WV FAMILY PLANNING PROGRAM 340B POLICY AND PROCEDURES MANUAL

September 2019





Self-Audit Information and Signature Page

HRSA has identified a list of seventeen specific areas to assist covered entities in developing the necessary specificity for their 340B-related policies and procedures. These policies and procedures help covered entities mitigate their risk of non-compliance. These policies and procedures are requested as part of the HRSA audit data request, which takes place before the HRSA regional auditor arrives onsite. These site-specific policies and procedures should reflect actual practice and, therefore, be continually monitored, evaluated and modified to reflect both the needs and work of the organization.

Policies and procedures provide guidelines for decisions and actions within a 340B covered entity by promoting compliance with the 340B statute, guidance, and policy requirements while also standardizing practices throughout the organization. Policies and procedures provide clarity both internally and externally regarding how the covered entity operates a compliant 340B Program. Policies and procedures should include elements of program requirements, including methodologies for routine self-auditing and internal corrective action. Covered entities are strongly encouraged to review and update their policies and procedures for all facets of the 340B Program on a regular basis in order to improve program integrity within their organization.

The WV Family Planning Program (FPP) will complete the self-audit tool at least annually and upon issuance of updated guidance by HRSA. All results will be documented with notes for areas of strength and improvement. All areas of improvement will be address by a corrective action plan. The signature on this page, indicates the member of the FPP staff who completed the audit and the date of completion. Results of audits will be kept at the end of this manual in a Section labeled, "Audit Results."

| FPP Staff Name and Title (please print): | |
|--|-------|
| Signature: | Date: |
| FPP Staff Name and Title (please print): | |
| Signature: | Date: |
| FPP Staff Name and Title (please print): | |
| Signature: | Date: |
| FPP Staff Name and Title (please print): | |
| Signature: | Date: |
| FPP Staff Name and Title (please print): | |
| Signature: | Date: |
| FPP Staff Name and Title (please print): | |
| Signature: | Date: |
| FPP Staff Name and Title (please print): | |
| Signature: | Date: |

1. OVERVIEW

This document contains descriptions of the procedures used by the WV Family Planning Program (FPP) to maintain compliance with the 340B Program.

1.1 AREA OF RESPONSIBILITY

This guideline applies to the FPP (grantee) and all its entities (sub-recipients and service sites).

1.2 BACKGROUND

In 1992, Congress extended to safety-net providers the same kind of relief from high drug costs that Congress provided to the Medicaid program with the Medicaid rebate law. In particular, Congress enacted Section 340B of the Public Health Service Act (created under Section 602 of the Veterans Health Care Act of 1992). Section 340B requires pharmaceutical manufacturers to enter into an agreement, called a pharmaceutical pricing agreement (PPA), with the HHS Secretary. Under the PPA, the manufacturer agrees to provide front-end discounts on covered outpatient drugs purchased by specified providers, called "covered entities," that serve the nation's most vulnerable patient populations. According to congressional report language, the purpose of the 340B program is to enable covered entities "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

1.3 ENTITY INFORMATION

The entity information for the FPP is:

- Type: Family Planning (Title X only)
- 340B ID: FP253015.
- Mailing address: 350 Capitol Street, Room 427, Charleston, WV 25301; and
- Ship to address: 900 Bullitt Street, Charleston, WV 25301.

1.4 RESPONSIBLE STAFF

The responsibility to ensure compliance with 340B Program requirements rests solely with covered entities and manufacturers that participate.

1.4.1 STAFF ASSOCIATED WITH 340B COMPLIANCE

The following FPP staff are engaged with 340B program compliance:

- FPP Program Director is responsible as the principal officer in charge for the compliance and administration of the program;
- FPP Epidemiologist is responsible for annually attesting to the compliance of the program in form of recertification, day to day management of the program, assuring appropriate safeguards and system integrity, and 340B cost savings reports; and
- FPP Program Specialists are responsible for knowledge and documentation
 of policy and procedures and any changes that impact the 340B program
 which includes, but not limited to, HRSA/OPA rules and Medicaid changes.

2.0 GUIDELINES STATEMENTS

The FPP will meet all 340B Program eligibility requirements. The specific eligibility requirements as well as a listing of the FPP covered entity locations can be found at: http://opanet.hrsa.gov/opa.

2.1 GENERATED SAVINGS

The FPP will ensure that any savings generated from participation in the 340B program are in accordance with 340B Program intent: To permit covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992).

2.3 340B DATABASE LISTING

The FPP will ensure the 340B Database covered entity listing is complete and up-to-date.

2.4 GROUP PURCHASING ORGANIZATIONS

The FPP will not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement, except in accordance with GPO Policy Release on 02-07-2013.

2.5 SUB-RECIPIENT DESCRIPTION

All FPP sub-recipients are non-reimbursable, have a separate NPI, or are not located within the four walls of the grantee may use a separate number to purchase clinic administered drugs as allowed by HRSA/Apexus guidance.

2.6 REQUIREMENTS AND RESTRICTIONS

The FPP will 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, the prohibition against duplicate discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient for which the FPP is the pay source.

2.6.1 COMPLIANCE RECORDING

The FPP will maintain auditable records demonstrating compliance with 340B requirements.

2.6.2 PRESCRIBER EMPLOYMENT

The FPP will ensure that the prescriber is employed by the sub-recipient, or under contractual or other arrangements with the sub-recipient, and the individual receives a health care service from this professional such that the responsibility for care remains with the sub-recipient.

2.6.3 SUB-RECIPIENT RECORD RETENTION

The FPP will require all sub-recipients to maintain records of the individual's health care.

2.6.4 OUTPATIENT VERIFICATION

The FPP will ensure that all patients are outpatients at the time medication is administered/dispensed.

2.7 DUPLICATE DISCOUNTS

The FPP has reflected its information on the OPA website/Medicaid Exclusion File, which is "carving in."

2.7.1 INFORMATION CHANGES

The FPP will inform OPA immediately of any changes to its information on the OPA website/Medicaid Exclusion File.

2.7.2 MEDICAID AND NPI

The FPP Medicaid billing number used to bill Medicaid for 340B drugs and NPI will appear on the OPA website.

2.7.3 SUB-RECIPIENT CARVE-IN STATUS

The FPP will provide OPA a list of all the sub-recipients which will be all "carved-in" and the corresponding NPI numbers.

Prescription drugs provided by the FPP through the Materials Management Warehouse cannot be used for patients other than those paid for by the FPP; however, the 340B ID issued under the FPP entity name can be used to purchase drugs for other patients as long as the client meets the definition of a Title X patient and any medications are used for the purposes for which Title X is intended.

It is the responsibility of the provider to ensure that prescription drugs from 340B used for Medicaid patients are clearly tracked through the use of specific identifiers. Drugs dispensed at the Point of Sale (POS) must be identified as follows: Submission Clarification Field (SCC) 420-DK=20, Basis of Cost Field 423-DM=08. Physician Administered Drugs (PADS) must be identified as follows: Modifier UD.

Pursuant to 42 USC 256b(a)(5), a manufacturer may audit and seek recoupment of the duplicate discount from covered entities found to be non-compliant with 340B requirements.

2.7.4 PATIENT FEES

The FPP requires all sub-recipients to charge patients with family incomes between 101% and 250% of the Federal Poverty Level, in accordance with the WV Family Planning Program Sliding Fee Scale. The Sliding Fee Scale can be accessed at www.wvdhhr.org/fp.

2.7.5 RECORDING OF PHARMACEUTICALS

The FPP requires all providers record receipt of all pharmaceuticals as "in-kind" transactions within a separate budget for Title X funds.

2.7.6 SHIPPING INFORMATION

While sub-recipients are required to maintain a supply of contraceptives and supplies on-site, the FPP will list the address for Central Facilities Management as the "ship to" site with OPA, as this serves as the "hub" for initial receipt of all pharmaceuticals.

2.8 COMPLIANCE STANDARDS

The FPP will establish systems and/or mechanisms and internal controls to reasonably ensure ongoing compliance with all 340B requirements, such as requiring each sub-recipient to maintain a separate budget which includes pharmaceuticals, utilize a perpetual inventory system at each service site, and keep up-to-date inventory records for three years.

3. DIVERSION

Drug diversion is defined as a 340B drug being provided to an individual who is not an eligible outpatient of that entity and/or dispensed in an area of a larger facility that is not eligible.

3.1 ASSURANCE OF DISTRIBUTION

340B drugs will not be used, dispensed, resold, or otherwise transferred to anyone other than patients for whom the FPP is the payor for services.

3.2 340B AND FAMILY PLANNING FORMULARY

For a prescription for a self-administered drug written by a provider at a sub-recipient service site, the prescription will be filled with 340B drugs purchased by the FPP if the drugs are listed as part of the FPP formulary.

3.3 BONA FIDE AGENTS

FPP sub-recipients and/or service sites will not transfer 340B drugs to a party other than a patient, unless the party is a bona fide agent (e.g., a family member who picks up a prescription on behalf of the patient) of the patient.

3.4 SERVICE SITE INVENTORY

FPP sub-recipients will require service sites to 340B drugs inventory physically separate from its non-340B drugs.

3.4.1 TRACKING SYSTEM

The sub-recipients will be required to maintain a tracking system to prevent drug diversion and the FPP will review the tracking system to assure no 340B drug diversion. The tracking system will compare patient prescriptions and 340B drug ordering and purchasing to dispensing records, on a monthly basis. These tracking systems may be extended to quarterly reviews if no discrepancies are found over a six-month period.

3.5 REPLENISHMENT OF STOCK

When a drug is near depleted, or its stock level is below a "safe" number, an order for the drug's replenishment with a 340B drug will be placed with a contracted pharmaceutical company which is in compliance with 340B requirements, such as Cardinal and/or Moore Medical. 340B drugs will not be replenished with non-340B drugs.

3.6 SUB-RECIPIENT AUDITS

The FPP will perform audits of all sub-recipients to ensure compliance with 340B rules and regulations.

3.9 RESPONSIBILITY FOR REVIEW

The FPP is responsible to review the records of sub-recipients and/or service sites that receive 340B drugs for compliance with this guideline and all OPA 340B rules and regulations.

4. GROUP PURCHASING ORGANIZATION (GPO) EXCLUSION

The GPO prohibition is a statutory requirement that applies to disproportionate share hospitals (DSH), children's hospitals (PED), and free-standing cancer hospitals (CAN). Upon registration for the 340B Program, these covered entity types must acknowledge that they understand the restriction with using a GPO for covered outpatient drugs, and during the 340B annual recertification process, they must attest to compliance with the GPO prohibition.

4.1 GPO ATTESTATION

The FPP will ensure that all program participant hospitals impacted by this statute will not participate in a GPO or other group purchasing arrangements for obtaining covered outpatient drugs.

4.2 PRIME VENDOR UTILIZATION

The FPP will ensure impacted hospitals will utilize the prime vendor program (Apexus) for procurement of covered outpatient drugs.

4.3 GPO EXCLUSION

When drugs subject to the GPO exclusion do not have a 340B price, the FPP will purchase the drugs at a price negotiated by the prime vendor program (Apexus) for non-340B drugs and/or may negotiate a non-GPO price with the manufacturer for the drug.

4.4 340B AND NON-340B CONTRACTS

The FPP will maintain two separate contracts, 340B and non-340B contracts with our prime distributor.

5.0 CONTRACT PHARMACIES

Many 340B covered entities elect to dispense 340B drugs to patients through contract pharmacy services, an arrangement in which the 340B covered entity signs a contract with a pharmacy to provide pharmacy services. This helps facilitate program participation for those covered entities that do not have access to available or appropriate 'in-house' pharmacy services, for those covered entities that have access to 'in-house' pharmacy services but wish to supplement these services, and covered entities that wish to utilize multiple contract pharmacies to increase patient access to 340B drugs. The FPP does not utilize contract pharmacies.

6. 340 B ENROLLMENT, RECERTIFICATION AND CHANGE REQUESTS

340B covered entities must annually recertify their eligibility to remain in the 340B Drug Pricing Program and continue purchasing covered outpatient drugs at discounted 340B prices.

6.1 RECERTIFICATION PROCEDURE

OPA requires entities to recertify their information as listed in the OPA database annually. The FPP's Epidemiologist annually recertifies information by following the directions in the recertification email sent from the OPA by the requested deadline.

6.2 ENROLLMENT PROCEDURE – NEW CLINIC SITES

The FPP Specialist evaluates a new sub-recipient or service site application against Title X Program Requirements to determine if the location is eligible for participation in the program. After determination that a new clinic meets these criteria and it is added to the FPP provider list, the FPP Epidemiologist will complete the online registration process for 340B registration during the registration window (January 1–January 15 for an effective start date of April 1; April 1– April 15 for an effective start date of July 1; July 1–July 15 for an effective start date of October 1; and October 1– October 15 for an effective start date of January 1). This includes submitting cost report information, as required by OPA. http://www.hrsa.gov/opa/eligibilityandregistration/index.html

6.3 CHANGES TO INFORMATION ON THE OPA DATABASE

It is the FPP's ongoing responsibility to immediately inform OPA of any changes to its information or eligibility. As soon as the FPP is aware that a sub-recipient or service site has lost eligibility, OPA will be notified immediately and purchasing stopped (or may be required to repay manufacturers).

6.3.1 ONLINE CHANGE REQUESTS

An online change request will be submitted to OPA by the FPP's Epidemiologist for changes to the FPP's information outside of the annual recertification timeframe. Change forms will be submitted to OPA as soon as the FPP is aware of the need to make a change to its database entry. It is expected that changes will be reflected within two weeks of submission.

6.3.2 MANUAL SUBMISSIONS

Changes requiring a manual paper change form will be completed by the authorizing official or designee and submitted to OPA.