

# The 340B ACCESS Act Ensures the 340B Program Benefits Patients and True Safety-Net Providers

ASAP  
340B



**The 340B Drug Pricing Program (340B program) is well-intentioned, but the evolution of our health care system over three decades has exposed flaws in how the program is structured.** The 340B ACCESS Act represents a comprehensive, meaningful solution needed to ensure the 340B program can fulfill its mission of helping underserved communities by increasing access to affordable drugs and health services. If enacted, the 340B ACCESS Act will ensure that the 340B program reduces drug costs for the patients who need it the most.

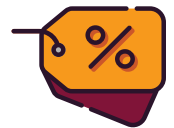
**ASAP340B supports the 340B ACCESS Act, which is broadly aligned with our organization's ten policy principles and our collective belief that changes are needed to put the 340B program on a sustainable path for the future. The bill:**

## 1 **Makes 340B a true safety-net program for patients.**



The 340B program is intended to help support safety-net providers serving underserved and vulnerable patients by increasing access to affordable drugs and health services for these communities. As a result of the changes in the 340B ACCESS Act, nearly 50 million patients in the U.S. will be eligible for lower drug costs.

## 2 **Ensures 340B prescriptions are offered to patients at a discount.**



The 340B ACCESS Act reduces eligible patients' out-of-pocket costs for 340B medicines. It requires hospitals participating in the program to have a sliding fee scale for patient cost-sharing that, at a minimum, applies to uninsured patients and privately insured patients with incomes under 200% of the federal poverty level. Grantees are also required to support access to medicines consistent with their grant's scope that qualifies them for the 340B program and ensures their patients are not denied access to medicines based on their ability to pay.

## 3 Updates the 340B patient definition with strong safeguards.



Patient definition is an essential element in determining if a prescription is eligible for the 340B discount. The 340B ACCESS Act addresses challenges with the current overly broad patient definition by including strong safeguards to improve the integrity of the 340B program. To be considered a 'patient' of a covered entity, an individual must be seen by a provider employed by or contracted with the covered entity and be seen in-person at least once a year (for most hospitals) or once every two years (for grantees and small rural hospitals). Additionally, the covered entity must maintain a consistent responsibility for care and reflect a direct connection between the patient's medical condition and the services being provided or managed (through permitted referrals). Under the bill, referrals are permitted for grantees and small rural hospitals when a patient is referred to an outside specialist for care.

## 4 Strengthens 340B hospital eligibility requirements.



Critical to improving the 340B program is the creation of additional accountability requirements to ensure eligible hospitals are supporting underserved communities as true safety-net providers. The 340B ACCESS Act establishes new eligibility requirements for hospitals that vary by hospital type. One common-sense reform in the bill adds new standards for disproportionate share hospitals to ensure that more of these hospitals are focused on outpatient safety net care. The bill also prohibits hospitals participating in the program from engaging in aggressive medical debt collection practices. Rural hospitals are protected, as the bill maintains current eligibility requirements for critical access hospitals (CAH) and sole community hospitals (SCH), and it allows more hospitals to take advantage of the new Rural Emergency Hospital (REH) designation without losing their 340B eligibility. The bill closes the loophole that allows hospital systems to register rural referral centers as 340B-eligible even if they do not serve rural communities.

## 5 Addresses standards for 340B child sites and subgrantee eligibility.



Hospitals use the current lack of clarity in 340B program guidance to expand to offsite clinics, known as child sites. This legislation requires each child site to provide as much Medicaid and charity care (as a percent of revenue) as the parent hospital or the average for all hospitals in the state (whichever is higher), be located in a medically underserved area, and have the same sliding fee scale requirement to ensure the program is reaching the intended populations. Child sites must provide a meaningful range of clinically relevant services beyond dispensing, infusing or otherwise providing prescriptions. Similarly, the bill strengthens oversight for subgrantees by creating explicit eligibility criteria to ensure the eligible entities are serving the intent of the program—including requiring that subgrantees be a public or non-profit entity.

## 6 Establishes clear criteria for 340B contract pharmacy arrangements to improve access.



Contract pharmacy arrangements, which are not currently binding for drug manufacturers, would be recognized in the 340B statute and new policies would be put in place to prevent abuse and preserve access for patients. While grantees and small rural hospitals would be allowed an unlimited number of contract pharmacies including specialty pharmacies in their service area and use of mail order for patients in their service area (or patients residing in a rural area in the case of critical access or sole community hospitals), other hospitals would be allowed five non-mail order contract pharmacies. Contract pharmacies also must provide the same patient affordability assistance for 340B prescriptions that is provided at the covered entity and must take certain steps to prevent diversion and duplicate discounts.

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### Prevents middlemen and other for-profit entities from diverting funds meant for patient care.



Protections are added in the 340B ACCESS Act to prevent for-profit companies, such as pharmacy benefit managers (PBMs), from siphoning off 340B savings intended to help patients by reducing reimbursement for 340B-qualifying prescriptions. The legislation prohibits PBMs from imposing discriminatory contracts on covered entities and from interfering with a patient's choice to receive a 340B drug from a covered entity or contract pharmacy. Additionally, fees that pharmacies and other for-profit third parties charge for 340B-related services would be limited to ensure covered entities and the patients they serve receive most of the savings associated with the program.

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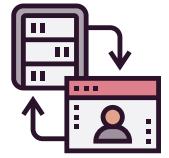
### Facilitates public reporting of 340B program data.



Through reforms in the 340B ACCESS Act, DSH hospitals will be required to report basic information about their involvement in the 340B program to Health and Human Services (HHS), including the total acquisition cost and reimbursement for 340B discounted medicines and the total amount spent to administer the 340B program. Additionally, grantees subject to reporting will report how they are using their 340B margin.

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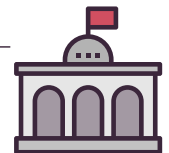
### Creates a 340B data clearinghouse.



The 340B ACCESS Act establishes a national clearinghouse capable of receiving Medicare, Medicaid, and commercial claims data to verify 340B claim eligibility. This neutral clearinghouse will build accountability and coordination for covered entities without increasing administrative burdens for safety-net providers. Data provided to the clearinghouse would be de-identified and subject to safeguards that prohibit use for marketing or other unauthorized purposes.

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### Enhances federal administration and oversight of the 340B program.



The 340B ACCESS Act grants targeted rulemaking authority to the relevant HHS agencies to the extent needed to implement specific legislative provisions. Additional and improved program integrity measures to help enforce program requirements and legislative reforms are also included. The bill clarifies that the 340B program is governed exclusively by federal law superseding any state or local law, regulation or other provision relating to or that could otherwise affect the 340B program.