



**FAMILY PLANNING PROGRAM  
POLICY AND PROCEDURE MANUAL**

**SECTION:**Program Administration

**SUBJECT:** 340B Policy & Procedure

**POLICY:** Each agency must have local 340B policies and procedures to ensure compliance with the 340B Program.

**GUIDELINES:**

1. Each agency must use any savings generated from 340B in accordance with 340B Program intent.
2. Each agency must meet all 340B Program eligibility program requirements are met including, but not limited to:
  - a. The OPA Database of the covered entity listing is complete, accurate and correct.
  - b. Designation is consistent with that conferring 340B eligibility.
3. Each agency 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:
  - a. Prohibition against duplicate discounts or rebates under Medicaid.
  - b. Prohibition against transferring drugs purchased under 340B to anyone other than the patient of the covered entity.
4. Each agency must maintain audible records demonstrating compliance with 340B requirement described in the previous number.
  - a. Family Planning agency maintains records of the individual's health care.
  - b. If agency bills Medicaid for 340B drugs, billing follows **State Medicaid guidelines** and covered agency has reflected it's information on the OPA website/Medicaid Exclusion File
5. Each agency must have an internal audit plan conducted annually to ensure ongoing compliance with all 340B requirements.
6. Each agency may elect to use contract pharmacy services and the contract pharmacy agreement is in accordance with OPA requirements and guidelines.



7. Each agency acknowledges the responsibility to contact OPA as soon as possible if there is any change in 340B eligibility or material breach by the Family planning agency of any of the foregoing policies.
8. Each agency 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. Covered agency may be subject to payment of interest and/or removal from 340B eligible list.
9. Each agency may elect to receive information from trusted sources including, but not limited to:
  - Office of Pharmacy Affairs
  - 340B Prime Vendor Program (Managed by Apexus)
  - Any OPA contractors
10. Recommended that staff involved with 340B program compliance review the 340B University PowerPoint presentation on the 340B and Prime Vendor Program website.
11. Each agency will recertify their information as listed on OPA database annually as OPA requires.
12. Each agency must separate 340B and non-340B inventory. Staff must dispense 340B drugs only to patients that meet all criteria.
  - a. Staff places 340B orders from a wholesaler (of choice) through periodic inventory review at an interval of agency's choosing.
  - b. Staff checks 340B inventory by examining the wholesaler invoice against the order and reports inaccuracies to the wholesaler.
  - c. Staff maintains records of 340B transactions for a period of (agencies choosing) that is easily retrievable and auditable. (Suggest keeping audit records for 1 year.)
  - d. 340B inventory is securely stored and access is limited to designated staff.
  - e. Audit results are shared with appropriate staff as needed.
13. Reimbursement for 340B drugs from Medicaid and private insurers must be done in accordance with the above 340B regulations.



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References:

1. Section 340B of the Public Health Services Act (1992)
2. Public Law 102-585, Section 602
3. 340B guidelines
4. 340B policy releases