# White Paper: 340B Eligible Patient Definition

## Introduction

Recent legal proceedings, including *Genesis Healthcare Inc. v Alex Azar (Genesis)*, as well as reports from the field, have highlighted uncertainty with regard to the 340B patient definition, and the extent to which HRSA can assess diversion risk attributed to patient definition findings in 340B Program audits. Covered entities (CEs) may recognize these developments as an opportunity to reevaluate how they define a 340B eligible patient within their policies and procedures, and implement operational changes that could potentially expand their opportunity to access 340B priced medications.

## Patient Definition – Rules, Regulations & HRSA Enforcement

Diversion prevention is a fundamental element of 340B Program compliance. Covered entities (CEs) participating in the 340B Program are prohibited by section 340B(a)(5)(B) from reselling or otherwise transferring a 340B drug to a person who is not a patient of the entity. Failure to comply with this provision of the 340B statute may result in U.S. Health Resources and Services Administration (HRSA) audit findings and subject a covered entity to repayment of 340B discounts back to affected manufacturers. However, it was recognized shortly after enactment of the statute that there was ambiguity in what constitutes a CE patient, therefore HRSA published guidance in 1996 (Federal Register, 61 Fed. Reg. 55156-55158 Oct. 24, 1996) which was meant to provide clarity around this issue and establish an "entity patient" definition (see Figure 1.).

**Figure 1. HRSA Patient Definition**

| |
|---|
| (1) the CE has established a relationship with the individual, such that the CE maintains records of the individual's health care |
| (2) the individual receives health care services from a health care professional who is either employed by the or provides care under a contractual or other arrangement (e.g. referral for consultation) such that responsibility for the care remains with the CE |
| (3) for grantee-qualifying CEs, the individual receives health care from the CE which is consistent with the scope of services of its grant funding. |

In 2019, the Trump Administration issued an executive order (Federal Register, 84 Fed. Reg. 55235-55238 Oct 15, 2019) that rendered guidance documents published by federal agencies as non-binding and not legally enforceable. CEs have experienced the impact of this executive order in how pharmaceutical manufacturers have restricted or, in some cases, fully eliminated sale of 340B drugs through contract pharmacy channels. The basis for these manufacturer actions is that the use of contract pharmacies to support 340B CE program operations is, like the patient definition, outlined in non-binding guidance, and therefore not legally enforceable. Also, the HRSA audit experience has undergone a degree of evolution since the issuing of this order. The Government Accountability Office (GAO) issued a report in December 2020 on HRSA's efforts to oversee CE compliance with 340B Program requirements. The report noted that, starting in the fall of 2019, HRSA began to relax its auditing standards by which it would only issue findings for areas of non-compliance that are directly related to requirements stipulated in the 340B Program statute. Any areas of compliance gaps with provisions outlined in guidance documents (e.g., contract pharmacy use, patient definition) would fall outside of HRSA's enforcement capability and would not result in audit findings.

A recent legal case, *Genesis Healthcare v. Azar*, highlights one CE's successful effort to challenge HRSA audit findings in the absence of clear statutory violations. Genesis, a South Carolina grantee-type CE, filed a lawsuit in federal court against HRSA in 2019 after receiving a HRSA final audit report with diversion findings that resulted in Genesis being temporarily terminated from participation in the 340B Program. Genesis argued that the audit findings, which were based on adherence to "HRSA's interpretation of 'patient'" defined in guidance, contradict the plain language of the law and overextended HRSA's enforcement capability. HRSA ultimately

reinstated Genesis in the 340B Program, voided its audit, and the district court dismissed the lawsuit. Genesis has since appealed the dismissal, pressing the court for a declaratory judgment that the 340B patient definition issued through guidance is illegal. Oral arguments for the appellate case were heard in March 2022.

With HRSA's recent shift in audit focus to statutory compliance only, and the outcome of the Genesis appeals case looming, this perhaps serves as an inflection point for CEs in how an eligible patient is defined within their respective 340B Program operations. A conventional 340B eligible patient definition, as outlined in the Apexus 340B Prime Vendor Program™, suggests determination of several variables, including:

- Service Location – validating that the site of care is eligible (e.g., at the parent location or a child site or associated grantee site of the CE)
- Patient Status – confirming outpatient status at the time of drug administration/dispensation
- Patient Health Record – maintaining detailed medical records of the patient's health care
- Entity-Provider Relationship – ensuring provider is employed by or contracted with the entity
- Scope of Grant (for grantee CE types) – verifying health care rendered is consistent with grant funding

While these variables offer a more granular interpretation of how to define patient eligibility, it should be noted that these elements are not specified in detail in the 340B statute, and stringent adherence to all of these variables may suggest that this "traditional" definition of patient eligibility is more narrow than what the law may allow. For example, "referral capture", or qualification of 340B eligible prescriptions written by external providers from encounters at ineligible locations pursuant to a formal referral for consultation, has routinely satisfied HRSA audit criteria and has evolved to become a recognized application of compliant 340B Program activity.

### 340B Eligibility and "Continuum of Care"

At the heart of the Genesis case is the argument that by the nature of being a Federally Qualified Health Center (FQHC), Genesis maintains responsibility for the primary care of their patients, even when services are rendered by outside providers or at outside locations, invoking a "continuum of care" relationship that establishes eligibility for use of 340B drugs. Additionally, FQHC and other grantee type CEs may further defend their claim for responsibility for care of the patient across the continuum, as their grant funding commonly requires them to pay for all or a portion of patients' medications, even for specialty care received outside of the CE. What is less clear is the extent to which this "continuum of care" logic applies for hospital CE types that are more predominantly providing acute care services, rather than primary care. Incidental episodes of acute care at the hospital (e.g., Emergency Department visits) may not serve as compelling examples to claim responsibility of care for the patient following discharge. However, there may be more complicated clinical scenarios (e.g., transplant care, cancer care, sickle cell anemia) where the hospital CE serves as the nexus of the patient's care plan, with follow-up care coordinated with and supported by outside providers.

### 340B Eligibility and Non-Reimbursable Hospital Locations

HRSA guidance published in 1994 (Federal Register, 59 Fed. Reg. 47884-47886 Sep 19, 1994) outlines how hospital CEs should address the inclusion of its outpatient departments within their 340B Program operations, stating that reimbursable outpatient facilities of the hospital may be considered eligible. But with the more relaxed HRSA audit standards monitoring for statutory compliance only, prescriptions issued from non-reimbursable hospital departments, which typically are allocated to Medicare Cost Report (MCR) Worksheet A, Line 190.00 or below (i.e., "below the line" clinics), have satisfied audit criteria when the patient had a previous encounter at a 340B eligible hospital location. It is noted that HRSA will not accept registration of these departments as child sites of a hospital CE on the Office of Pharmacy Affairs Information System (OPAIS), but hospitals may argue that these are integral parts of their facility, often located on hospital property, and routinely supported by the same hospital ancillary departments that service 340B eligible reimbursable hospital departments. So where "service location" functions as a variable in a CE's patient definition, broader

inclusion of non-reimbursable hospital departments, particularly those with expenses allocated to MCR Line 190.00 or below is up for debate.

## Conclusion

The Genesis case serves as one of the most significant tests to date of the conventional understanding of what defines a 340B eligible patient. While the elements of the court case more directly apply to grantee CEs, all 340B CEs should use this as an opportunity to reevaluate their respective policies and procedures as it relates to patient definition, particularly as HRSA has acknowledged through its audit activity that elements of the patient definition exist in guidance documents, which are currently outside the boundaries of its enforcement capabilities. Broadening the patient definition may provide CEs with significant value in terms of 340B savings optimization, and may be permissible according to law, given the lack of specificity of "patient definition" outlined in 340B Program statute and regulations.

## Recommended Next Steps

CEs may want to take this opportunity to review their policies and procedures, and dissect how their definition of a 340B eligible patient is determined, noting which elements satisfy 340B statutory requirements versus guidance. Some considerations when performing this evaluation include:

- Assess for scenarios where a "continuum of care" relationship may apply, particularly where there is an intersection between care provided directly by the CE and care provided by outside providers/locations.
- Review non-reimbursable hospital departments (e.g., Line 190 clinics) that may be integral to the CE.
- Estimate whether there would be a positive financial impact from liberalizing the definition of a patient. Without significant upside in terms of 340B Program savings, there may be no reason to consider changing.
- Ensure any modifications to patient definition are clearly articulated in policies and procedures.
- Engage key legal and/or compliance stakeholders, including your 340B Steering Committee, to assess liabilities that may be associated with broadening your patient definition.
- Recognize that current HRSA audit standards reflect the agency's limited enforcement authority, and these standards could evolve should they receive rule-making authority and/or the ability to enforce 340B Program guidance.