

Rural Referral Centers: 340B Eligibility, Enrollment, and Participation

Background

- The 340B Drug Pricing Program (340B Program) administered by the Health Resources and Services Administration’s Office of Pharmacy Affairs (OPA) was established in 1992 by Federal statute.
- Section 340B of the Public Health Service Act limits the cost of covered outpatient drugs to covered entities enrolled in the 340B Program. Significant savings on pharmaceuticals may be seen by those entities that participate.
- Section 7101 of the Patient Protection and Affordable Care Act allows certain qualifying Rural Referral Centers (RRC) to access 340B discounted drugs.

Purpose

The purpose of this document is to provide eligible Rural Referral Centers and other interested parties basic background information about the 340B Drug Pricing Program, instructions on how to enroll and to provide additional sources for information related to the 340B Program.

Key Points for Eligibility & Enrollment

340B Program Requirement	How To
1. Certify that the hospital is a "Rural Referral Center" as defined by section 1886(d)(5)(C)(i) of the Social Security Act and 42 CFR 412.96.	Review cost reporting status with the Centers for Medicare and Medicaid Services (CMS) and confirm that the hospital meets the statutory definition of a rural referral center and that such status is recognized by CMS.
2. Certify that the hospital is eligible with a disproportionate share adjustment percentage equal to or greater than 8 percent in the hospital’s most recently filed Medicare cost report.	Review the hospital’s most recently filed cost report and confirm whether disproportionate share adjustment percentage is equal to or greater than 8 percent. Hospitals may be asked to submit Worksheet E, Part A from their most recently filed Medicare cost report.
3. Certify that the hospital is: (a) a private non-profit hospital under contract with State or local government to provide health care services to low-income individuals who are not eligible for Medicare or Medicaid; (b) owned or operated by a unit of State or local government; or (c) a public or private non-profit corporation that is formally granted governmental powers by a unit of State or local government.	Complete and submit the relevant form or supporting documentation: <ul style="list-style-type: none"> • For (a), complete “Certification of a Contract” form. • For (b) or (c), provide supporting documentation as directed on registration form.
4. Certify that outpatient clinics meet eligibility criteria.	Rural Referral Centers will use the same process to add outpatient facilities as disproportionate share hospitals (59 FR 47884). An appropriate official must be able to attest to the following: <ol style="list-style-type: none"> a. the 340B eligible outpatient clinics are integral parts of the hospital; and b. the outpatient facility is reimbursable on the most recently filed Medicare cost report
5. Certify that the hospital will abide by all requirements of the 340B Program.	Complete and submit the 340B Program Registration Form for Rural Referral Centers.



Basic 340B Program Limitations and Restrictions

- All 340B covered entities are prohibited from selling or otherwise transferring covered outpatient drugs purchased under the program to anyone other than a patient of the covered entity (see 61 FR 55156 Oct. 24, 1996 for guidelines on the definition of patient)
- All 340B covered entities are prohibited from requesting payment under Medicaid for a covered outpatient drug purchased under the 340B Drug Pricing Program if the State claims a Medicaid rebate for the same covered outpatient drug from the manufacturer. If the covered entity will bill Medicaid for drugs purchased under 340B, then the entity must provide OPA with the Medicaid billing number.
- All 340B covered entities must maintain auditable records that demonstrate compliance with 340B Program requirements.
- All 340B covered entities must comply with all other applicable Federal, State and local laws.
- For covered entities described in subparagraph (M), (N), or (O) (includes Rural Referral Centers) of subsection (a)(4), the term “covered outpatient drug” shall not include a drug designated by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition, an “orphan drug.”

Registration Deadlines

The quarterly deadlines for application submission to OPA are a month before the start date in the 340B Program. The deadlines are **December 1, March 1, June 1 and September 1**. OPA is utilizing a rolling admissions process during the first quarter of eligibility for the newly added entity types starting August 2, 2010 through September 30, 2010.

Additional Resources

CMS Factsheet for Rural Referral Centers.	http://www.cms.gov/MLNProducts/downloads/RuralRefCtrfctsht2008.pdf
Office of Pharmacy Affairs (OPA) 340B Information and Registration forms.	http://www.hrsa.gov/opa/
Pharmacy Services Support Center (PSSC) The PSSC is a resource to assist HRSA grantees and eligible health care sites optimize the value of the 340B Program and provides clinically and cost-effective pharmacy services that improve medication use and advance patient care at no cost.	Phone:(800) 628-6297 Email: pssc@aphanet.org
Prime Vendor Program (PVP) PVP is responsible for negotiating pharmaceutical pricing below the 340B price and improving access to affordable distribution sources for pharmaceuticals to covered entities.	Phone: (888) 340-BPVP (340-2787) Email: Technical Support- 340TechSupport@340bpvp.com Customer Service- 340CustomerService@340bpvp.com
Answers.gov Access to a list of FAQs about Sole Community Hospitals.	http://answers.hrsa.gov Search for “Rural Referral Centers”