Sept. 11, 2026

Comparison of 340 Reform Proposals in the 119th Congress

The following chart compares provisions of existing 340B reform proposals in the 119th Congress.[i] [ii] [iii]

Issue Area	***SECURE 340B Act*** *(H.R. 9599 – Reps. Peters/Joyce [PA] bill)*	***SUSTAIN 340B Act*** *(S. 5244 – Senate Gang of Six Bill)*	***340B for Patients Act*** *(Sen. Cassidy discussion draft)*	***340B ACCESS Act*** *(H.R. 5256 – Reps. Carter [GA]/Harshbarger bill)*
Defining a 340B Patient	A "patient" must have a relationship with the CE and must have received a prescription related to a covered outpatient service within the preceding 2 years. Services must be billable under Medicare, meaning current telehealth restrictions apply.	A "patient" must also have received a covered outpatient service within two years, while the CE must maintain an auditable relationship with the patient. A prescription must be pursuant to the service, billable under Medicare or Medicaid, or an in-patient or ER referral	A "patient" must have received a drug as a result of outpatient care at a covered entity within the preceding two years. Reimbursement under Medicare is not specifically defined, meaning telehealth restrictions do not apply. Drugs furnished through an AIDS drug assistance program are exempt.	A "patient" must have received a prescription directly related to a service provided by a CE. For grantees, sole community hospitals, and critical access hospitals, a service must have been provided within the preceding two years, while other hospitals must have provided a service within the preceding year. All CEs must maintain auditable patient records.
Regulating Contract pharmacies	Contract pharmacies are permitted, and such agreements must be registered with HHS. The bill does not place limits on the number, location, or mail-	Contract pharmacies are permitted, and such agreements must be registered with HHS. CEs may contract with an unlimited number of	Contract pharmacies permitted and must be registered and annually recertified with HHS. Most CEs are limited to 5 contract pharmacies located	Contract pharmacies are permitted, and such agreements must be registered with HHS. Up to 5 contract pharmacies, located within a CE's service

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	order use of contracted pharmacies. Contract pharmacy arrangements would be subject to independent audits every two years.	pharmacies, although HHS is granted authority to conduct oversight on CEs with "a high number" of contract pharmacies. Contracts with pharmacies that fail to dispense a covered outpatient drug in a prior year are voided.	within a service area, excluding mail order pharmacies. Mail order pharmacies are permitted when dispensing within a service area, or for SCHs and CAHs dispensing to rural areas.	area are permitted for a majority of hospitals. Restrictions on mail order are based on CE type and geographic boundaries, as in the Cassidy discussion draft.
340B Child Sites	Child sites are permitted if they meet a community need standard. Under the bill, this means the site is located in a qualifying ZIP code tabulation area, or that at least 40% of the patients served are on Medicaid, are uninsured, or have incomes at or below 200% of the Federal Poverty Level. Entities with a demonstrated safety net purpose are exempt from this standard. Child sites must also be majority-owned and registered by the CE; meet Medicare provider-based standards and be listed on the CE's Medicare cost report; adhere to the same financial assistance policies as the parent	Child sites must be registered, owned, and controlled by the CE. They must meet Medicare provider-based standards, offer financial assistance in the same matter as the parent entity, and offer a range of integrated clinical services in line with those offered at the parent entity. Previously ineligible child sites purchased after enactment of this bill would not be eligible as a child site for three years, while newly constructed sites must be compliant to remain eligible.	Child sites are permitted if they are: wholly owned by the CE; meet Medicare provider-based standards; are located in a professional-shortage area; comply with the parent's charity care and sliding fee scale policies; and derive Medicaid revenue that equals or exceeds the parent entity or state's average. Noncompliant sites must deregister and disclosure improper purchases of covered drugs.	Child sites are permitted if they are: wholly owned by the CE; meet Medicare provider-based standards; are located in a professional-shortage area; comply with the parent's charity care and sliding fee scale policies; and derive Medicaid revenue that equals or exceeds the parent entity or state's average. Noncompliant sites must deregister and disclosure improper purchases of covered drugs.

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	CE; and provide a clinically meaningful range of services.			
Retrospective Rebate Policies	340B rebates are explicitly prohibited. HHS will implement an independent 340B claims clearinghouse and may permit rebates after four years depending on the clearinghouse's performance.	HRSA must end its rebate model pilot within one year of enactment.	Discounts may be provided through: a rebate within 10 days of receiving a data submission; an upfront discount if the CE agrees to pass the discount through to the patient in it's entirety; or after the claim is submitted to a data repository created and maintained by HHS.	Does not mention 340B rebates.
340B Referrals	A non-CE must dispense a drug within 24 months of receiving a referral. Eligible CEs under this bill include FQHCs that are Patient-certified medical homes, CAHs and SCHs. A patient must have received care from the eligible CE within 24 months of the referral.	Referrals are permitted for 340B grantees, CAHs, and SCHs. A covered drug must be prescribed within 12 months of receiving the referral.	No restrictions on 340B referrals.	Referrals are permitted for 340B grantees, SCHs and CAHs, as a result of care coordination. The referral must be for specialty care not available at the CE. Grantees affiliated with hospitals or earning over $1 billion annually. The service must occur within one year of the referral.
Drug Diversion and Duplicate Discounts	HHS must promulgate rules for contract pharmacy arrangements to ensure the prevention of duplicate	Duplication in primarily prevented through the 340B claims clearinghouse established by the bill. HHS is	Does not include a specific section on duplication. The 340B claims repository established by HHS under the bill would be	To prevent duplicate discounts with the Medicaid Drug Rebate program, HHS must promulgate regulations within a year of

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	discounts. CEs and contract pharmacies are subject to both HHS and manufacturer audits. The 340B claims data clearinghouse established under the bill would be utilized for preventing duplication and diversion.	also granted authority to identify duplication and diversion. HHS must issue a report to Congress within one year of enactment detailing efforts to prevent duplication.	tasked with preventing duplication or diversion. Data generated for audits or by standard claims may be used in prevention efforts.	enactment describing methodologies for state Medicaid programs and CEs. Duplicate discounts must also be identified by the clearinghouse established under the bill.
Covered Entity Eligibility	Does not make substantial changes to CE eligibility. CEs contracted with state or local governments must submit their arrangements to HHS.	Private nonprofit hospitals contracted with state or local governments must submit their contracts for HHS for verification.	Does not make substantial changes to CE eligibility. Subgrantees of grants under Title XXVI (HIV prevention and treatment) or Sec. 318 (sexually transmitted disease prevention and treatment) of the PHSA must verify eligibility with HHS. Subgrantees that receive in-kind contributions only are prohibited.	Urban DSH hospitals must provide care to low-income patients, those outside the top 40% of hospitals in a state for revenue from Medicaid or uncompensated care prohibited. All DSH hospitals must have charity care costs that equal or exceed an annual 340B margin. Rural referral centers must show that 60% of revenue is derived from rural patients. Nonprofit hospitals contracted with state or local governments must amend their contracts to ensure that care to low-income patients is provided.

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Patient Affordability Protections	Hospitals must make a financial assistance policy available to patients earning up to 400% of the FPL, while other CEs must make it available to patients earning up to 200% of the FPL. A sliding fee scale must be made available to patients earning up to 400% of the FPL, with nominal copays permitted. Such requirements apply to child sites and contract pharmacies. The bill also places restrictions on medical debt collections by hospitals.	All CEs shall ensure that a transparent patient financial assistance policy is made available to patients earning at least 200% of the FPL or less. A sliding fee scale or other approved policy must be implemented. Patient financial assistance policies must apply to child sites and contract pharmacies.	Hospitals must implement a sliding fee scale for covered outpatient drug cost sharing, starting at $0 for patients below the FPL, and the lower of a percentage or flat fee for others up to 200% of the FPL. Such protections must be made available at contract pharmacies. Hospitals must also submit their scale to HHS for review. Nonhospital CEs must ensure that low-income patients are not denied access to a drug.	Hospitals must implement a sliding fee scale for covered outpatient drug cost sharing, starting at $0 for patients below the FPL, and the lower of a percentage or flat fee for others up to 200% of the FPL. Such protections must be made available at contract pharmacies. Nonhospital CEs must ensure that low-income patients are not denied access to a drug.
Clearinghouse /Claims Repository	HHS must contract with a third-party clearinghouse within a year of enactment to identify claims subject to duplicate discounts, and to share data with manufacturers. CEs are required to submit claims-level data to the clearinghouse.	HHS must contract with a third-party clearinghouse within a year of enactment to identify claims subject to duplicate discounts, and to share data with manufacturers. CEs must submit claims-level data, although CEs with a hardship exemption may submit aggregate data.	HHS must establish its own 340B claims repository, rather than contract with a third-party clearinghouse.	HHS must contract with a third-party clearinghouse within a year of enactment to identify claims subject to duplicate discounts, and to share data with manufacturers.

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Contract Terms and Fees	TPA fees are limited to a bona fide service fee, not tied to the price of a drug or discount offered. HHS must generate a report on dispensing fees within a year of enactment. Insurers and PBMs may not impose discriminatory contract terms on CEs, contract pharmacies, or patients in relation to 340B drugs.	HHS must conduct a study on dispensing fees and publish report within 2 years of enactment. Insurers and PBMs may not impose discriminatory contract terms on CEs, contract pharmacies, or patients in relation to 340B drugs.	TPA fees must be a flat dollar amount, reflective of the fair market value for the service provided. Contract pharmacy fees are limited to a flat fee per drug dispensed, less than 125% of the average dispensing fee granted to other payers.	TPA fees are limited to a bona fide flat dollar amount not tied to the price of a drug. Contract pharmacy fees are also limited to a flat fee per drug dispensed, less than 125% of the average dispensing fee. Insurers and PBMs may not impose discriminatory contract terms on CEs, contract pharmacies, or patients in relation to 340B drugs.
Transparency and Reporting Measures	All CEs must generate and file annual reports to HHS on the total number of patients dispensed, total number of covered outpatient prescriptions filed, charity costs incurred, use of 340B savings, financial assistance policies implemented, and 340B operating costs.	CEs must generate annual reports to HHS on the total number and characteristics of 340B patients served. Such report must also include the number of 340B drugs dispensed, contract pharmacy arrangements, costs incurred for charity care, and how 340B savings are used.	DSH hospitals earning less than $200 million in annual net revenue must annually report the overall 340B margin. DSH hospitals earning over $200 million must report on the 340B margin, broken down by component. Both metrics also apply to child sites. All CEs earing over $1 billion must report on patients receiving 340B drugs, broken down by payer and the costs incurred for charity care. Grantees earning over $200 million must describe	DSH hospitals, as well as other hospitals determined by HHS, must report annually to HHS on the number of patients served, costs incurred for charity care, costs incurred for furnishing care to patients by each payer type, the 340B margin, and how the margin was used.

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			how the 340B margin is used on different categories of services.	
Program Funding	Establishes an annual user fee program beginning in FY 2027. Fees are 0.1 percent of the dollar amount paid by the CE for covered outpatient drugs in the preceding year. The user fee program is designed to support program activities and oversight but does not supplant federal appropriations. HHS is granted authority to establish a user fee program through notice-and-comment rulemaking.	Establishes an annual user fee program for CEs beginning in 2031. Fees would be based on a CE's share of all 340B drugs dispensed in the preceding year. Fees are to be collected in four installments, quarterly. HHS must notify each CE of the amount of annual user fees imposed before Dec. 31 of the fiscal year in which fees apply. The user fee program is designed to supplement but not replace existing federal appropriations. HRSA is granted hiring authority for staff to carry out program requirements.	Each fiscal year, the Department of the Treasury must transfer the total amount of civil monetary penalties collected to HRSA for program administration.	Does not mention program funding.

[i] 340B Reform Bills: 119th Congress. Tiber Creek Group. Aug. 17, 2026 https://files.constantcontact.com/e7416597501/542eadd3-f947-487e-80a4-e5ac61fa36af.pdf?rdr=true

[ii] Comparison of Major Provisions of New and Recent 340B Legislation. Manatt Health. July 7, 2026.

[iii] Summary of the 340B for Patients Act and SECURE 340B Act. AMCP. July 14, 2026. https://www.amcp.org/letters-statements-analysis/summary-340b-patients-act-and-secure-340b-act