



- 1) **340b Drug Pricing Program:** A federal program, run by the Office of Pharmacy Affairs at the Health Resources and Services Administration (HRSA), that requires drug manufacturers to provide outpatient drugs to certain health care entities at significantly reduced prices. The 340B program is designed to help health centers “stretch scarce federal resources as far as possible, reach more eligible patients, and provide more comprehensive services.” 340b refers to the section of the Public Health Service Act where these requirements are found.
- 2) **Covered entity:** Providers that are eligible for 340B are called “covered entities.” Covered entities are determined by law and include:
  - a. Hospitals: Disproportionate Share (DSH) Hospitals, Children’s Hospitals, Critical Access Hospitals, Free-standing Cancer Hospitals
  - b. Federal Grantees
    - i. Federal Qualified Health Centers
    - ii. Ryan White Providers
    - iii. Title X Family Planning Providers
    - iv. Hemophilia clinics
    - v. STD clinics (Section 318, see item #6)
    - vi. TB clinics (Section 317)
- 3) **340b Definition of Patient/ Eligible Patient:** Covered entities can only provide drugs they purchase through 340B to patients who meet the program’s patient definition. An individual is a patient of a 340B covered entity (with the exception of State-operated or funded ADAPs) only if:
  - the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; *and*
  - the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; *and*
  - the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding... status has been provided to the entity.
- 4) **STD “Definition of Patient”:** After meeting the first two prongs of the patient definition, NCSD recommends the following for entities to “meet” the third prong of the patient definition for STDs:

At a minimum, a patient should receive a sexual health history and review of STD risk factors with a provider at every visit. That patient should then receive any STD testing and treatment warranted, per CDC STD Guidelines, from that sexual health history.
- 5) **STD/318 “subgrantees”:** Entities that have a financial relationship with an STD program or another program that receives 318 grant funding may be eligible for 340b. These entities must receive either direct financial support through the federal STD grant (starting in 2019, the PCHD grant) or receive in-kind contributions through the STD grant.



- 6) **318 grants:** Any grant from CDC that uses Section 318 of the Public Health Service Act as its legislative authority may qualify for 340b under the “STD clinic/ Section 318” covered entity type. Review the “statutory authority” section of a grant to confirm that grant’s legislative authority.
- 7) **Definition of “In-kind contributions”:** Per HRSA: “An entity receiving in-kind contributions through section 317 or 318 may qualify for the 340B Drug Pricing Program provided all the remaining 340B requirements are met. Qualifying in-kind contributions must be paid for by section 317 or 318 grant funds to qualify a site as 340B eligible. In-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and goods and services directly benefiting and specifically identifiable to the project or program.”
- 8) **Authorizing Official (AO):** This individual is the main contact for the covered entity for the 340B program and bears the responsibility for the program’s 340B compliance. Per HRSA, he/she is “fully authorized to legally bind a 340B covered entity into a relationship with the federal government and has knowledge of the practices and eligible programs at that site.” This individual is responsible for registering the site with HRSA and complementing the annual recertification process. NCSO recommends that the Authorization Official be as close to the provision of services as possible. For “subgrantees,” that would be at that clinic site.
- 9) **Primary Contact:** A secondary contact for the covered entity listed with HRSA. They receive information from HRSA but have no authority to change or update the entity’s information with HRSA, nor do they have the responsibility of the Authorizing Official.
- 10) **Registration:** Covered Entities must first register for the 340B Program in order for HRSA’s Office of Pharmacy Affairs (OPA) to verify that entities meet all statutory requirements prior to participation. Registration is only required to occur once. It occurs quarterly and there is a “lag” time between the registration period and the effective start date. Visit [www.hrsa.gov/opa/registration](http://www.hrsa.gov/opa/registration) for more information.
- 11) **Recertification:** 340B covered entities must annually recertify their eligibility to remain in the 340B Drug Pricing Program. HRSA will send emails to the Authorizing Official and the Primary Contact for the covered entity notifying them that recertification is upcoming. The Authorizing Official has the only access to recertify the covered entity. This process happens annually and if programs fail to recertify, they will be removed from the program.
- 12) **Diversion:** 340B Covered entities must not resell or otherwise transfer 340B drugs to ineligible patients, patients who do not meet the 340B patient definition. This would be considered diversion and the entity would be out of compliance with the 340B program.
- 13) **Duplicate Discount:** Manufacturers are prohibited from providing a discounted 340B price and a Medicaid drug rebate for the same drug. Covered entities must accurately report how they bill Medicaid fee-for-service drugs on the Medicaid Exclusion File, a file maintained by HRSA.