ADVOCATES FOR COMMUNITY HEALTH

Comparing 340C, PROTECT 340B Act, and ASAP 340B			
Provision	**340C**	**PROTECT**	**ASAP 340B**
Overview	Opt-in subset to the existing 340B program that offers certain new program elements if entities agree to certain accountability and transparency standards.	The PROTECT 340B Act would prohibit health insurers and PBMs from discriminating against 340B providers or their contract pharmacies on the basis of their status as providers or pharmacies that dispense 340B drugs.	340B reform effort that aims to realign the 340B program in the interest of safety-net providers and the communities they serve.
Status of Proposal and Source of Information	Legislation Drafted – 340C	Introduced in the House as H.R. 2534; potential Senate companion being considered.	Principles Published - ASAP 340B Principles.
Champions/Sponsors	Advocates for Community Health.	Reps. Abigail Spanberger (D-VA-07) and Dusty Johnson (R-SD-AL); Supported by many in the 340B community, including 340B Health, NACHC, National Rural Health Association, and others.	Alliance to Save America's 340B Program (ASAP 340B) Members.

Prepared by Advocates for Community Health
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Provision	340C	PROTECT	ASAP 340B
Eligibility for Participation	Open to any entity that currently participates in the 340B program.	No changes made to eligibility.	**Proposes changes to hospital eligibility requirements.** "New hospital eligibility criteria should be added to existing requirements to ensure the program is supporting true safety-net hospitals, including quantitative metrics that appropriately identify hospitals treating a disproportionately large share of low-income patients on an outpatient basis. Current eligibility requirements should be maintained for rural hospitals, specifically critical access hospitals and sole community hospitals, and eligibility should be updated so critical access hospitals that convert to the new rural emergency hospital designation do not lose 340B eligibility. In addition, proposes new eligibility standards for child sites." **Proposes changes to subgrantees**. "The eligibility criteria for subgrantees should be revisited to ensure they are accomplishing their intended purpose."
Patient Definition	No changes made.	No changes made, although patients are protected against exclusions, terms, conditions, and choice of how they receive a 340B drug (in person, mail, or other shipment).	**Updates the patient definition**. "For example, to be considered a "patient" of a covered entity, an individual should be required to have periodic in-person visits with a provider employed or contracted by the covered entity and the covered entity should be required to maintain a consistent responsibility for care of such individual. Additionally, prescription eligibility for a 340B discount should reflect a direct connection between the patient's medical condition and the services being provided or managed (through permitted referrals) by the covered entity."

Provision	340C	PROTECT	ASAP 340B
Contract Pharmacies	Entities can contract with pharmacies as necessary, without limitations.	Does not address this issue.	"Contract pharmacy arrangements, which are not currently binding on manufacturers, should be permitted for: 1) covered entities located in a medically underserved area or an area serving a medically underserved population, or 2) grantees providing care to a specific population, such as patients with HIV or chronic illness, for qualified prescriptions provided within the scope of the grantee's 340B-qualifying Department of Health and Human Services (HHS) grant."
Protection against Discrimination by PBMs and Insurers	Included, subject to civil monetary penalties up to $5,000 per day.	Included, subject to civil monetary penalties up to $5,000 per day.	Included, enforcement mechanism not specified.
Reimbursement for 340B Drugs Purchased for Medicaid Beneficiaries	Requires Medicaid to reimburse at wholesale acquisition cost plus adequate and reasonable dispensing fees.	Not addressed.	Not addressed.
Program Governance	Provides authority to HHS to issue regulations as necessary.	Requires regulations to implement enforcement mechanism within 180 days of enactment.	Proposes targeted rulemaking authority for relevant HHS agencies to the extent needed to implement specific legislative provisions.
Public Reporting	None required.	None required.	"Covered entities should be required to report to HHS basic information about their involvement in the 340B program, including the total acquisition cost and reimbursement for 340B discounted medicines and the total amount spent to reduce out-of-pocket costs for patients receiving 340B discounted medicines."

Provision	340C	PROTECT	ASAP 340B
Requirements Related to Reinvestment of 340B Savings	Requires that entities reinvest any funds generated from participation into program operations, patient care, and other appropriate and beneficial activities, as determined by the covered entity leadership, to the populations served.	Not addressed.	Not addressed.
Discounts on 340B Drugs for Patients	Not addressed.	Not addressed.	"Covered entities in the 340B program should increase access to affordable medicines for the patients that need help the most. Hospitals participating in the program should have a sliding fee scale for medicines that, at a minimum, applies to uninsured patients and patients with incomes under 200% of the federal poverty level with private insurance. Grantees should provide support for access to medicines that is consistent with the scope of their grant that qualifies them for the 340B program and at least as generous as any sliding fee scale requirements for other medical care."
Audits	A covered entity shall permit the Secretary (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits, which shall be no more frequent than once every three years) to audit at the Secretary's expense the records of the entity that directly pertain to the entity's compliance with the bill's requirements.	Not addressed.	Not addressed.

Provision	340C	PROTECT	ASAP 340B
340B Claims Clearinghouse	Not addressed.	Authorizes third party entity to review 340B claims and report any findings to states.	Proposes establishing a national clearinghouse to strengthen program integrity and create transparency for manufacturers to monitor compliance. Data provided to a clearinghouse would be deidentified and subject to safeguards that prohibit use for marketing or other unauthorized purposes.