

### 8.17.3 340B DRUG DISCOUNT PROGRAM

**Policy:** As a recipient of Title X funds, sub-recipient and satellite clinics qualify for participation in the 340B drug discount program. The 340B program makes it possible for covered entities, such as Title X clinics, to purchase drugs at a significant discount.

The 340B program is administered by the Health Resources and Services Administration's (HRSA) Office of Pharmacy Affairs. All pharmaceutical manufacturers participating in Medicaid are required to participate in the 340B program as part of the Pharmaceutical Pricing Agreement (PPA), which mandates that manufacturers provide up-front discounts on covered outpatient drugs purchased by covered entities.

The list of covered entities are defined in statute and includes, but is not limited to, Title X health centers, STD clinics (entities receiving funds under Section 318 of the Public Health Service Act), hospitals serving a high percentage of uninsured clients, and federally qualified health centers (FQHCs). Covered entities participating in the 340B program may purchase discounted drugs through wholesalers, state purchasing programs, and group purchasing programs. They may also purchase drugs directly from the manufacturer.

**Procedure:**

1. To become a covered entity and participate in the 340B program, each sub-recipient must register their clinic, as well as their satellite clinics, with the Office of Population Affairs through the HRSA website (<http://www.hrsa.gov/opa/eligibilityandregistration/index.html>). Once registered, the sub-recipient must re-certify annually.
2. Once the sub-recipient is registered as a covered entity in the 340B program, they can receive 340B price lists. These prices must be honored by manufacturers and can even be negotiated downward by the sub-recipient.
3. Sub-recipients may choose to participate in the federally contracted group-purchasing Prime Vendor Program, currently run by Apexus. Apexus is responsible for negotiating lower drug prices for covered entities.
4. Title X clinics (sub-recipient and satellite clinics) can only provide drugs that they receive under the 340B program to clients meeting the following requirements:
  - a. The clinic has an established relationship and maintains records of care
  - b. The client receives health care services from a health care professional employed and contracted with the clinic
  - c. The client receives services consistent with the scope of Title X
5. All Title X clinics can provide 340B drugs to all clients regardless of insurance status, including Medicaid.
6. Title X clinics must maintain separate, auditable records for all 340B purchasing, storage and dispensing.
7. Providing 340B drugs to anyone other than a client is considered drug diversion and is illegal.
8. *42 USC 256b(a)(5)(A)(i)* prohibits duplicate drug discounts through the 340B program. Drug manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug (see <http://www.hrsa.gov/opa/programrequirements/medicaidexclusion>).
9. If the DPHHS Medicaid program receives a drug rebate for drugs purchased under the 340B program, Title X clinics can bill Medicaid only for the acquisition price for the drug. This requirement is outlined in the May 23, 2008 MT Healthcare Programs Notice and in MT ARM 37.85.905 (see MT TX FP Administrative Manual, Resources 10.13, *MT Healthcare Programs Notice* and 10.14, *MT ARM 37.85.905*).

10. Upon enrollment in the 340B Program, sub-recipients must determine whether they will use 340B drugs for their Medicaid clients (carve-in) or whether they will purchase drugs for their Medicaid clients through other mechanisms (carve-out).
  - a. **Carve-In.** Covered entities that will carve-in are required to inform HRSA (by providing their Medicaid provider number/NPI) at the time they enroll in the 340B Program that they will purchase and dispense 340B drugs for their Medicaid clients. If covered entities decide to bill to Medicaid for drugs purchased under 340B with a Medicaid provider number/NPI, then ALL drugs billed to that number must be purchased under 340B and that Medicaid provider number/NPI must be listed on the HRSA Medicaid Exclusion File.
  - b. **Carve-Out.** For covered entities that opt to purchase Medicaid drugs outside of the 340B Program, (e.g. carve-out Medicaid prescriptions) ALL drugs billed under that Medicaid provider number/NPI must be purchased outside the 340B Program, and that Medicaid provider number/NPI should not be listed on the HRSA Medicaid Exclusion File. The sub-recipient is required to notify the DPHHS Medicaid program of the intent to carve-out the purchase of 340B drugs.
11. Sub-recipients must report any changes in billing of 340B drugs to Medicaid to the Office of Pharmacy Affairs and the DPHHS Medicaid program before implementing the billing change. It is your responsibility as a 340B covered entity to ensure that the information in the HRSA Medicaid Exclusion File is correct.
12. Title X clinics must ensure program integrity and maintain accurate records documenting compliance with all 340B Program requirements. Covered entities are subject to audit by manufacturers or the federal government. Failure to comply may make the 340B covered entity liable to manufacturers for refunds of discounts obtained.

For questions about 340B, Title X sub-recipients may contact:

Email: [ApexusAnswers@340bpbp.com](mailto:ApexusAnswers@340bpbp.com)

Phone: 1-888-340-2787

Live chat: [www.340bpvp.com](http://www.340bpvp.com)

Hours: Monday through Friday, 9 am – 6 pm Eastern Time

For questions regarding MT Medicaid, Title X sub-recipients may contact Medicaid Provider Relations:

Phone: 1-800-624-3958 or 406-442-1872