

340B Program Eligibility Guide for Non-Profit Hospitals

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Date: December 15, 2025

1. Executive Summary

The 340B Drug Pricing Program offers significant savings for eligible non-profit healthcare organizations, enabling them to stretch scarce federal resources as far as possible. However, eligibility for private non-profit hospitals is strictly regulated. This guide outlines the detailed federal requirements and state-specific nuances that non-profit entities must navigate to qualify and maintain compliance.

2. Federal Eligibility Requirements

To participate in the 340B Program, a private non-profit hospital must meet **all** of the following federal criteria established by the Health Resources and Services Administration (HRSA):

2.1. Classification Requirement

The hospital must be classified as one of the following entity types: * **Disproportionate Share Hospital (DSH)** * **Children's Hospital (PED)** * **Free-standing Cancer Hospital (CAN)** * **Sole Community Hospital (SCH)** * **Rural Referral Center (RRC)** * **Critical Access Hospital (CAH)**

2.2. Ownership & Contractual Status

A private non-profit hospital must demonstrate its "governmental" relationship through one of the following: 1. **Owned or operated** by a unit of state or local government. 2. **Formally granted governmental powers** by a unit of state or local government (e.g., power of eminent domain, taxation). 3. **Contract with State/Local Government:** Most common for private non-profits. The hospital must have a valid, written contract with a state or local government to provide health care services to low-income individuals who are not eligible for Medicare or Medicaid.

Critical Requirement: The government contract must be signed by an authorized government official and a hospital executive. It must explicitly state the obligation to serve low-income populations.

2.3. Disproportionate Share Adjustment Percentage

For DSH, PED, and CAN classifications, the hospital must have a disproportionate share adjustment percentage greater than **11.75%** for the most recently filed Medicare cost report. * Note: SCH and RRCs must have an adjustment percentage of at least **8%**. * Note: CAHs are exempt from this percentage requirement.

2.4. Group Purchasing Organization (GPO) Prohibition

DSHs, PEDs, and CANs are subject to the GPO Prohibition. They **cannot** use a GPO to purchase covered outpatient drugs. They must purchase these drugs through separate accounts (e.g., WAC or 340B accounts).

3. The "Government Contract" Requirement: Detailed Breakdown

For private non-profit hospitals that are not government-owned, the **government contract** is the linchpin of eligibility.

3.1. Essential Contract Elements

HRSA requires the contract to contain specific language. A compliant contract must: * **Be in writing** and currently in effect. * **Identify the parties:** Clearly state the hospital and the specific unit of state or local government. * **Service Obligation:** Explicitly state that the hospital is obligated to provide health care services to low-income individuals. * **Target Population:** Specify that these services are for individuals who are **not eligible for Medicare or Medicaid**. * **Signatures:** Be signed and dated by authorized representatives from both parties.

3.2. Common Pitfalls

- **Expired Contracts:** Contracts must be active at the time of registration and recertification.
- **Vague Language:** "Serving the community" is insufficient. The contract must specify "low-income individuals not eligible for Medicare or Medicaid."
- **Missing Signatures:** Unsigned drafts or letters of support do not qualify.

4. State-Specific Reporting & Compliance Nuances

While 340B is a federal program, many states have enacted additional reporting requirements or protections for covered entities. Non-profits must be aware of these to ensure full compliance.

4.1. State Reporting Laws (2024-2025 Trends)

Several states have passed laws requiring 340B covered entities to report savings and how they are used. * **Minnesota:** Requires detailed reporting on 340B net income and its allocation to patient services. * **Washington:** Mandates transparency reports for hospitals participating in 340B. * **Ohio, Indiana, Colorado:** Have recently enacted or proposed legislation requiring annual reporting of aggregate 340B acquisition costs and reimbursement data.

4.2. Contract Pharmacy Protections

Many states (e.g., Arkansas, Louisiana, West Virginia) have passed laws prohibiting pharmaceutical manufacturers from restricting 340B drug distribution to contract pharmacies. * **Impact:** Non-profits in these states may have broader access to contract pharmacy networks, but must also adhere to stricter state-level compliance monitoring to prevent diversion.

5. Documentation Checklist for Registration

Before registering on the 340B OPAIS database, ensure you have: * [] **Medicare Cost Report:** Most recently filed report (Worksheet S-2, Line 20 for ownership type). * [] **Government Contract:** PDF copy of the signed, active contract (for private non-profits). * [] **Authorizing Official:** Designated individual who can legally bind the organization. * [] **Tax-Exempt Status:** IRS 501(c)(3) determination letter.

6. References

1. HRSA. "Disproportionate Share Hospitals - Eligibility." <https://www.hrsa.gov/opa/eligibility-and-registration/hospitals/disproportionate-share-hospitals>
2. 340B Health. "Criteria for Hospital Participation." <https://www.340bhealth.org/members/340b-program/criteria-for-hospital-participation/>
3. RWC-340B. "State 340B Covered Entity Reporting Laws Roundup." <https://rwc340b.org/state-340b-covered-entity-reporting-laws-roundup/>