entities to submit corrective action plans, including standards for timelines for correction and compliance that are "reasonable and proportionate to" the violation in question. Such processes must consider circumstances for temporary suspensions of covered entity eligibility, de-identified public reporting of violations, disenrollment of covered entities, and civil monetary penalties scaled to the frequency of violations.

The SECURE 340B Act would also place additional certification criteria on private, nonprofit hospitals eligible for or seeking eligibility for the 340B program as a result of their contract with a state or local government to provide services to underserved patients not covered by Medicaid or Medicare. For such entities, HHS must verify the hospital's contract with a state or local government. HHS would be required to conduct verification within one year of enactment. HHS would also be permitted to verify the nonprofit status of private hospitals participating in the 340B program, using publicly available information on the hospital's federal tax status.

Sec. 8 – Facilitating data exchange to improve program integrity

Sec. 8 of the SECURE 340B Act would establish a new, national 340B Program Data Clearinghouse, while barring the use of retrospective rebate discounts for four years while the clearinghouse is implemented and evaluated. To establish the clearinghouse, HHS would be required to contract with an independent, third-party clearinghouse entity that does not hold conflicts of interest with any

covered entity, participating manufacturer, health plan, or pharmacy benefit manager (PBM) within one year of enactment. Such clearinghouse contracts would be carried out in four year terms, to be renewed through a competitive bidding process at the completion of each term. The contracted clearinghouse entity would be required to:

1. Establish a procedure for collecting 340B pharmacy and medical benefit claims data, including traditional electronic data elements such as information on the date of service; the prescription or claim number; quantity dispensed or furnished; National Drug Code or Healthcare Common Procedure Coding system code; provider or prescriber identifier; and 340B identification number of the covered entity; information on the corresponding wholesaler; and additional data elements as determined by HHS.
    a. HHS would determine a timeframe in which claims-level data must be submitted and adjudicated;
    b. Covered entities may not reclassify historical claims from non-340B to 340B beyond six months after a drug is furnished;
2. Request and establish a timeline for receipt of claims-level rebate data from state Medicaid agencies; claims-level data from covered entities, contract pharmacies, health plans, and PBMs; claims-level rebate file data from commercial claims also eligible for 340B discounts;
3. Ensure the confidentiality of pharmacy and medical benefit claims data received;
4. Evaluate the accuracy of data received and rectify errors or incompleteness from the covered entity;
5. Notify the covered entity, HHS, or applicable manufacturer of instances of duplicate discounts with Medicaid rebates;
6. Provide applicable manufacturers with claims-level data to identify 340B drugs that may generate *voluntary* rebates with commercial plans;
7. Share relevant data with covered entities, HHS, state Medicaid agencies, and manufacturers, to prevent violations of the federal ban on pharmacy gag clauses, duplicate discounts with drugs receiving Medicare Part B or Part D inflationary rebates, and duplicate discounts for drugs selected for Medicare price negotiation;
    a. "Relevant' data is addressed in paragraph 10 of the bill text. The third-party clearinghouse must identify and allow manufacturers to access to claims data on covered outpatient drugs that are selected for Medicare price negotiation, subject to the IRA's inflationary rebates, received a 340B discount request for the same unit of a drug from two or more covered entities, or received reimbursement under a state plan, ensuring such drug did not also receive a Medicaid drug rebate;
8. Allow covered entities, except for Disproportionate Share Hospitals, to submit required claims-level data in a batched, retrospective basis;
9. Determine the total sales of 340B drugs to all patients, in order to determine program user fees as would be established by the bill's Sec. 10;
10. Connect claims data and purchasing order data in a streamlined, timely manner;
11. Allow state Medicaid agencies to access claims data deemed necessary to prevent Medicaid drug rebate duplicate discounts,
12. Respond to requests from covered entities or manufacturers in a timely manner (as determined by HHS);
13. Facilitate manufacturer inquiries, audits, duplicate discount and diversion reviews, or other program integrity activities by producing data necessary to carry out such activities,

14. Establish standards, aligned with current state and federal law, for the confidentiality, access, use, retention, and security of data transmitted to the clearinghouse, applied to covered entities, manufacturers, plans, PBMs, and other program participants,
15. Document incomplete or inaccurate information submitted by covered entities;
16. Maintain data submitted to the clearinghouse for ten years.

The third-party clearinghouse would be prohibited from selling the claims-level data it generates and may not collect pricing information on non-340B drugs. Under this section, covered entities are required to comply with the data reporting requirements outlined in the bill text, in addition to data elements that HHS may request through future rules. Covered entities must share data with the third-party clearinghouse in a timely manner, to be determined by HHS through notice-and-comment rulemaking. Covered entities in violation of the reporting requirements must rectify such violations within 30 days of being notified, while manufacturers may suspend 340B payments to covered entities until the violation is remediated. 340B manufacturers, health plans, PBMs, and other third parties who utilize clearinghouse data must only use the information for the purposes of preventing duplicate discounts or diversion. Any entities that utilize clearinghouse data for an unlawful purpose would be subject to civil monetary penalties established by HHS.

For the purposes of repaying duplicate discounts or diversions back to manufacturers, the SECURE 340B Act's would require HHS to establish a repayment process through notice-and-comment rulemaking. Covered entities, as well as state Medicaid programs, would be required to submit repayment plus accrued interest upon identification of a duplicate discount or diversion. PBMs and group health plans are explicitly prohibited from interfering with the ability of covered entities, contract pharmacies, or manufacturers to prevent duplicate discounts and recoup errant payments, while state Medicaid agencies must establish a process to identify when 340B drugs are dispensed to Medicaid beneficiaries and to exclude such drugs from Medicaid rebate requests.

Within a year of implementation of the clearinghouse, HHS would be required to allow an independent, annual compliance audit of the clearinghouse. HHS may take appropriate action, including civil monetary penalties or contract termination, upon identifying noncompliance. HHS would also be required to submit a report to Congress on the coordination of federal drug discount programs. HHS would be granted authority to promulgate necessary regulations to implement this section through notice-and-comment rulemaking.

In addition to compliance evaluations, HHS would also evaluate the third-party clearinghouse on its performance, benchmarked to several standards outlined in the SECURE 340B Act text. Manufacturers would be statutorily required to provide the 340B ceiling price upfront during the first four year period after enactment, to allow for the initial clearinghouse entity's performance to be evaluated. This prohibition on retrospective 340B rebates, which does not apply to rebates for the AIDS Drug Assistance Program, would rescind if HHS determines that the 340B clearinghouse has not satisfied its required performance benchmarks within four years of enactment. The clearinghouse performance benchmarks are considered satisfied if:

1. All 340B claims are submitted to and processed by the clearinghouse;
2. At least 90% of the value of claims submitted to the clearinghouse in the most recent calendar year are unique and do not result in duplicate discounts or diversion;

3. At least 90% of the value of all 340B claims is adjudicated within the timeframe established by HHS;
4. At least 95% of the value of all 340B claims contains the necessary data required by this section and is verified as complete and accurate when submitted.

If HHS determines these performance standards to be satisfied at the conclusion of initial four-year performance period, the HHS Inspector General would be tasked with continued performance evaluations and the issuing of public reports. Such reports would be required within two years after the initial four year performance period, within five years after the initial four year performance period, and again every five years thereafter. If a report determines that any benchmark is unsatisfied, the third-party clearinghouse has up to six months to rectify the issue. Within 60 days of a six-month corrective period, the HHS Inspector General would be required to issue a follow-up report on the effectiveness of said correction. If the follow-up report determines a benchmark to remain unsatisfied or a corrective action to be unsatisfactory, manufactures may begin to offer retrospective 340B rebates. HHS must issue a preliminary progress report on these activities within two years. This section also includes a special rule for drugs selected for Medicare price negotiation, wherein covered entities would also be required to submit claims data directly to manufacturers for the purposes of avoiding duplicate discounts.

- Sec. 9 – Prohibition on discriminatory practices and contracting

Sec. 9 of the SECURE 340B Act would establish guidelines for group plans, insurers offering individual or group coverage, Medicare Part D and Medicare Advantage prescription drug plans (MA-PDs), and PBMs contracted with 340B covered entities. Such plans and PBMs would be barred from engaging in discriminatory practices against covered entities, contract pharmacies, or beneficiaries by imposing requirements, terms, or conditions due to their nature as 340B participants. Specifically, such plans and PBMs would be barred from reimbursing covered 340B entities at lower rates than noncovered entities; imposing alternative terms on fees, clawbacks, pharmacy networks, or audits to those offered to noncovered entities; interfering with a patient's medication delivery choice; requiring identification of 340B drugs other than through the third-party clearinghouse; refusing to contract with a covered entity due to their 340B status; and denying coverage of a drug on the basis of it being a 340B drug. Covered entities would also be explicitly prohibited from sharing any 340B savings generated with a plan or PBM. Part D and MA-PD plan sponsors are also prohibited from requiring covered entities to utilize contract pharmacy sites that are not compliant with the bill's restrictions. Under this section, covered entities fees to third-party administrators would be delinked from the price of a covered drug, instead limited to a bona fide service fee.

- Sec. 10 – Ensuring HRSA has adequate resources to oversee the program

Sec. 10 of the SECURE 340B Act would establish a user fee program for *all* covered entities participating in the 340B. Policymakers have proposed a 340B user fee program on several previous occasions, all to no avail. Under the SECURE Act, HHS would begin to collect user fees at the start of Fiscal Year (FY) 2027. Fees would be collected on an annual basis, in an amount determined by HHS through notice-and-comment rulemaking. The bill text provides an initial guideline for such fee, defined in general as 0.1% of the dollar amount paid by the covered entity for 340B drugs in the previous year. HHS must ensure that user fees are used to maintain 340B program integrity, including through the development of a web-based fee collection system, establishment of the third-party 340B

claims data clearinghouse, audits, and other program integrity purposes. The user fee program is designed to supplement, but not supplant, traditional appropriations allocated to HHS and HRSA for the program. HHS is granted the authority to carry out all necessary regulations to establish the user fee program, as well as exceptions to the fee amount. The HHS Inspector General would receive oversight capabilities to conduct an annual review of and congressional report on the user fee program for its first five years. This section would also appropriate an additional $3,000,000 annually for FYs 2027 to 2031 for oversight and enforcement activities, along with an additional $9,000,000 annually for FY 2028 to 2031 for general program purposes. After enactment, HHS is granted with direct-hire authority to appoint a minimum of 20 new positions to carry out 340B program management.

- Sec. 11 – Studies and reports

Sec. 11 includes requirements for publicly available reports and studies on the effectiveness of the 340B program. Such reports cover topics including dispensing fee and reimbursement practices for 340B and non-340B drugs, 340B discounts retained by covered entities and payers, and the debt collection practices of hospitals. This section would also require annual reports to Congress on state and covered entity contracts, rates of charity care, reimbursement rates, and compliance.

- Sec. 12 – Meanings

Sec. 12 would codify definitions for the terms "child site" and "contract pharmacy."

- Sec. 13 – Requirements for nonhospital covered entities and subgrantees

Sec. 13 outlines additional requirements for nonhospital covered entities and subgrantees. Nonhospital covered entities are required to be nonprofits or public entities; be eligible to purchase 340B drugs under the scope of their federal grant or authorizing statute; oversee the activities of any subgrantees; and require subgrantees to comply with all legal provisions applicable to the covered entity. Nonhospital covered entities must maintain written records demonstrating a compliant relationship with the subgrantee, and that the subgrantee is authorized to provide 340B drugs. Subgrantees receiving in-kind contributions from section 318 (relating to treatment of STDs) and section 317(j)(2) covered entities (relating to tuberculosis treatment) must demonstrate to HHS that the share of 19 to 64 year old Medicaid beneficiaries receiving services onsite, divided by total patients receiving services provide services, is greater than or equal to the overall number of 19 – 64 year olds enrolled in the state Medicaid plan divided by all 19 to 64 year old individuals living in the state. Such subgrantees must also provide a written plan to HHS outlining how grant funds are utilized, and a plan outlining the termination of any agreement once funding has lapsed. Section 318 and 317(j)(2) entities operating on or before Jan. 1, 2025 are exempt from this requirement. All subgrantees must disenroll if they no longer meet the aforementioned requirements and must disenroll from the program entirely or reenroll with a new covered entity within 30 days should a covered entity become ineligible. This section also provides a statutory definition of "340B subgrantee."

- Sec. 14 – Effective date

Sec. 14 of the SECURE 340B Act establishes an effective date, except where otherwise stated, of the date of enactment. HHS would be granted the power to promulgate final regulations, through notice-and-comment rulemaking, to implement the bill within 180 days of enactment. HHS may establish

appropriate transitional periods for covered entities, manufacturers, contract pharmacies, and other parties to comply with the bill. Transitional periods must be at least 180 days from the enactment of any new compliance obligation, unless otherwise mentioned.