



Freestanding Cancer Centers: 340B Eligibility, Enrollment and Participation

The 340B Drug Pricing Program (340B Program) enables certain qualifying Freestanding Cancer 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
Demonstrate that the hospital is a “Freestanding Cancer Center” excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(v) of the Social Security Act.	The hospital must show that it is independent and not part of a larger institution by demonstrating financial and administrative independence.
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 for the most recent cost reporting period that ended before the calendar quarter involved, the hospital had a disproportionate share adjustment percentage greater than 11.75%.	Provide to the Office of Pharmacy Affairs either of the following: <ul style="list-style-type: none"> • an official document from the Department of Health and Human Services or a contractor authorized to make official determinations showing that the hospital meets the DSH adjustment percentage requirement for the most recent cost reporting period; or • a copy of the pages of the most recently filed Medicare cost report that contain data necessary to calculate the DSH adjustment percentage, as well as a concise description of any mathematical calculations.

Certify that outpatient clinics meet eligibility criteria	Have an appropriate official attest that the 340B-eligible outpatient clinics are (a) integral parts of the hospital and (b) reimbursable on the most recently filed Medicare cost report.
Certify that the Freestanding Cancer Center will abide by all requirements of the 340B Program.	Complete and submit the 340B Program Registration Form for Freestanding Cancer 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 Freestanding Cancer 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>