



Rural Referral Centers: 340B Eligibility, Enrollment and Participation

The 340B Drug Pricing Program (340B Program) enables certain qualifying Rural Referral Centers to register with the program and purchase covered outpatient drugs at 340B prices, which can offer significant savings on pharmaceuticals.

Eligibility and Registration

340B Program Requirement	How to Qualify
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.
Certify that the hospital is: <ul style="list-style-type: none"> (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. 	If hospital is certified under requirement <ul style="list-style-type: none"> (a) Complete and submit the Hospital Certification of Contract with State/Local Government to Provide Health Care Services to Low Income Individuals form downloaded from the 340B Program website. (b) or (c) Provide supporting documentation as directed in the on-line registration form.
Certify that the hospital had a disproportionate share adjustment percentage greater than 8% in the most recently filed Medicare cost report.	Hospitals may be asked to submit Worksheet E, Part A from the most recently filed Medicare cost report.
Certify that outpatient clinics meet eligibility criteria.	Have an appropriate official attest that the 340B-eligible outpatient clinics are <ul style="list-style-type: none"> (a) integral parts of the hospital and (b) reimbursable on the most recently filed Medicare cost report.
Certify that the Rural Referral Center will abide by all requirements of the 340B Program.	Complete and submit the 340B Program Registration Form for Rural Referral Centers.

Basic 340B Limitations and Restrictions

All 340B covered entities ...

- Are prohibited from selling, giving or otherwise transferring covered outpatient drugs purchased under the program to anyone other than a patient of the covered entity (see 61 FR 55156, October 24, 1996, for guidelines on the definition of patient);
- 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;
- Must maintain auditable records that demonstrate compliance with 340B Program requirements; and
- Must comply with all other applicable Federal, State or 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.

Registration Deadlines

Following are the deadlines for your on-line registration and supporting documentation (that must be scanned and e-mailed to the Office of Pharmacy Affairs on the same day you submit your on-line registration form):

- Register between January 1 and 15 for an April 1 start date.
- Register between April 1 and 15 for a July 1 start date.
- Register between July 1 and 15 for an October 1 start date.
- Register between October 1 and 15 for a January 1 start date.

For More Information

340B Program website: <http://www.hrsa.gov/opa>