



ADVOCATES FOR
COMMUNITY HEALTH

United for Health and Innovation

A 340B Policy Update for Community Health Centers and other Stakeholders

June 10, 2024

12:00 p.m. ET

This webinar is being recorded. We will begin shortly.

Agenda

- I. Welcome and Introductions
- II. Latest Developments: 340B
- III. ACH Position on the 340B Access Act
- IV. ACH Analysis: 340B Access Act
- V. 340C and New White Paper
- VI. Discussion & Q&A
- VII. Conclusion



ACH Position on the 340B Access Act

While Advocates for Community Health (ACH) strongly supports Congressional efforts to address ongoing issues within the 340B Drug Discount Program, ACH is unable to support the 340B ACCESS Act in its current form. The provisions in this legislation would result in an unacceptable reduction in the value of the 340B program to health centers, which would restrain their ability to care for patients and continue expanding access to care for those most in need.



Analysis: 340B ACCESS Act

ACHI



Overview

- While the bill mostly applies to hospitals, several of the bill's provisions would make it very hard for health centers to continue to benefit from the 340B program.
- For example, in the patient definition section, 340B eligibility is determined on a prescription-by-prescription basis, which is NOT how it is done now, especially in the wake of the Genesis decision. This would be a huge administrative burden for community health centers, particularly smaller ones, and would significantly decrease the value of the program.
- The patient definition section also notes that drugs must be dispensed or administered at the covered entity location, except for qualifying referrals, which are VERY limited.
- Contract pharmacies can only be used in the covered entity service area, which will harm health centers in rural areas that depend on contract pharmacies for dispensing drugs to patients who may not live close to the health center. The bill includes new civil monetary penalties (\$13,946 for each claim) for not abiding by contract pharmacy rules.
- There are also extensive requirements on compliance that will be hard to maintain for health centers.



Patient Definition

Based on our analysis, the 340 Access Act's limitations on who can be defined as a patient of a health center are **administratively unworkable** and severely limit health centers' ability to derive value from the program.

- Patients are considered by a “prescription by prescription” mechanism
- The drug must be ordered or prescribed by a covered entity (CE) provider; dispensed or administered on site at a CE location; directly related to an outpatient service provided at the CE.
- Qualifying referrals provide exceptions to the requirements for drugs:
 - A CE provider must evaluate and recommend, during an in-person encounter at the CE site, that they received a specific type of service not provided at the CE, and this is “contemporaneously documented” in the medical record
 - Individual receives the service within 1 year of referral, and CE must receive written documentation of the services provided and diagnoses received connected to the prescription within 1 year of referral
- Infusion-only patients are not eligible



Contract Pharmacy Restrictions

Based on our analysis, the 340 Access Act **will limit patient access to affordable medications**, create new rules that are not in alignment with HRSA regulation, and further reduce the value of the 340B program.

- Permits FQHCs and other grantees to use contract pharmacies in a **newly defined “service area”** that loosely overlaps (but may not be identical with, or fully cover) their BPHC-approved service area. This area is defined as “the public use microdata area” (PUMA) in which such entity is located and up to 3 PUMAs that are contiguous with the PUMA in which the entity is located.
- Drugs purchased must be within the scope of the federal grant that qualifies the CE for 340B
- Contract pharmacies must be registered with HHS before use
- Mail order pharmacies are **only permitted** for patients that reside within the CE’s service area
- Manufacturers operating limited distribution networks (exclusive use of a specialty pharmacy, etc) are “deemed to have satisfied their obligations” with respect to contract pharmacy
- New civil monetary penalties (\$13,946 for each claim) for not abiding by CP rules



Access to Specialty

A CHC's ability to access specialty drugs for its patients is unclear under this bill

“A manufacturer of a covered outpatient drug requiring exclusive use of a specialty pharmacy, or a restricted distribution network shall be deemed to have satisfied its obligations ... with respect to contract pharmacy”

The bill offers no further guardrails, restrictions or criteria for establishing these restricted distribution networks

No protections for CEs - no mechanism for filing complaints, nor any CMPs for manufacturer errors



WHITE PAPER

PROTECTING THE 340B PROGRAM FOR HEALTH CENTERS WITH 340C



Advocates for Community Health (ACH) envisions a 340B program that works exactly as it was designed: to stretch scarce federal resources in support of access to care for underserved patients and their communities. This vital program must be fortified so it can remain a resource for community health

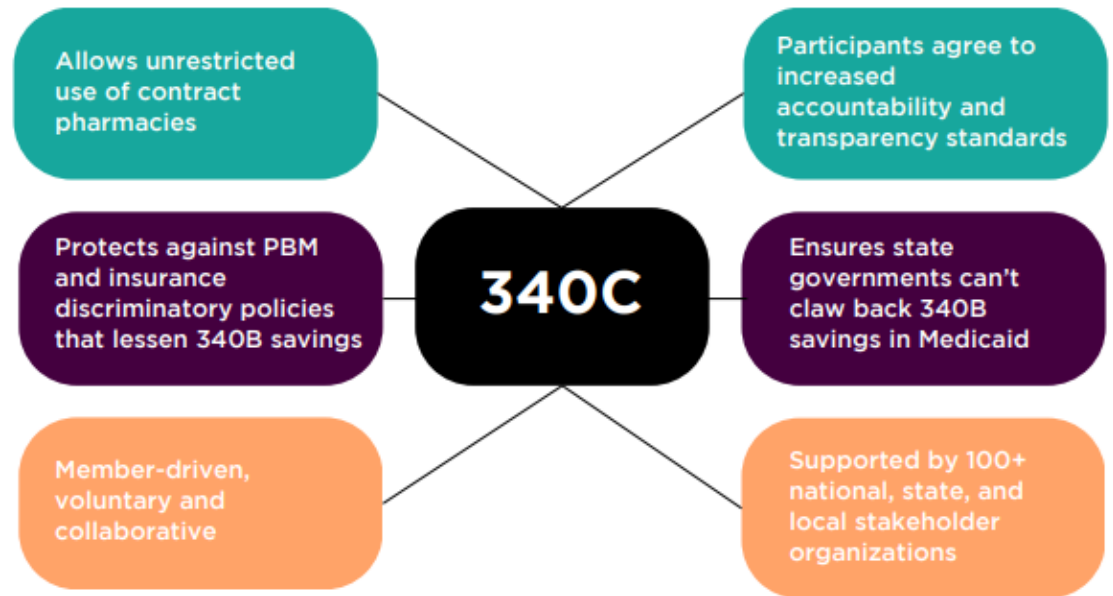
New!
ACH White Paper:
Protecting the 340B
Program for Health
Centers with 340C



340C

- Calls on Congress to prioritize health centers' unique needs
- 340C: "opt-in" option for all 340B covered entities
- Increase transparency and accountability
- Under 340C, all savings must be reinvested into patient care
- Entities that meet accountability standards would then be entitled to:

- (1) Protection against discriminatory network and reimbursement actions by health insurers and PBMs,
- (2) Unlimited use of contract pharmacies, and
- (3) Reimbursement at wholesale acquisition cost (WAC) for all Medicaid drugs





Discussion/ Q&A

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