**Advocates for Community Health – Summary of the *340B Access Act***

U.S. Representatives Larry Bucshon, MD (R-IN-08), Buddy Carter (R-GA-01), and Diana Harshbarger (R-TN-01) introduced the *340B Affording Care for Communities and Ensuring a Strong Safety-Net Act* (*340B ACCESS Act)* on May 28, 2024. The Representatives stated that they introduced the bill to provide “critical oversight and transparency of the 340B program.”  Below is a brief summary of Advocates for Community Health’s initial review of the legislation – key provisions and our takeaway. This document is subject to change upon additional legal review.

Patient Definition

* The bill codifies the patient definition as a “prescription by prescription” mechanism
* Requires that drugs must be dispensed or ordered at the covered entity (CE) location, “as a result of” a service provided by the entity within the scope of the grant that qualifies it for 340B, and the entity must have auditable records EXCEPT in the case of qualifying referrals
  + ***Qualifying referrals*** occur when:
  + a CE provider evaluates and recommends, 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”
  + Individual receives the service within 1 year of referral
  + CE must receive written documentation of the services provided and diagnoses received connected to the prescription
  + CE retains overall responsibility for the care of the individual

**These types of 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.**

Contract Pharmacy

* Technically permits FQHCs and other grantees to use contract pharmacies registered with HHS that are located within an 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 additional public use microdata areas that are contiguous with the public use microdata area in which the entity is located”
* New civil monetary penalties ($13,946 for each claim) for not abiding by CP rules
* Mail-order pharmacies are allowed for CHCs, as long as the patient resides within the CHC’s service area.
* Language is unclear regarding CHCs’ ability to obtain 340B-priced specialty drugs at out-of-area contract pharmacies.

**These limitations 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.**

Limitations on Certain CHCs

* Unlike other CHCs, these CHCs affiliated with a hospital or with over $1 billion in annual revenues are not permitted to use 340B drugs for any referral prescriptions or for mail-order pharmacies.
* Also, any off-site pharmacies they own will only be 340B-eligible if they fall within the 4 PUMAs allowed as their ASAP-designated service area.

**These limitations are arbitrary and offer no additional transparency or protections to taxpayers.**

Requirements for Non-Hospital Covered Entities

* New requirements firming up contracts, oversight of subgrantees

**We do not have objections to reasonable reporting requirements or clarifications on who is using the 340B program.**

Claims Modifiers

* All claims submitted by any in-house or contract pharmacy to any payor must include a modifier, indicating whether the prescription was filled a 340B drug or a non-340B drug.

**We do not have objections to additional reporting requirements that prevent duplicate discounts.**

Covered Entity Requirements

* Annual reporting on the scope of the grant that provides eligibility for 340B
* Authorizes (but does not require) HHS to impose significant reporting requirements on CHCs, including precise calculation of 340B margin, and breaking down how the CHC spends this margin into 12 different categories (e.g., transportation, language assistance).

**We do not have objections to additional reporting requirements, but have a more workable set of proposals for CHC reporting in ACH’s 340C proposal.**