NATIONAL HEALTH COUNCIL

NHC 340B Initiative

Side-by-Side Comparison of Three Major 2026 340B Proposals

Patient-Centered Priorities for 340B Reform

- 340B savings should demonstrably improve patient affordability, access, and services.
- Policy changes should not delay access to prescribed medications.
- Patient privacy must be protected in reporting and data sharing.
- 340B should prioritize underserved populations, including rural, rare disease, and specialty-care communities.
- Patients should have a meaningful voice in 340B reforms and ensure savings benefit patients.

H.R. 9599 SECURE 340B Act	**Cassidy Discussion Draft** 340B Drug Pricing Integrity and Affordability for Patients Act	**Gang of 6 Senate Bill** SUSTAIN 340B Act	**Patient Priorities**
UPFRONT DISCOUNTS VERSUS REBATES			
For four years, manufacturers would use the 340B price as an upfront discount. After four years, the model will be reconsidered based on performance.	Manufacturers would choose between a rebate or an upfront discount.	The bill would end the Rebate Model Pilot Program and move to a clearinghouse model instead.	• The financial exchange of 340B discounts must not cause treatment delays because of reimbursement disputes, rebate processing, or other financial issues. • HHS should monitor implementation and adjust the model if patient access or affordability problems arise.

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DEFINITION OF A 340B PATIENT			
Requires an outpatient service from a prescribing provider at the covered entity within 24 months. The service generally must be Medicare-reimbursable, the prescription must relate to that service, and the relationship must be supported by auditable records retained for at least five years.	Requires an outpatient service at the covered entity within two years, an auditable medical record retained for at least three years, and a prescription or order from a qualifying practitioner resulting from the service or a referral.	Must have received services from a covered entity in the last two years.	• Ensure that definitions are clear, actionable, and flexible enough to reflect legitimate care relationships.
PRESCRIPTIONS AND REFERRALS			
FQHAs and other unique sites will have a separate, protected referral pathway. Requirements include ongoing clinical involvement, auditable accounting, monitoring volume, and penalties for non-compliance.	Prescriptions that meet the patient definition are included.	Covered entities would need to document the referral and the prescriber's connections to the covered entity. Referral volume is capped at 20% of total covered outpatient drugs. Entities will have to report referral data annually to HHS.	• Patients need to be able to fill prescriptions with as few "hoops" to jump through as possible. • All administrative additions to 340B should be evaluated for their impact on patient access, adherence, and continuity of care.
ACCESS TO PHARMACIES AND OTHER METHODS OF PRESCRIPTION FULFILLMENT			
No numerical or geographic limitation on contract pharmacies. Includes transparency. Treats mail order, specialty and other delivery methods as contract pharmacies and limits manufacturers from directing patients to particular fulfillment options. Contracts must be reported to and reviewed by HHS.	Limits some 340B sites to five contract pharmacies outside of mail order and pharmacies must be in a defined service area. Limits mail-order availability. Contracts must be reviewed by HHS with significant options for penalties for noncompliance.	Contract pharmacy arrangements would be restored without volume limitations and manufacturers would be required to allow both contract pharmacies and covered entity pharmacies. Provisions are designed to codify and protect contract pharmacy use while creating new oversight requirements.	• Oversight should prioritize program integrity partnered with requirements for passing through savings to patients at contract pharmacies.

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PATIENT AFFORDABILITY ASSISTANCE			
Requires financial assistance from covered entities and hospitals must have a copayment sliding scale	Sets per-drug maximum for patients on a sliding scale.	Defines requirements for what counts as financial assistance. Policies must be applied consistently across child sites and contract pharmacies.	• Any program changes related to patient out-of-pocket (OOP) costs must consider how those costs are appropriate and scalable to patients based on their household means. • Oversight and reporting requirements that demonstrate how 340B savings improve the overall affordability of and access to care, rather than focusing solely on prescription expenses
MEDICAL DEBT PROTECTIONS			
Prohibits selling of patient debt by covered entities, sharing of debt information with credit bureaus, and limits collections and denial of care for debt.	N/A	Requires GAO and HHS studies on hospital debt collection practices	• Patient protection from medical debt when seeking care at a covered entity is important to patients.

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TRANSPARENCY AND PUBLIC REPORTING			
Requires annual reporting by every covered entity, including all sites and pharmacy arrangements. Reporting includes patients and prescriptions by payer, charity care, use of savings, patient demographics, government contracts, TPAs, operating costs, and pharmacy locations. HHS must publish searchable information by covered entity.	Uses a tiered reporting structure. Reporting starts with DSH hospitals and other entities designated by HHS. Larger entities have more reporting. Reporting emphasizes 340B margin, patient categories, charity care, and uses of margin, with public entity specific publication.	HHS would collect and publish a wide range of data from covered entities, patient volume, insurance mix, charity care, savings usage, and more.	• Transparency on the use of savings is critical for patients and advocates to help ensure the appropriate use of program funds and understand the mechanisms behind 340B. • Data collection, transparency, and reporting requirements should be reasonable, appropriately tailored, and designed to avoid unnecessary administrative burden that could divert resources away from patient care or create barriers to patient access. • Reporting categories must have input from patients and other neutral parties.
CLAIMS-DATA EXCHANGE AND CLEARINGHOUSE			
Creates a federal claims clearinghouse. Four-year initial upfront discount period will be reviewed to identify issues such as duplicate discounts.	Requires standardized data that can flow directly to the manufacturer or a federal repository.	HHS would contract with an independent clearinghouse to manage claims level data aimed at preventing duplicate discounts.	• Standardized, reliable data systems can benefit all stakeholders and help support greater transparency and accountability. • Minimize the collection of personally identifiable information and ensure that patient data is used solely for authorized program purposes. • Data collection, transparency, and reporting requirements should be reasonable, appropriately tailored, and designed to avoid unnecessary administrative burden that could divert resources away from patient care or create barriers to patient access.

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AUDITS AND ENFORCEMENT			
Authorizes HHS audits and requires biennial independent audits for all aspects of a covered entity.	Authorizes routine and as needed audits by HHS and manufacturers.	Both HHS and manufacturers have the right to regular audits. Entities using contract pharmacies must undergo annual independent audits.	• Congress should further strengthen 340B program integrity audits such as those conducted by HRSA to ensure transparency and accountability. • Privacy protections must be built in. • Audits must be fair, transparent, consistent, and standardized.
PBM DISCRIMINATION AND VENDOR COMPENSATION			
Prohibits PBMs and insurers from setting conditions that limit access. TPAs cannot tie PBM reimbursement to 340B revenue or volume.	Limits TPA fees to a flat rate, fair market value system.	Prohibits PBMs and insurers from setting conditions that limit access.	• PBM reform is critical and 340B reform is a mechanism for moving forward some aspects of that. Patient access and affordability must be monitored and addressed in a timely manner.
FUNDING			
Imposes a covered entity user fee to fund the clearinghouse, audits and other activities.	Relies on penalties and prime-vendor reform.	Imposes a covered entity user fee.	• Administrative funding must be adequate and must not affect patient access and affordability.