

What's Happening in 340B Litigation & Legislation

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Disclosure Statement

- R. Logan Yoho has no relevant financial relationships with ineligible companies to disclose.
and
- None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.

Learning Objectives

At the completion of this activity, the participant will be able to:

1. Review recent court decisions and cases waiting for decisions
2. Review state legislation & federal affecting 340B covered entities and contract pharmacies



FEDERAL LEGISLATION

SUSTAIN Act

TAM24101 KD2

Discussion draft

S.L.C.

118TH CONGRESS
2D SESSION

S. _____

To _____ .

IN THE SENATE OF THE UNITED STATES

Mr. THUNE (for himself, Ms. STABENOW, Mrs. CAPITO, Ms. BALDWIN, Mr. MORAN, and Mr. CARDIN) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To _____ .

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Supporting Underserved and Strengthening Trans-
6 parency, Accountability, and Integrity Now and for the
7 Future of 340B Act” or the “SUSTAIN 340B Act”.

8 (b) TABLE OF CONTENTS.—The table of contents for
9 this Act is as follows:

The Gang of 6



Senator John Thune
(R-SD)



Senator Debbie Stabenow
(D-MI)



Senator Shelley Moore Capito
(R-WV)



Senator Tammy Baldwin
(D-WI)



Senator Jerry Moran
(R-KS)



Senator Ben Cardin
(D-MD)

Key Points of the Draft Act

Contract Pharmacy



- 340B pricing access at CRx protections
- Submit CRx agreements to HHS
- Solidifies contract pharmacy essential elements in statute
- Register CRx under both parent and child sites
- CRx must provide data to entity for clearinghouse submission
- **10-year auditable record retention**

Patient Definition



- TBD
- **Seeking feedback through additional RFI, due April 1st**

Child Sites



- Must be wholly-owned
- Must offer same financial assistance as other sites
- Must participate in Medicare and Medicaid programs
- **Providers must have clinical responsibility for the health care services related to the 340B drug dispensed**
- Must have integrated or readily accessible medical records with the entity
- HHS to issue final rule for procedure for child sites historically eligible but no longer eligible under new criteria

Key Points of the Draft Act

Transparency

- **Annually report** number of patients receiving 340B drugs, number of prescriptions filled with 340B drugs (by payer type), cost of charity care by location, description of the entity's use of savings, financial demographics of patients of the entity, policies related to medication access, government contracts (if applicable), TPAs, contract pharmacies, estimated discount realized, number of patients receiving outpatient services at entity, and operational costs of 340B program operation
- Reports to be published on HHS public website, with proprietary information redacted from contracts
- HHS to submit an annual report to Congress on information collected



Integrity

- **Protocol for audits to be publicly available**
- Audits will not be closed until corrective action plan has been fully implemented, if applicable
- HHS to issue final rule for auditing entity's 340B Program eligibility and establish that failure to meet Program eligibility requirements can not be corrected retroactively



Duplicate Discount Prevention

- **HHS may issue rules for duplicate discount prevention and clearinghouse**
- Clearinghouse to prevent duplicate discounts offered by independent entity without conflicts with any stakeholders
- Claims level rebate file data from State Medicaid agencies and claims level data from covered entities to be collected and used to identify any duplicate discounts
- Covered entity, Secretary, State Medicaid agency, and manufacturer notified of any violations



Key Points of the Draft Act

Equitable Treatment

- Group health plan, health insurance issuer, or pharmacy benefit manager **may not discriminate** against a covered entity, a contract pharmacy, or a participant by imposing requirements, exclusions, reimbursement terms, or other conditions that differ from an entity or pharmacy that does not dispense 340B drugs



User Fee Program

- Secretary to assess and collect fees annually from entities participating in the 340B Program
- **Fees = 0.01%** of the average difference (over the last 5 years) of **WAC – 340B** price paid by the entity for purchased covered outpatient drugs
- Fees collected will be used for enhancing 340B Program integrity and oversight, including fee collection web-based system, data clearinghouse, OPAIS maintenance, manufacturer compliance tools, and audits
- HHS may establish rules to carry out the user fee program
- Inspector General of HHS will annually review the user fee program for the first 5 years

Studies and Reports

- Medicaid and CHIP Commission must submit a report to Congress on their efforts to prevent **duplicate discounts**, within 1 year
- HHS to conduct a study on **dispensing fees** and submit report to Congress within 2 years



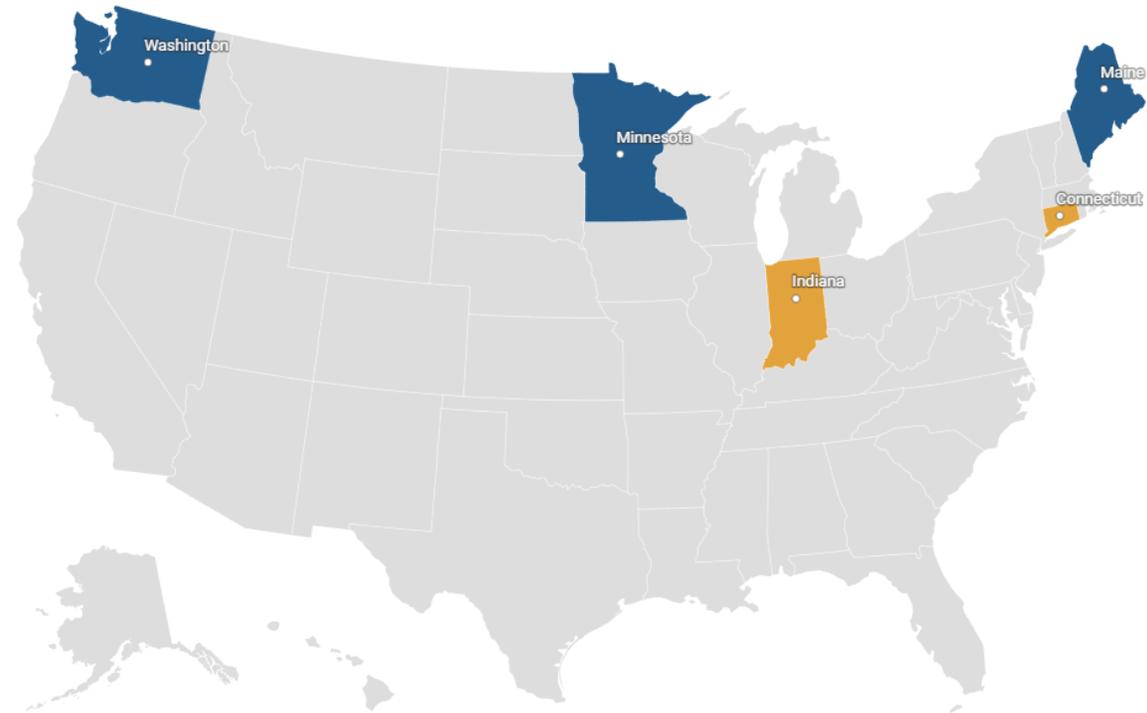


STATE LEGISLATION

340B Reporting Requirements

340B REPORT Legislation Tracker: 2023-2024 State Bills and Laws that Implement 340B Provider Reporting Requirements

■ Bill passed ■ Bill introduced



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Map: updated as of Feb. 23, 2024 • Created with [Datawrapper](#)

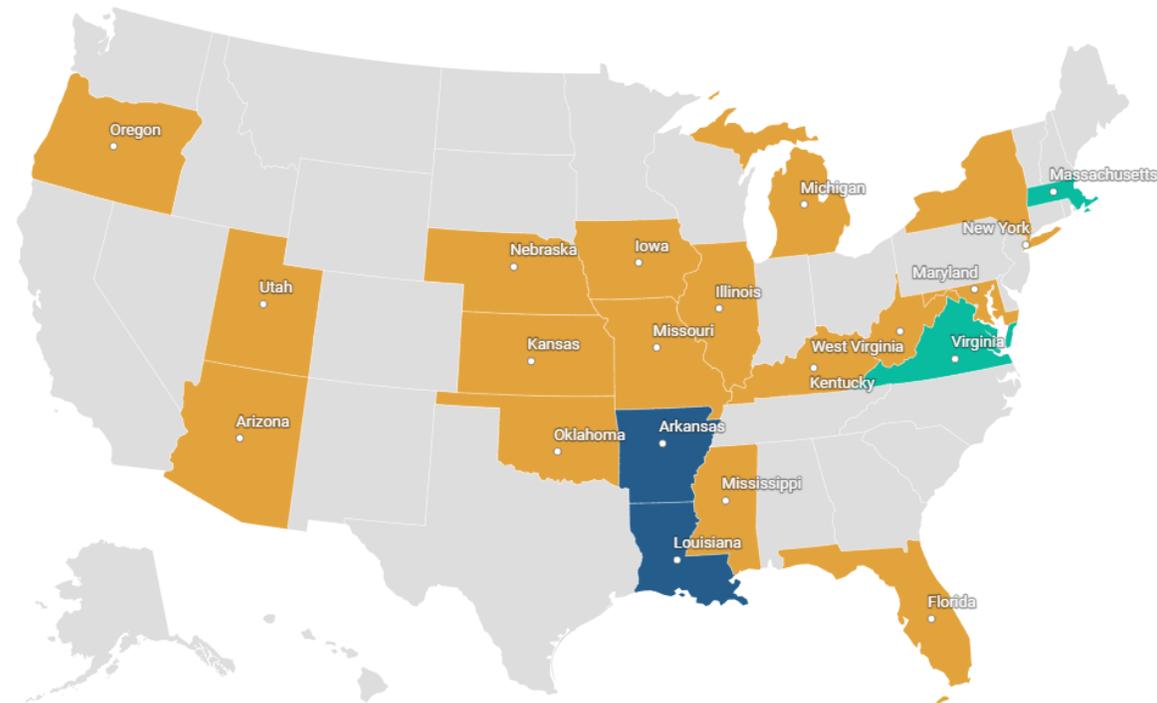
<https://340breport.com/legislative-map/covered-entity-reporting-requirement-bills/>

Accurate on 2.27.24

Contract Pharmacy Protections

Legislation Tracker: 2023-2024 State Bills and Laws that Prohibit Drugmaker 340B Contract Pharmacy Restrictions

 Bill passed  Bill cleared a legislative chamber  Bill introduced



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Map: updated as of Feb. 23, 2024 • Created with [Datawrapper](#)

<https://340breport.com/legislative-map/contract-pharmacy-protection-bill/>

Accurate on 2.27.24

A photograph of a library shelf filled with law books. The books are bound in dark red or brown leather with black spine labels. The labels are printed with 'LAW REPORTS' and volume numbers. The books are arranged in a perspective that recedes into the distance. The text 'PRIMER ON 340B REGULATION' is overlaid in a bold, dark blue font in the lower-left quadrant of the image.

PRIMER ON 340B REGULATION

Layers of 340B

Regulatory
Legally Enforceable

Statute:
[Section 340B of the Public Health Service Act](#)

Regulations:
[340B Program Regulations](#)

Guidance:
[Policy Releases](#)

Sub-Regulatory
Non-Binding Guidance

Program Updates
& [HRSA FAQs](#)



340B Statute: 340B-Eligible Patients

Section (5) (B) PROHIBITING RESALE OF DRUGS.—With respect to any covered outpatient drug that is subject to an agreement under this subsection, **a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.**

**This is the sole reference to patient in
the 340B Statute**

340B Guidance: Patient Definition

An individual is **“patient”** of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if:

1. the covered entity has **established a relationship** with the individual, such that the **entity maintains records** of the individual’s health care; and
2. the individual receives health care services from a **health care professional** who is either **employed** by the covered entity or provides health care **under contractual or other arrangements** (e.g. **referral for consultation**) such that responsibility for the care provided remains with the covered entity; and
3. the individual receives a health care service or range of services from the covered entity which is **consistent with the service** or range of services for which **grant funding** or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

An individual will not be considered a “patient” of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self- administration or administration in the home setting.

An individual registered in a State operated or funded AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the PHS Act will be considered a “patient” of the covered entity for purposes of this definition if so registered as eligible by the State program.



340B LITIGATION UPDATE

BREAKING NEWS

Reinforces 1996

Federal Judge ~~Strikes Down~~ 340B Patient Definition

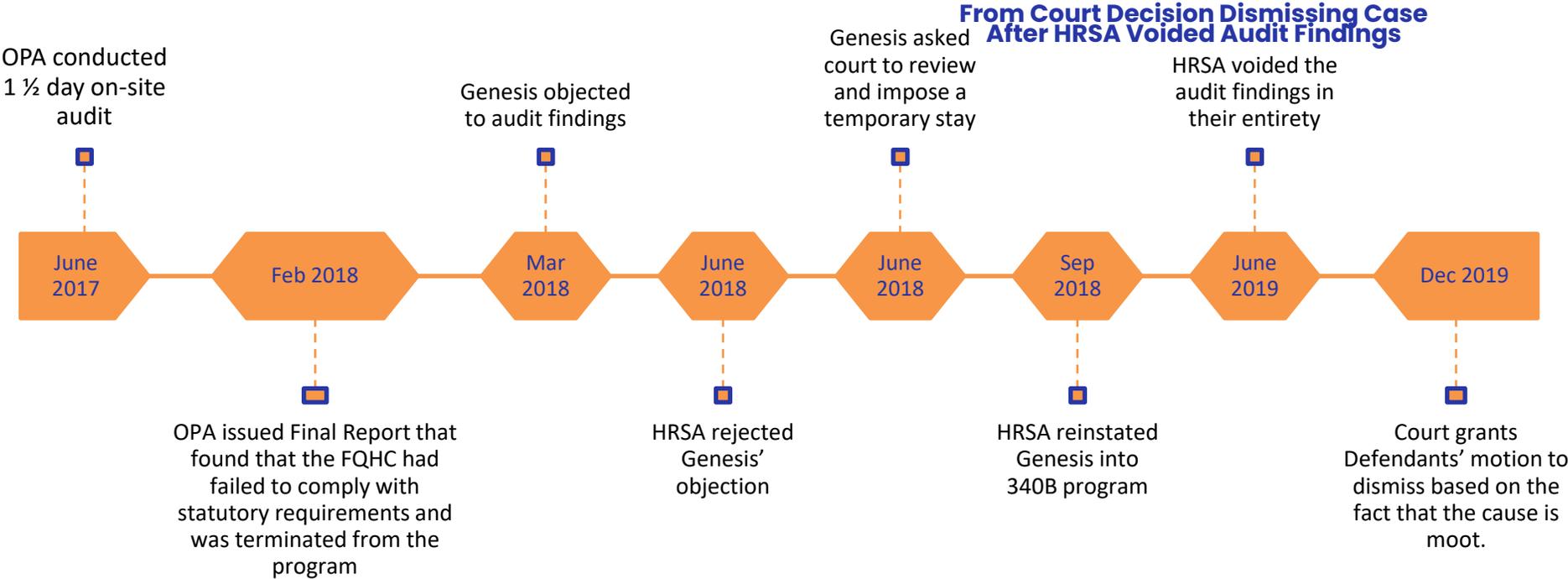
November 3, 2023  Tom Mirga Editor at Large



Genesis Health Care successfully challenged HRSA's 340B patient definition in the U.S. District Court for the District of South Carolina.

A federal district judge in South Carolina late today struck down the 340B program's patient definition, as federal regulators described it to a federally qualified health center (FQHC) in a 2019 audit letter.

Genesis Case History



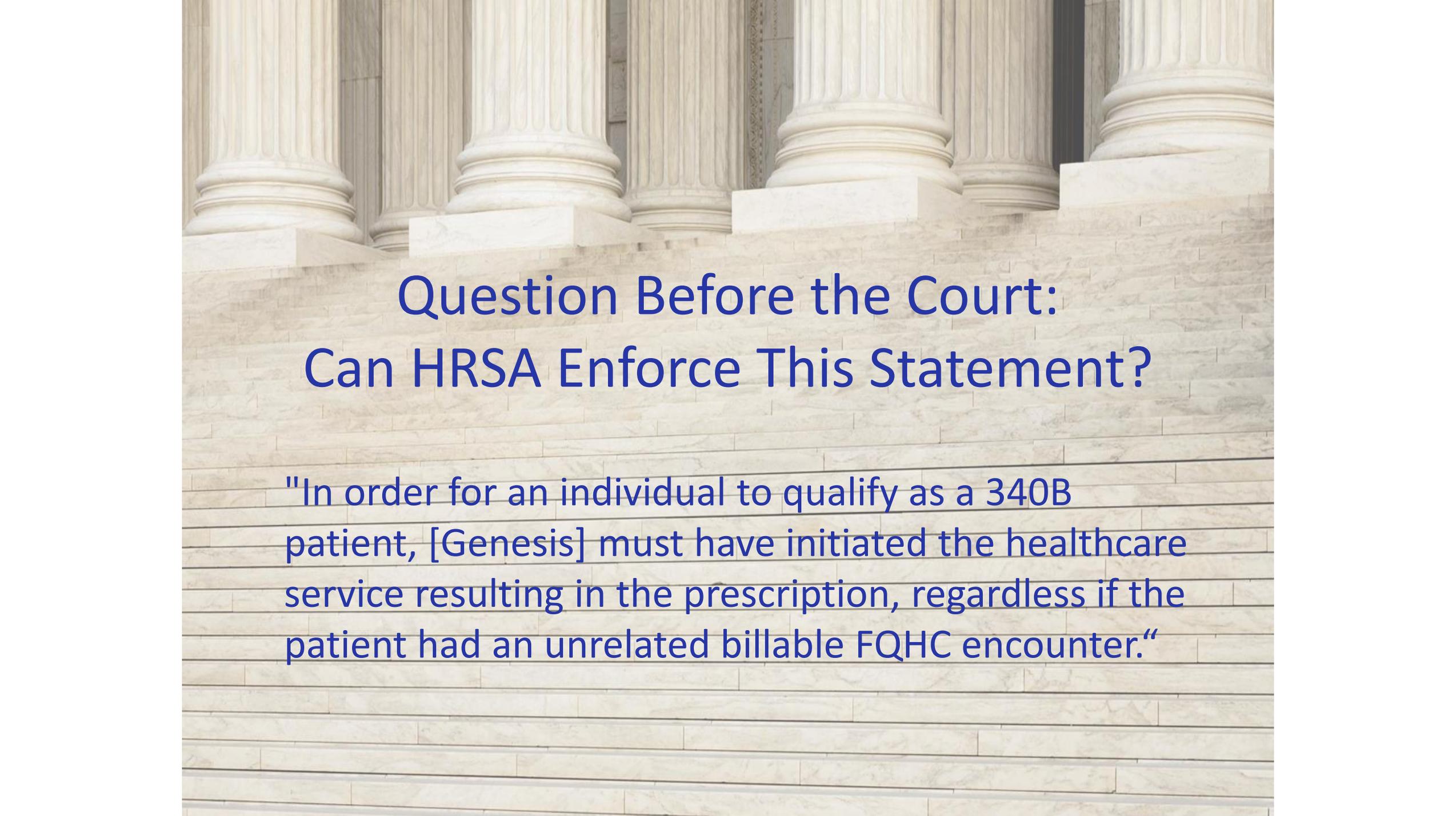
Genesis Case History (continued)

Genesis successfully appeals to have the case reopened, citing the need to recertify to compliance but still not having clarity on patient definition.



Genesis' motion for summary judgment GRANTED in part. Defendants indicated language Genesis challenges can only be found in now-voided March 20, 2019 audit letter & Defendant's interpretation of "patient" in that letter is contrary to the plain wording of the 340B statute. Defendants are enjoined from enforcing its March 20, 2019 interpretation of the term "patient" against Genesis until further Order of this Court.

Key reports submitted and testimony provided on the definition of a patient. HRSA acknowledged that its 1996 guidance provides a "flexible" definition to apply across varied contexts **but does not include language requiring that a 340B covered entity initiate the healthcare service for a resulting prescription to be filled with a drug purchased through the 340B program.** Amicus Filings in support of Defendants and Plaintiffs permitted.



Question Before the Court: Can HRSA Enforce This Statement?

"In order for an individual to qualify as a 340B patient, [Genesis] must have initiated the healthcare service resulting in the prescription, regardless if the patient had an unrelated billable FQHC encounter."

Key Takeaways From Court Decision

340B statute does not define "patient"; must apply "plain" meaning: "an individual awaiting or under medical care and treatment"

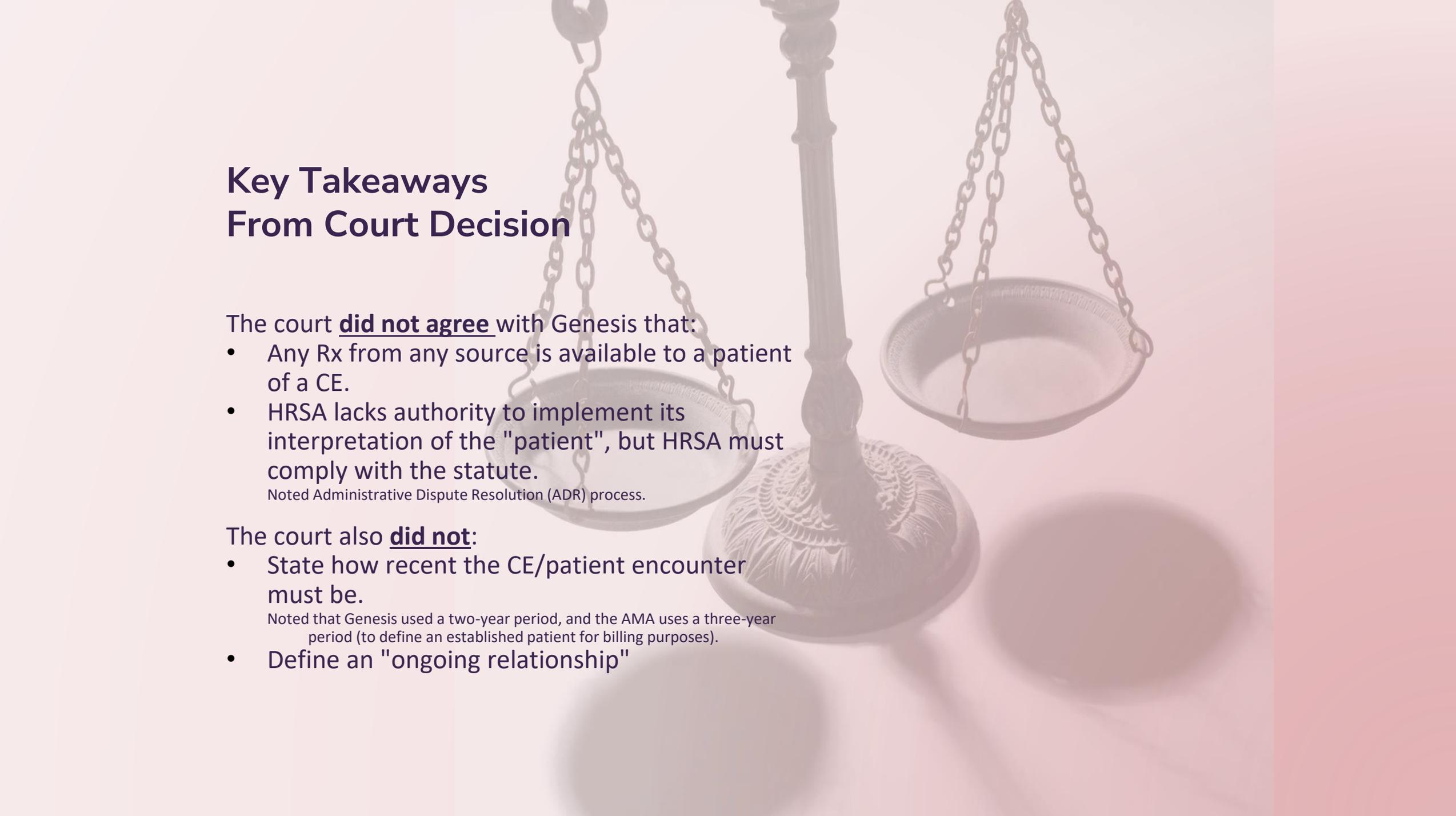
A broad definition of the term 'patient' complies with congressional intent

340B statute does not require that Rx be initiated from a CE or contract provider for the CE

One purpose of 340B statute is to make CEs profitable so they could stretch Federal resources as far as possible, reach more eligible patients, and provide more comprehensive services

Cited statements from HRSA's 1996 patient definition guidance that definition is intended to be flexible

Found that CE must have "ongoing relationship" with individual, but disagreed that Rx must originate from that relationship



Key Takeaways From Court Decision

The court **did not agree** with Genesis that:

- Any Rx from any source is available to a patient of a CE.
- HRSA lacks authority to implement its interpretation of the "patient", but HRSA must comply with the statute.

Noted Administrative Dispute Resolution (ADR) process.

The court also **did not**:

- State how recent the CE/patient encounter must be.

Noted that Genesis used a two-year period, and the AMA uses a three-year period (to define an established patient for billing purposes).

- Define an "ongoing relationship"

1996 Patient Definition 340B Eligibility Test

Covered
Outpatient Drug
Order/ Prescription

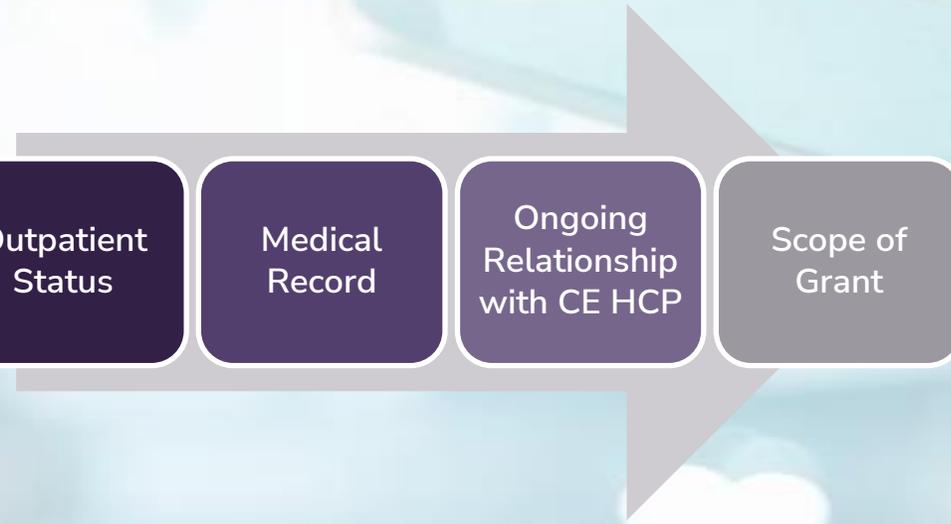
Outpatient
Status

Medical
Record

Ongoing
Relationship
with CE HCP

Scope of
Grant

340B-Eligible
Drug





No “Forever Patient”

- **Seeing a patient once does not make them the covered entity’s patient forever**
- Court Determination
 - While the 1996 Patient Definition guidance does not dictate time-period or look-back period during which the "patient" must have had a health care encounter with the "covered entity", **HRSA expects CEs to define an appropriate time-period based on care delivery standards and other pertinent State or Federal regulations.**
- Sample Policy Language
 - To be considered a patient of the covered entity, i.e. 340B eligible, the patient must have a documented encounter, either face-to-face or via telemedicine, with a health care professional employed by or contracted with the health center within the past two years.
 - *It is important for the covered entity to define the timeframe for patient eligibility.*



340B Drug Eligibility

- Not 340B eligible just because drug dispensed in in-house pharmacy
 - “An individual will not be considered a “patient” of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self- administration or administration in the home setting.”
– 1996 Patient Definition Guidance
- Court Case Determinations
 - **Must be a patient of the covered entity**
 - “The only *statutory* requirement for 340B eligibility of a person is that the person be a patient of a covered entity, as clearly stated in 42 U.S.C.”
 - **Must demonstrate ongoing relationship with patient**
 - “The Court agrees that the statute does require an ongoing relationship between the individual and the covered entity.”
 - **Does not need to initiate the prescription-related service**
 - “The plain wording of the 340B statute does not require the 'covered entity' to have initiated the healthcare service resulting in the prescription.”

Need More Information?

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