Summary of 340B Access Act

This document is the official NACHC summary of the 340B Affording Care for Communities and Ensuring a Strong Safety-net Act, known as the 340B ACCESS Act. We focus on the sections relevant to health centers in our summary. This legislation is based on Alliance to Save America's 340B Program and ASAP 340B's policy principles. If you have any questions, please email regulatoryaffairs@nachc.org.

Section 2. Definitions

Patient Definition

Context: Patient definition is not in the 340B statute. Patient definition is currently governed by HRSA's 1996 guidance found here. Additionally, the recent November 2023 US District Court for South Carolina issued a decision in Genesis Health care, Inc. v. Becerra, finding that the government's restrictive interpretation of the term "patient definition" was contrary to the plain language of the 340B Statute and frustrates the goals of the 340B Program. The *Genesis* decision is being interpreted to apply to that specific health center. However, the decision has created a lot of questions and concerns we hope to clarify through legislation to protect health centers' interests.

Legislative language: The draft legislative text would codify a patient definition in statute. The elements of this definition would clarify which drugs could qualify for 340B discounts on a prescription-by-prescription basis. Below is how this language specifically applies to health centers:

1) The covered outpatient drug needs to be directly related to the health care service furnished at the covered entity,
    a. Considering that primary care is a very broad umbrella of "health care services".
2) Ordered or prescribed by a covered entity provider *as a result of* the service furnished,
    a. As a result, there is a connection between the care being provided and the prescriptions being captured.
    b. Prescriber would have to be an employee or independent contractor of the covered entity.
3) Service needs to be within the scope of the eligible grant, and
4) The patient has an ongoing relationship with the covered entity.
    a. The covered entity is responsible for the individual's health care service, directly or through a referral, that resulted in the prescription.
    b. The covered entity has provided a health care service through an in-person visit within the past 24 months.
        i. This aligns with existing Health Center Program requirements.

5) Telehealth: Health centers are permitted to capture telehealth prescriptions if they have conducted an in-person examination of the patient within 6 months prior to the telehealth visit.
    a. Disability exception
6) Referrals
    a. Permits health centers, including those affiliated with hospitals prior to 2023, to capture "qualifying referrals" via telehealth or in-person.
        i. Qualifying referrals mean a recommendation to seek a specified type of specialty care not available to the covered entity.
        ii. Requires documentation at the time of the encounter.
            1. Encounter is not defined in the statute.
        iii. The patient receives a health care service from a medical specialist within one year of the date of the encounter.
        iv. The health center receives written documentation specifying the service(s) furnished to such individual and the diagnosis made in connection with such services.
        v. The health center retains overall responsibility of care for the patient.

Patient Definition Examples

Patient goes to a 340B-eligible health center with concerning symptoms, their primary care provider (PCP) conducts an examination and refers them to an oncologist	The oncologist, who works at a non-340B facility, diagnoses the patient with cancer and prescribes a medication.	Patient sees their regular PCP for checkups and the PCP receives all relevant health records from the oncologist to facilitate the management of the patient's care.	**Patient's Prescription Would Be 340B Eligible**
A patient living in a rural area sees their usual PCP for their annual checkup at their health center.	5 months later, the patient sees their PCP via telehealth to discuss their worsening seasonal allergies.	Their PCP prescribes a new medicine to the patient and schedules a telehealth follow up in a few months.	**Patient's Prescription Would Be 340B Eligible**

Section 3. Prevention of Medicaid Duplicate Discounts; Oversight of Covered Entities

Regulatory Authority: The HHS Secretary shall issue final regulations through notice and comment rulemaking describing:

1) Methodologies State Medicaid programs, covered entities, and contract pharmacies should use to identify duplicate discounts in Medicaid, including Managed care.
2) Procedures for State Medicaid programs to exclude requests for Medicaid rebates on 340B drugs.

Use of 340B Margin: A covered entity shall permit the Secretary to audit, at the Secretary's expense, the records of the covered entity to determine how a covered entity uses its 340B margin.

Section 5. Contract Pharmacies

Context: The 340B statute does not define contract pharmacies. After a series of litigation, several courts have stated that Congress needs to clarify the program's intent and the intended use of contract pharmacies. Currently, the use of contract pharmacies is governed by HRSA's 2010 guidance, which can be found here.

Affirmative Obligation for Manufacturers: a manufacturer of covered outpatient drugs ***shall*** ship or facilitate the shipment of such drugs to contract pharmacies at the request of such covered entity.

The Covered Entity is required to:

1) Establish and implement compliance procedures,
2) Register the contract pharmacy,
3) Certify that the pharmacy will comply with the new statutory requirements, and
4) Submit contract pharmacy contracts to the HHS Secretary in a form and manner designated by the Secretary.

Health Center use of Contract Pharmacy:

1) Unlimited use of all contract pharmacies, including mail order and specialty pharmacies.
    a. Specialty pharmacy is not specifically noted in the statute because it does not have an existing statutory definition.
2) Service area:
    a. Contract pharmacies must be located within the service area.

i. Service area is defined using the Census Bureau's Public Use Microdata Areas (PUMAs), these are areas with 100,000 to 200,000 people.
ii. The service area is defined by the PUMA where the covered entity is located and may include up to **three** immediately adjacent PUMAs.
iii. Each health center site would select its service area. This process would be established by HRSA guidance, which has not yet been determined.

b. For mail-order pharmacies, patients are required to live in the established service area.
    i. Mail-order pharmacy is defined as a pharmacy that dispenses covered outpatient drugs "primarily through the mail." The definition is based on Medicaid Drug Rebate Program guidance.

Limited distribution: Notwithstanding any other provision in this section, 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 under this subparagraph with respect to a contract pharmacy if such manufacturer offers each covered entity such drug for purchase at or below the applicable ceiling price is through a wholesaler, distributor, or pharmacy included in the restricted distribution.

Penalties for Contract Pharmacy Compliance Violations

1) First instance- be liable to the manufacturer for an amount equal to the reduction in the price of the 340B drug, plus interest, which shall be compounded monthly.
2) Second instance- plus above, and be required to pay a civil monetary penalty equal to $13,946 for each claim for a drug that is subject to the violation.
3) Third instance- plus above, and be removed from the program and disqualified from reentry into such program for a period of not less than two years, or longer determined by the Secretary.

Definition of Entity-owned Pharmacy for Health Centers

1) Licensed as a pharmacy by the relevant State; and
2) The same legal entity as the covered entity and located within the covered entity's service area.

Section 6. Ensuring Patient Affordability of Drugs Purchased Under Section 340B

Context: The current 340B program does not require medications to be affordable. This requirement would create an affirmative obligation for all covered entities to offer affordable medications at all pharmacies.

Health Center Requirement: Grantees required to provide affordability assistance would also be subject to new patient affordability requirements for patients 200% or below the federal poverty level. These requirements require them to establish a policy that provides discounts on

340B drugs that are "sufficient to ensure such patient is not denied access to such drug based on such patient's ability to pay."

1) HRSA would have to issue additional guidance for implementation.

Section 7. Requirements for Nonhospital Covered Entities and Subgrantees

Both subgrantees and grantees would be subject to new requirements designed to ensure these entities participate in the 340B program consistent with the scope of the relevant Federal grant. These requirements include the following:

1) A subgrantee must be a public or non-profit entity and could only receive 340B discounts for patients treated at a registered grantee or subgrantee location within the scope and timeframe of the Federal grant that qualifies a grantee or subgrantee for eligibility to participate in 340B.
2) A grantee would have to maintain an enforceable written agreement with each subgrantee that requires the subgrantee to comply with all applicable 340B program requirements, oversee its subgrantees' participation in 340B, and be directly liable for any 340B non-compliance by its subgrantees.
3) Eligible subgrantees would have to meet new requirements related to in-kind contributions received from the grantee. Resources that do not directly support the provision of health care services would not be sufficient to qualify recipients of in-kind contributions for participation in 340B.
4) A subgrantee would be subject to all 340B statutory obligations applicable to the covered entity with which it has a written agreement to participate in 340B and would be required to immediately notify the HHS Secretary and disenroll from 340B if at any time it no longer satisfies an applicable eligibility or compliance requirement.

Section 8. Claim Modifiers; Covered Entity Data Submission

Modifiers: Requires that all claims submitted to a payor, including Medicare and Medicaid, by a covered entity or a contract pharmacy should include the relevant 340B modifier established by the HHS Secretary under Medicare Part B or the submission clarification code of 20.

Clearinghouse: This clearinghouse would engage in the following activities:

1) Identifying potential Medicaid/340B and Maximum Fair Price/340B duplicate discounts;
2) Sharing identified 340B units reimbursed by Medicare with CMS for exclusion from Part B and Part D inflation rebates;
3) Identifying duplicate covered entity claims for 340B discounts on the same units and preventing manufacturers from paying more than one discount on such units; and
4) Providing manufacturers access to a specified list of claims-level data elements for the dispensing of their 340B drugs.

Section 10. Ensuring Covered Entity Transparency

Context: Congress and HRSA have called for greater transparency in the 340B program and reporting on how 340B savings are used. It is important health centers maintain our position that we support transparency that is not administratively burdensome.

Reporting 340B Margin: As drafted, only hospitals are required to report to the HHS Secretary. However, the Secretary has the discretion to require reporting for other covered entities.

Use of Savings: If grantees are required to report at a future time, the legislation requires grantees to report how they are using 340B savings using standardized rules established by HHS. These rules are consistent with reporting requirements that Federally Qualified Health Centers use for Uniform Data System (UDS) reporting.

Section 13. 340B Program

Context: The commonly used "stretch scare federal resources" language is not in the 340B statute. It is found in a legislative report from the early 1990s. The intent of the 340B program is not currently defined in the statute.

Intent language: "The intent of this section is to provide for manufacturer price reductions that enable covered entities, whose mission is to serve underserved or otherwise vulnerable communities, to increase access to affordable drugs and health services for these communities."

Section 17. Limitation on Administrator Service Fees and Contract Pharmacy Fees

1) **Pharmacy fees:** Contract pharmacy fees charged to covered entities would be limited to flat fair-market value fees that could not exceed 125% of the average per-prescription dispense fee paid to pharmacies by all third-party payers.
2) **TPA fees:** Third-party administrator (TPA) fees charged to covered entities would be limited to flat fair market value fees.
3) **Written records:** Covered entities would be required to retain copies of written records with TPAs and contract pharmacies, and make copies of those agreements available to the HHS Secretary or a designee upon request.
4) **Enforcement:** Civil monetary penalties would be imposed on Pharmacy Benefit Managers (PBMs), TPAs, and contract pharmacies that do not comply.

Section 18. Clarification

Preemption: The legislation would clarify that provisions in the 340B statute supersede any State or local laws that relate to the 340B statute.

Section 2730. Requirements relating to the 340B Drug Discount Program

Context: The 340B Access Act incorporates language from the PROTECT 340B Act.

- Discriminatory contracts: PBMs would be prohibited from imposing specified discriminatory contract terms (e.g., fees or chargebacks) due to a covered entity's or pharmacy's participation in 340B.
- Interference with provider or pharmacy choice: Health plans, insurers and/or PBMs would be prohibited from interfering with identifying 340B claims or allowing an individual to choose to receive a 340B drug from a covered entity or contract pharmacy.