340B Reform Bills: 119th Congress

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See below for a high-level comparison of some of the major provisions across four 340B bills:

- **340B ACCESS Act:** Carter (R-GA), Harshbarger (R-TN), introduced in the House. *Text // Press Release*
- **340B for Patients Act:** Cassidy (R-LA), a discussion draft in the Senate. *Text // Press Release*
- **SECURE 340B Act:** Peters (D-CA), Joyce (R-PA), introduced in the House. *Text // Press Release*
- **SUSTAIN 340B Act:** Moran (R-KS), Baldwin (D-WI), Capito (R-WV), Kaine (D-VA), Boozman (R-AK), Hickenlooper (D-CO), introduced in the Senate. *Text // Press Release*

Provision	340B ACCESS	340B for Patients	SECURE 340B	SUSTAIN 340B Act
Patient Definition	Defines patient as an individual who, on a per-prescription basis, is dispensed or administered a covered outpatient drug directly related to a health care service provided by a covered entity (CE) provider with whom the individual has a care relationship, on site at the CE or its child site or pharmacy, or at a contract pharmacy or through mail-order as applicable, within the last one or two years depending on CE type.	Defines patient as an individual who has recieved outpatient care at the CE in the past two years, maintains a relationship with the CE, and whose prescription is written by one of the CE's practitioners.	Defines patient as an individual who received a covered outpatient health care service within the past two years from a provider at a CE with whom they have a relationship, and the prescription received was pursuant to the service provided.	Defines patient as an individual who received a covered outpatient health care service within the past two years from a provider at a CE with whom they have a relationship such that there is an auditable medical record of the patient, and the prescription received was pursuant to the service provided or as a referral from an ER or inpatient stay.
Contract Pharmacies	Allows CEs to use contract pharmacies, with requirements on compliance procedures and registration of contract pharmacies. For certain CEs, limits the number of allowable contract pharmacies to 5 (excluding mail-order pharmacies) within a specified service area.	Allows CEs to use contract pharmacies but sets conditions, including that pharmacies must be registered and recertified annually. For certain CEs, limits the number of allowable contract pharmacies to 5 (excluding mail-order pharmacies) within a specified service area.	Allows the use of contract pharmacies without limit on number or location. CEs must register contract pharmacies.	Allows the use of contract pharmacies without limit on number or location; requires contract cancelation with any contract pharmacies that have not dispensed any covered outpatient drugs within the past year, with exceptions. Allows HHS to develop oversight regarding a "high number" of contract pharmacies and impose transparency requirements. CEs must register contract pharmacies.

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Provision	340B ACCESS	340B for Patients	SECURE 340B	SUSTAIN 340B Act
Diversion and duplicate discounts	Requires HHS to promulgate regulations setting methodologies State Medicaid programs and CEs must use to prevent duplicate discounts and diversion, and establishes requirements for using the clearinghouse to prevent duplicate discounts.	Not specifically addressed outside of data reporting/audits made pursuant to rebate model or contract pharmacy arrangements.	Sets rules for contract pharmacies to prevent duplicate discounts, including the use of a data clearinghouse and subjecting both CEs and contract pharmacies to audits.	Authorizes HHS to conduct additional audits to assess diversion and duplicate discounts; establishes a clearinghouse to prevent and detect duplicate discounts, and requires a report to Congress on duplicate discount prevention efforts.
Child sites	Allows child sites if they meet certain criteria, including being wholly owned, providing outpatient care, meeting certain provider-based standards, meeting revenue, charity care, and sliding scale policies and levels, being located in a shortage area, and other criteria. Requires non-compliant child sites to deregister and self-disclose improper purchases.	Allows child sites if they meet certain criteria (including being wholly owned, being located in a shortage area, and meeting certain charity care requirements); requires CEs to deregister any newly nonconforming sites and disclose improper purchases.	Allows use of child sites, limited by requiring that 50% of patients of child sites come from qualifying census tracts; allows exception if 40% of patients are Medicaid, low-income, or uninsured. Requires child sites to be wholly owned by the CE, integrated financially, and registered.	Allows child sites, provided they are registered, owned and controlled by the CE, apply the same financial assistance policy as the CE, comply with Medicare provider-based rules, offer a range of clinical services, are clinically, operationally, and financially integrated with the CE, and other requirements. Places participation restrictions on newly acquired and newly built child sites.
Patient affordability	Requires CEs to establish a sliding fee scale for patients up to 200% FPL, with patients at or over 200% receiving the lesser of 30% of the out-of-pocket obligation or a $50 copayment.	Requires CEs to establish a sliding fee scale for patients up to 200% FPL, with patients at or over 200% receiving the lesser of 30% of the out-of-pocket obligation or a $50 copayment.	Requires CEs to extend a patient financial assistance policy to patients up to 400% FPL for cetain CEs and 200% FPL for all other CEs, and a sliding fee scale for patients up to 400% FPL with copayments considered “nominal in amount.”	Does not set FPL-related guidelines on financial assistance policy but requires such policy be a sliding fee scale or other approved alternative, made clear to patients, and publicly reported. The policy must also apply at child sites and contract pharmacies.

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Provision	340B ACCESS	340B for Patients	SECURE 340B	SUSTAIN 340B Act
Transparency and data reporting	Requires CEs to report on charity care costs and how the 340B margin is utilized, requires claims to include a 340B claims modifier; includes a transparency section closely based on H.R.3290 (118th), the 340B Transparency Act.	Requires hospital CEs to annually report data on individuals who received 340B drugs, costs incurred, charity care, and margin generated from 340B drugs.	Requires CEs to report on the number of prescriptions filled, charity care, patient demographics, margin generated from 340B and how the funds are used.	Requires CEs to report annually on the number and demographics of individuals who received 340B drugs, number of drugs dispensed, charity care, uncompensated care, how savings are used, and other data.
Contracting and fees	Requires TPA fees be flat dollar amounts based on fair market value rather than drug prices, discounts, or a percentage of revenue.	Requires TPA fees be a flat fee per unit of service, consistent with fair market value. Also requires contract pharmacy remuneration be a flat fee per dispense not exceeding 125% of the average per-prescription dispensing fee in the applicable calendar year.	Requires TPA fees be flat dollar amounts based on fair market value rather than drug prices, discounts, or a percentage of revenue.	Directs HHS to study dispensing fees and report to Congress within 2 years.
Data clearinghouse	Requires HHS to contract out to create a third-party data clearinghouse within 1 year of enactment to improve program integrity and provide manufacturers with data on 340B. Requires CEs to submit claims data within 45 days of dispensing the covered drug, with a 340B claims modifier, and specifies certain claims-level data elements to be included.	Not specifically addressed, though an HHS-operated "claims repository" is discussed under the rebate model section.	Requires HHS to contract out to create a third-party data clearinghouse within 1 year of enactment, intended to facilitate data exchange and improve program integrity. Identifies required data to be collected, including specific claims-level data.	Requires HHS to contract out to create a third-party data clearinghouse designed to ensure proper accounting and prevent duplicate discounts. The contract will be a 4-year term. Lists out specific duties of the clearinghouse and requires CEs to submit requested claims-level data, with a hardship exemption.

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Provision	340B ACCESS	340B for Patients	SECURE 340B	SUSTAIN 340B Act
Audits and program integrity	Includes a transparency section closely based on H.R.3290 (118th), the 340B Transparency Act, providing for audits, including on the use of the 340B margin. Generally authorizes audits on various requirements and authorizes CMPs for various violations.	Not specifically addressed outside of audits and oversight pursuant to rebate model or contract pharmacy arrangements. Authorizes CMPs for various violations.	Requires CEs to have an independent audit conducted biennially; establishes requirements for CE timely responses to inquiries and audits. Authorizes CMPs for various violations.	CEs must report on child site and contract pharmacy arrangements annually; HHS is authorized to conduct additional audits, including of CEs on diversion and duplicate discounts, and of manufacturers on provision of the ceiling price. Failed audits may result in a corrective action plan and/or being removed from the program.
Rebate model	Does not address.	Allows manufacturers to use a rebate model with certain guidelines, **OR** covered entities may choose how to recieve rebates rather than be subject to the manufacturers' choice, given the CE passes along all discounts or rebates to 340B patients.	Prohibits manufacturers from using a rebate model for 4 years post-enactment, allowing that if the clearinghouse does not meet performance metrics within that 4 year period, rebate models may be possible following that period.	Requires HHS to conclude the rebate model pilot within 1 year of enactment.
CE eligibility	Generally narrows CE eligibility, including for nonhospital entities and subgrantees, and requires DSH in urban areas to be in the top 40% of hospitals in their state for both Medicaid/CHIP outpatient revenue and uncompensated care to remain 340B eligible CEs.	Requires subgrantees of grants awarded under Title XXVI or Sec. 318 of the Public Health Service Act to submit information to HHS to verify eligibility as a CE. Subgrantees are prohibited from being CEs if they receive only in-kind contributions from the primary grantee.	Does not address.	Adds additional requirements and vertification of certain non-profit hospital CEs.

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Provision	340B ACCESS	340B for Patients	SECURE 340B	SUSTAIN 340B Act
Discriminatory practices and contracting	Establishes protections against discrimination by health plans, insurers, and PBMs against CEs, contract pharmacies, or plan beneficiaries such as imposing terms or conditions that differ from those applied to entities/beneficiaries not connected to the 340B program.	Does not address.	Establishes protections against discrimination by health plans, insurers, and PBMs against CEs, contract pharmacies, or plan beneficiaries such as imposing terms or conditions that differ from those applied to entities/beneficiaries not connected to the 340B program.	Establishes protections against discrimination by health plans, insurers, and PBMs against CEs, contract pharmacies, or plan beneficiaries such as imposing terms or conditions that differ from those applied to entities/beneficiaries not connected to the 340B program.
Resourcing 340B	Does not address.	Allows civil monetary penalties (CMPs) collected for violations in the 340B program to be used by HHS to cover the administrative costs of 340B.	Establishes a user fee program beginning FY2027 to fund 340B program administration from CEs, with the fee generally being 0.1 percent of the dollar amount paid by the CE for covered outpatient drugs in the previous year. Clarifies the user fee program should "supplement not supplant" other appropriations for 340B.	Establishes a user fee program beginning FY2031, where HHS will collect fees from CEs; the fee will be based on the CE's share of all 340B drugs dispensed the previous year. CEs will be notified annually amd the fee will be collected quarterly. Clarifies the user fee program will "supplement not supplant" other appropriations for 340B. Additionally authorizes personnel and funds for audits, oversight, and other activities created by the bill.

Other Notes:

- The 340B for Patients Act also makes changes to the **prime vendor program,** requiring HHS to provide CEs with a choice of at least two prime vendors and prohibiting prime vendors from negotiating procurement of other products for CEs.
- The 340B ACCESS Act includes provisions to establish that **the federal 340B statute supersedes any state or local laws** on the program, including regarding the use of contract pharmacies.
- Other 340B bills address certain elements of the program, including the **340B PATIENTS Act** on contract pharmacies and the **Community Health Center Drug Pricing Protection Act** on rebate models.
- Stakeholders should note the potential for **hearings on 340B** in both the House Energy and Commerce (E&C) Committee and the Senate Health, Education, Labor, and Pensions (HELP) Committee by the end of this year, given the uptick in legislative activity.