



1.9 340B PROGRAM

POLICY:

Each subrecipient must have local 340B policies and procedures to ensure compliance with the 340B Program.

PROCEDURE:

Each subrecipient must use any savings generated from 340B in accordance with 340B Program intent. The 340B Program enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible clients and providing more comprehensive services.

Each subrecipient must meet all 340B Program eligibility program requirements:

- HRSA 340B OPAIS covered entity listing is complete, accurate and correct
- Agency receives a grant or designation consistent with that conferring 340B eligibility

Each subrecipient must comply with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines, including, but not limited to:

- Prohibition against duplicate discounts or rebates under Medicaid
- Prohibition against transferring drugs purchased under 340B to anyone other than the client of the covered entity

Each subrecipient must maintain auditable records demonstrating compliance with 340B requirement described in the preceding item.

- The prescriber is employed by the subrecipient or under contractual or other arrangements with the subrecipient, and the individual receives a health care service (within the scope of the grant/designation for which 340B status was conferred) from this professional such that the responsibility for care remains with the subrecipient.
- The service site maintains records of the individual's health care.
- If the service site bills Medicaid for 340B drugs, billing follows State Medicaid guidelines and has reflected its information on the HRSA 340B OPAIS/Medicaid Exclusion File:
 - Agency informs HRSA immediately of any changes to its information on the HRSA 340B OPAIS/Medicaid Exclusion File.
 - Medicaid reimburses the agency for 340B state drugs per Medicaid's state plan and does not collect rebates on claims from the agency.

Each subrecipient has systems/mechanisms and internal controls in place to ensure ongoing compliance with all 340B requirements.

Each subrecipient may elect to use contract pharmacy services: the contract pharmacy agreement is in accordance with HRSA requirements and guidelines, including but not limited to:



- Subrecipient obtains sufficient information from the contractor to ensure compliance with applicable policy and legal requirements and has used an appropriate methodology to ensure compliance (e.g., through an independent audit or other mechanism).
- Signed Contract Pharmacy Services Agreement(s) comply with 12 contract pharmacy essential compliance elements.
- Each subrecipient acknowledges the responsibility to contact HRSA as soon as reasonably possible if there is any change in 340B eligibility or material breach of the service site of any of the foregoing policies.

Each subrecipient acknowledges if there is a breach of 340B requirements, they may be liable to the manufacturer of the covered outpatient drug that is the subject of violation and, depending on the circumstances, may be subject to payment of interest and/or removal from the list of eligible 340B entities.

Each subrecipient may elect to receive information from trusted sources including, but not limited to:

- 340B Drug Pricing Program | Official website of the U.S. Health Resources & Services Administration (hrsa.gov)
- 340B Prime Vendor Program | 340B Drug Pricing Program Partner (340bpvp.com)

Project staff participating in the 340B Program complete initial basic training via webinar on the 340B and Prime Vendor programs and should attend 340B University every 1–2 years.

HRSA requires entities to recertify their information as listed in the HRSA 340B OPAIS annually. The sub-recipients authorizing official annually recertifies the sub-recipient's information by following the directions in the recertification email sent from the HRSA to the agency's authorizing official by the requested deadline. Specific recertification questions should be sent to 340b.recertification@hrsa.gov.

Each service site must separate 340B and non-340B inventory and dispense 340B drugs only to clients that meet all criteria.

- Service site uses either only 340B inventory or electronically or physically separate 340B and non-340B purchased inventory.
- Staff places 340B orders through periodic inventory reviews and shelf inspections of periodic automatic replenishment (PAR) levels.
- Staff checks in 340B inventory by examining the wholesaler invoice against the order, and reports inaccuracies to the wholesaler.
- Staff maintains records of 340B-related transactions in a readily retrievable and auditable format.
- 340B inventory is stored securely, and access is limited to designated clinical staff.



RESOURCES:

HRSA Program Requirements

<https://www.hrsa.gov/opa/program-requirements>

Apexus 340B Prime Vendor Program [340B Prime Vendor Program - Apexus](#)

[340B Drug Pricing Program: Frequently Asked Questions for Title X Family Planning Agencies \(rhntc.org\)](#)

[340B Drug Pricing Program: Compliance Tips for Title X Agencies \(rhntc.org\)](#)

[Issues - Health Care Delivery - 340B - National Family Planning & Reproductive Health Association](#)

[Medicaid Covered Outpatient Prescription Drug Reimbursement Information by State | Medicaid](#)

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