

C6.1 – USE OF 340B MEDICATIONS

Purpose

The purpose of this policy is to have each SR describe their process for ensuring compliance with the expectation that all clinic locations enroll in the 340B Program and comply with all 340B Program requirements, including annual recertification and avoiding diversion or duplicate discounts. 340B Program requirements are available at <https://www.hrsa.gov/opa/program-requirements/index.html>. (FY22 Notice of Award Special Terms and Requirements)

Policy

All SRs must enroll in the 340B Program and comply with all 340B Program requirements, including:

- initial certification
- annual recertification
- avoiding diversion or duplicate discounts

Each SR is responsible for annual recertification of all clinic sites where 340B purchased medications are used. Failure to recertify will result in the agency being unable to use 340B medications in any clinic sites that are not certified.

Procedure

Each SR will be responsible for the following:

- Identify the staff member responsible for enrolling and recertifying the project.
- Recipient's process for monitoring SRs and service sites to ensure compliance with this expectation.
- Each SR must certify that reasonable safeguards are in place to assure compliance with the provisions of Section 340B of the PHS Act that prohibit Drug Diversion and Double Discounts/Rebates.
- Each SR will have a policy clearly describing their safeguards for Drug Diversion and Double Discounts/Rebates in their FP manual. SRs will describe how they will maintain control over their inventory of 340B medications.

Iowa HHS will confirm that each SR and service site are updated and certified via the [Office of Pharmacy Affair](#) electronic forms system. Enrollment and agency's system for tracking medications stored and dispensed is reviewed as part of the annual site visit and documented.

Date Revised	September 2023
References	340B Requirements and Program Participation https://www.hrsa.gov/opa/program-requirements Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html

	Title X Program Handbook, (https://opa.hhs.gov/sites/default/files/2022-08/title-x-program-handbook-july-2022-508-updated.pdf)
Additional Resources	IME Information Letter 699