



CHAPTER 3

340B Program Requirements and Compliance Issues

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This chapter summarizes the requirements and compliance issues applicable to providers and manufacturers that choose to participate in the 340B program. It also examines the enforcement authority of the federal agency charged with administering the program, the Health Resources and Services Administration (HRSA), which is located within the Department of Health and Human Services (HHS). Most of the 340B program's requirements are set forth in the 340B statute. As of April 2018, HRSA has issued only one regulation governing the 340B program; that regulation has still not been implemented.¹ All other instructions from HRSA are issued as guidance. Both providers and manufacturers struggle with discerning their 340B compliance responsibilities because, in the absence of implementing regulations, the program's only legally binding requirements are those found in the 340B statute. In most cases, it is drafted in broad terms. HRSA guidance deserves deference by program participants, but some policies may be unenforceable if they stray too far from the plain meaning of the law. For this reason, 340B providers and manufacturers would be well-advised to seek legal counsel to clarify their 340B rights and responsibilities.

KEY POINT

HRSA has issued only one regulation governing the 340B program, and that regulation has yet to be implemented. 340B rules are typically articulated as guidance and may be subject to change as HRSA considers new information and audit results.

PROGRAM ELIGIBILITY

Only certain healthcare providers are eligible to become “covered entities” under the 340B statute.² The original legislation allowed public or nonprofit acute care hospitals with a disproportionate share hospital (DSH) percentage above 11.75%, certain grantees, and federally qualified health center (FQHC) look-alikes to enroll in the 340B program.³ The Affordable Care Act (ACA)⁴ made five additional hospital categories eligible for the 340B program: children's hospitals,⁵ cancer hospitals, sole community hospitals (SCHs), rural referral centers (RRCs), and critical access hospitals (CAHs).⁶ Each of these categories of covered entities must meet additional criteria to participate in the 340B program (discussed below). A qualifying grantee may also be an outpatient department of a qualifying hospital. In these circumstances, the entity may register as a grantee or qualify

under the hospital's registration. HRSA encourages grantees with more than one qualifying grant to register under each grant in case the grantee loses one of the grants.

Hospital Eligibility

Both the eligibility criteria and compliance requirements applicable to the six categories of 340B hospitals vary by category. If a hospital qualifies under more than one category, it may participate under any one of the categories under which it qualifies, but must comply with the requirements relevant to the category it selects.

DSH Adjustment Percentage

Each hospital category, with the exception of CAHs, must meet a DSH adjustment threshold to participate in the 340B program.⁷ Acute care hospitals, children's hospitals, and cancer hospitals must have DSH adjustment percentage that exceeds 11.75%, based on the hospital's most recently filed Medicare cost report.⁸ Hospitals designated as SCHs or RRCs must have a DSH adjustment percentage of at least 8%.⁹ A hospital must contact HRSA if its DSH adjustment percentage falls below the requisite level based on its filed Medicare cost report and must stop purchasing 340B drugs immediately.

Hospitals can only become prospectively eligible for the 340B program. According to one of the three court cases addressing the 340B program, covered entities cannot become retroactively eligible for participation in 340B based on an amended Medicare cost report with a qualifying DSH percentage.¹⁰

Organizational Status

Each category of eligible hospital must meet the "government function" requirement, which mandates that a hospital be the following:

- Owned or operated by a unit of state or local government (a state, county, or city).
- A public or private nonprofit corporation that has been formally granted governmental powers by a unit of state or local government.
- A private nonprofit hospital with a contract with a state or local government to provide healthcare services to low income individuals who are not entitled to benefits under Medicare or Medicaid.¹¹

For-profit hospitals and hospitals that are not legally or contractually obligated to care for low-income patients are, therefore, not eligible to participate in the program.

KEY POINT

HRSA relies on a 340B hospital's Medicare cost report to determine whether a hospital and its child sites are eligible to participate in the 340B program. Pharmacists should confer with the hospital's Medicare cost report personnel to avoid violations of 340B eligibility requirements.

Defining the Scope of an Eligible DSH Hospital

Although the 340B statute is relatively clear in identifying the kinds of hospitals eligible to participate in the program, it is less specific about the scope of a qualifying hospital. HRSA has relied in large part on a 340B hospital's Medicare cost report for distinguishing between hospital facilities that are eligible and ineligible.