WV FAMILY PLANNING PROGRAM
340B POLICY AND PROCEDURES MANUAL

August 2017

WEST VIRGINIA
Department of
Health & Human Resources
BUREAU FOR PUBLIC HEALTH
Office of Maternal, Child and Family Health

Table of Contents

I. PURPOSE

This document contains descriptions of the policies and procedures utilized through the West Virginia (WV) Family Planning Program (FPP) and sub grantee service sites to maintain compliance with the 340B program. The FPP and all sub grantee services sites will henceforth be referred to as "The Project" when spoken of collectively.

II. DEFINITIONS

Definitions of terms may be found in Appendix I: 340B Glossary of Terms, other entity-specific definitions.

III. REFERENCES

References can be found in Appendix II: References and Resources.

IV. POLICY REVIEW, UPDATES, AND APPROVAL

This policy will be reviewed, updated, and approved by FPP staff at least once every project period with documentation.

V. BACKGROUND

Section 340B of the Public Health Service Act (1992) requires drug manufacturers participating in the Medicaid Drug Rebate Program to sign a pharmaceutical pricing agreement (PPA) with the Secretary of the Department of Health and Human Services. This agreement limits the price manufacturers may charge certain covered entities for covered outpatient drugs. The resulting program is called the 340B Drug Pricing Program. 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." The program is administered by the federal Health Resources and Services Administration (HRSA)/Department of Health and Human Services (DHHS).

Upon registration on the HRSA 340B database as a participant in the 340B program, an entity may access 340B drugs and agree to abide by specific statutory requirements and prohibitions.

VI. 340B POLICY STATEMENTS

As a participant in the 340B Drug Pricing Program, The Project's policies are:

- The Project uses any savings generated from 340B 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). Some documentation of cost savings in the form of a budget, cost report, or other record must be kept onsite.

- The Project meets 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.

- HRSA 340B Database covered entity listing is complete, accurate, and correct.

- The Project receives a grant or designation consistent with that conferring 340B eligibility. FPP Notice of Award must be kept onsite at WV Department of Health and Human Resources (DHHR) FPP headquarters. Sub grantees must have a Memorandum of Understanding (MOU) with FPP and store a current copy of the MOU/notice of continuing MOU at the parent site.

- The Project complies 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 of the entity. [Reference: Public Law 102-585, Section 602, 340B Guidelines, 340B Policy Releases]

- Each entity within The Project maintains auditable records demonstrating compliance with the 340B requirement described in the preceding item.
  - The prescriber is employed by the entity, or under contractual or other arrangements with the entity, and the individual receives a health care service (within the scope of Title X-Family Planning Services) from this professional such that the responsibility for care remains with the entity. A prescriber list will be available and kept up-to-date at each sub grantee service site where the prescriber is employed or contracted. Presence of this list will be verified by the Office of Maternal, Child, and Family Health (OMCFH) Quality Assurance Monitoring Team (QAMT) at monitoring visits.
  - Each entity within The Project maintains records of the individual's health care. Records regarding supplies received from the central distribution center (Material's Management) should be maintained in the Family Planning Electronic Database (FPEDS) under medical products dispensed. These supplies must only be used for clients for which Title X is the payor. Supplies ordered through individual sub grantee 340B certification (Title X certified) can be used for any client meeting the definition of a FPP user, those seeking to achieve or prevent a pregnancy, presenting at a Title X service site, regardless of payor source. Record of dispensing or prescribing these drugs/supplies must be documented in the client's health record and/or in FPEDS.

  - If any entity within The Project bills Medicaid for 340B drugs, billing follows state guidelines and the entity has reflected its information on the HRSA 340B Database/Medicaid Exclusion File:
    - The Project informs HRSA immediately of any changes to its information on the HRSA 340B Database/Medicaid Exclusion File.

    - Medicaid reimburses individual entities within The Project, as applicable, for 340B drugs per state policy and does not collect rebates on claims from the entity. The entity must keep documentation of these reimbursements/claims on file.

- Each individual entity within The Project has systems/mechanisms and internal controls in place to reasonably ensure ongoing compliance with all 340B requirements.
  - FPP reviews compliance of individual entities within The Project by monitoring central inventory/supply requests compared to client count/use, utilizing OMCFH QAMT monitorings to verify entities have updated 340B policies on hand and during the annual recertification to verify that information in the 340B database has been kept up-to-date.

  - Sub grantees must review in-house polices to assure internal compliance including maintaining separate and appropriate inventories and assuring providers/staff are trained on these policies and FPP guidelines.

- The Project has an internal audit plan recommended to be conducted annually.

- The Project will not obtain covered outpatient drugs through a Group Purchasing Organization (GPO) or other group purchasing arrangement, except in accordance with GPO Policy Release on 02-07-2013.
  - Any program participant hospitals impacted by this statute will not participate in a GPO or other group purchasing arrangements for obtaining covered outpatient drugs.
  - Impacted hospitals may utilize the prime vendor program (Apexus) for procurement of covered outpatient drugs.
  - When drugs subject to the GPO exclusion do not have a 340B price, entities within The Project may 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.
  - Entities within The Project will maintain two separate contracts with prime distributors, 340B and non-340B contracts.

- The Project will not require manufacturers to provide discounted 340B pricing and a Medicaid rebate for 340B drugs and supplies—otherwise known as duplicate discounting.
  - Entities within The Project will notify HRSA—by using the 340B electronic database—as to whether they will use 340B drugs for their Medicaid patients (carve-in) or whether they will purchase drugs for their Medicaid patients through other mechanisms (carve-out).

- 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.
  - 340B drugs will not be used, dispensed, resold, or otherwise transferred to anyone other than patients covered by the 340B entity certification in which the drug was ordered or received.

- The Project may elect to use contract pharmacy services; the contract pharmacy arrangement is performed in accordance with HRSA requirements and guidelines including, but not limited to, the following:
  - Sub grantees obtain sufficient information from the contractor to ensure compliance with applicable policy and legal requirements, and sub grantees have used an appropriate methodology to ensure compliance (e.g., through an independent audit or other mechanism).

  - Any signed Contract Pharmacy Services Agreement(s) comply with 12 Contract Pharmacy essential compliance elements. These agreements should be kept onsite for review as needed.

- The Project acknowledges its responsibility to contact HRSA as soon as reasonably possible if there is any change in 340B eligibility or material breach by any entity within the Project of any of the foregoing policies.

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

- The Project elects to receive information about the 340B program from trusted sources, including, but not limited to, the following:
  - HRSA
  - The 340B Prime Vendor Program, managed by Apexus
  - Any HRSA contractors

VII. RESPONSIBLE STAFF, COMPETENCY

The following FPP staff are engaged with 340B program compliance for the central distribution model. Sub grantee contacts and individual sub grantee Authorizing Officials must be engaged with their individual entity's compliance and also must be listed below in the space provided. All Project staff/providers associated with 340B should receive comprehensive training by the individual entity/sub grantee on the 340B program initially upon hire, reaching out to FPP and/or the Prime Vendor Network as needed. Competency is also validated annually by FPP Epidemiologist through verification of proper recertification. Further verification of competency and compliance should be completed by site administrators or designee as deemed appropriate by the individual entity.

FPP Staff Responsible for the Central Distribution Model

A. Authorizing Official for Central Distribution Center/FPP - FPP Program Director, responsible as the principal officer in charge for the compliance and administration of the program at the central distribution level, and responsible for annually attesting to the compliance of FPP in the form of recertification.
B. Primary Contact - FPP Epidemiologist, responsible for 340B and FPEDS database management, assuring system integrity, review of policies and procedures for the program, providing sub grantee technical assistance, and verifying sub grantee registration, termination, and recertification.
C. Secondary Contact - FPP Program Specialist, responsible for knowledge and documentation of policies and procedures, updating the manual with any changes that impact the 340B program which includes, but not limited to, HRSA/OPA rules and Medicaid changes, management of warehouse (central distribution center) inventory, and corresponding with sub grantees regarding upholding compliance and commitment to 340B and Title X mission, as well as providing technical assistance as needed.

Sub Grantee Staff Responsible for Individual Entities

A. Authorizing Official
Contact Name/Position title: _____

Role/Responsibilities: Responsible as the principal officer in charge for the compliance and administration of the program and responsible for annually attesting to the compliance of the entity in the form of recertification

Additional Roles:

_____

_____

_____

B. Primary Contact

Contact Name/Position title: _____

Role/Responsibilities: _____

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_____

_____

_____

_____

C. Secondary Contact
Contact Name/Position title: _____

Role/Responsibilities: _____

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VIII. 340B ENROLLMENT, RECERTIFICATION, CHANGE REQUESTS

Recertification Procedure

HRSA requires entities to recertify their information as listed in the HRSA 340B Database annually. Individual entities within The Project annually recertify each service site's information by following the directions in the recertification email sent from the HRSA to the entity's authorizing official by the requested deadline. Specific recertification questions should be sent to 340b.recertification@hrsa.gov.

Enrollment Procedure: New Clinic Sites

The FPP evaluates a new service area or facility to determine whether the location is eligible for participation in the 340B program. The criteria used include that the service area must be within the scope of the Title X grant received by The Project that confers 340B status, have outpatient drug use, and have patients who meet the 340B patient definition. A Change in Scope must be submitted to the Office of Population Affairs to be reviewed before an entity can be declared part of The Project.

If a new clinic meets these criteria, the FPP Epidemiologist will work with that clinic to determine an appropriate authorizing official from the new sub grantee or satellite service site, who will complete the online registration process 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).

Enrollment Procedure: New Contract Pharmacy(ies)

1. If Contract Pharmacy services are utilized or desired, the sub grantee staff ensures that a signed Contract Pharmacy services agreement, containing the 12 essential compliance elements in the Contract Pharmacy Guidance, is in place between the entity and Contract Pharmacy prior to registration on the HRSA 340B Database. This staff ensures that the sub grantees legal counsel has reviewed the contract and verified that all federal, state, and local requirements have been met.

2. Each entity's authorizing official completes the online registration process 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).

3. Each entity's authorizing official ensures that the Contract Pharmacy registration request is certified online within 15 days of the date the online registration was completed. The pharmacy's responsible representative may be the owner, president, CEO, COO, or CFO.

4. The sub grantees staff begins the Contract Pharmacy arrangement only on or after the effective date shown on the HRSA 340B Database.

Procedure for Changes to Individual Entity Information in HRSA 340B Database

It is each individual entity's ongoing responsibility to immediately inform HRSA of any changes to its information or eligibility. As soon as entities/FPP become aware that it/its sub grantee has lost eligibility, it must notify HRSA immediately and stop purchasing (or may be required to repay manufacturers).

An online change request will be submitted to HRSA by the individual entity's authorizing official for changes to information outside of the annual recertification timeframe. This includes staff changes for the primary contact and authorizing official. The change form will be submitted to HRSA as soon as the entity is aware of the need to make a change to its HRSA 340B Database information. The entity will expect changes to be reflected within about two weeks of submission of the changes/requests.

IX. PRIME VENDOR PROGRAM ENROLLMENT, UPDATES

Enrollment in Prime Vendor Program (PVP)

1. Individual entity completes online 340B program registration with HRSA or grandfathered in from prior FPP registration.

2. Individual entity completes online PVP registration (https://www.340bpvp.com/register/apply-to-participate-for-340b/).

3. The PVP staff validates information and sends a confirmation email to the entity.

4. The individual entity logs on to www.340bpvp.com and selects a user name/password.

Update PVP Profile:

To update your profile:

1. Access www.340bpvp.com.

2. Click **Login** in the upper right corner.

3. Input your log-in credentials.

4. In the upper right corner, click the orange triangle by your name, and click **My Profile.**

5. You will find a list of facilities; click on the 340B ID number hyperlink to view or change profile information for a given facility.

6. The **My Profile Change Request** form is divided into two categories: HRSA information and 340B PVP participation information.

7. To update HRSA information, complete the 340B Change Form detailed above. After the HRSA 340B Database has been updated, the PVP database will be updated during the nightly synchronization.

8. To update the 340B PVP participation information, you can edit your Drug Enforcement Administration (DEA) number, distributor and/or contacts, and click "Submit."

X. 340B PROCUREMENT, INVENTORY MANAGEMENT, DISPENSING

All 340B inventory is procured and managed at the central distribution level (used for clients with Title X as the payor source) and the service site/sub grantee level (used for FPP clients regardless of payor). Processes at these levels include:

- FPP administration
- Warehouse dispensary
- Inventory separation, tracking, and management
- FPP sliding fee scale for clinic visits
- Clinic administration
- In-house pharmacy or dispensary
- Contract pharmacy
- Third-party billing
- Process and notification for carving in/out in regard to Medicaid billing/reimbursement.

Warehouse Dispensary, Standard Processes

1. FPP uses either only 340B inventory, or electronically or physically separate 340B and non-340B purchased inventory.

2. FPP Specialist places 340B orders from contracted and qualified wholesalers through periodic inventory review and shelf inspections of periodic automatic replenishment (PAR) levels by reviewing reports and notice from warehouse storekeeper biweekly. Wholesaler contract documentation will be available upon request.

3. Storekeeper checks-in 340B inventory by examining the wholesaler invoice against the order, and reports inaccuracies to the wholesaler.

4. The storekeeper maintains records of 340B-related transactions in a readily retrievable and auditable format located in an electronic database.

5. 340B inventory is stored securely and access is limited to designated staff.

6. Individual entity staff place 340B supply orders from FPP distribution center/warehouse through periodic inventory review and shelf inspections of PAR levels by using perpetual inventory system as appropriate.

7. Storekeeper reviews monthly patient count and compares current request to past requests to see if the reported patient counts justify receiving requested supplies. Supplies are not sent if the patient count does not justify the request unless provider supplies are reported as below the safety level. All requests

are reviewed and recorded in an electronic database which updates the warehouse inventory counts and sub grantee record of supplies received. Data accuracy is verified daily by the storekeeper.

8. Storekeeper(s) gathers order from warehouse inventory, packs it into a shipping container with a copy of the request slip, and ships using FedEx.

9. FedEx requires someone from the business/service site to sign for the package upon receipt.

In-House Dispensary, Sample Standard Processes

1. Individual entity/sub grantee uses either only FPP 340B inventory, or electronically or physically separates FPP 340B, any entity 340B, and non-340B purchased inventory. Supplies received using different 340B certification must be kept separate and used only for appropriate clients. Many entities are registered as a community health center, a Family Planning site, and receive supplies from the central distribution center (FPP warehouse); all of these represent separate 340B certification and supplies must be kept separate.

2. Pharmacists, technicians, or designated clinical staff dispense 340B drugs only to patients meeting all the criteria for the given certification.

3. Staff place 340B orders from their designated wholesaler and/or the FPP central distribution center through periodic inventory review and shelf inspections of PAR levels by using a perpetual inventory system as appropriate. Other wholesalers with appropriate contracts/qualifications may be used in the event of product shortages.

4. Staff checks-in 340B inventory by examining the invoice against the order and reports inaccuracies to the wholesaler/FPP warehouse.

5. Staff maintains records of 340B-related transactions for a period of three years in a readily retrievable and auditable format located onsite, in FPEDS, and/or at the parent site.

6. 340B inventory is stored securely and access is limited to designated clinical staff.

7. Entity staff performs self-audits of individual sites as recommended and complies with FPP central distribution model self-audits.

Clinic-Administered Drugs, Standard Processes

Processes will vary based on state law, permit type, and so on. Individual entity may use In-House Dispensary, Sample Standard Processes (above) and customize.

Contract Pharmacy Sample Standard Processes (if applicable)

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. Individual entities are responsible for compliance regarding Contract Pharmacies and appropriate documentation should be kept on file.

XI. REIMBURSEMENT

Individual entities obtain reimbursement for 340B drugs from Medicaid, private insurers, etc., as applicable, and/or receive supplies in-kind from FPP (Title X funds) according to existing reimbursement policies. Policies are subject to change and appropriate documentation should be available at The Project site.

Resources for 340B Medicaid information include:

- HRSA website, Medicaid section
- HRSA Medicaid Policy Release
- 340B University Notes, Medicaid Section
- FAQs (search on specific keyword)

XII. RECOMMENDED MONITORING AND REPORTING

The entity uses the process outlined in 340B Compliance Self-Assessment: Self-Audit Process to Ensure 340B Compliance.

Additional monitoring or reporting include review of documentation by the OMCFH QAMT and cooperation with the FPP Epidemiologist in assuring compliance and recertification at least annually.

Reporting 340B Noncompliance

"The covered entity acknowledges its responsibility to contact HRSA as soon as reasonably possible if there is any ...material breach by the covered entity of any of the (points of 340B compliance)." In the event of noncompliance, a report must be made to HRSA/manufacturer, records kept, documentation, and plan for corrective action must be put in place. Entities may utilize the Self-Reporting Non-Compliance Tool to assess these matters.

XIII. Appendix I: 340B Glossary of Terms, Other Entity Specific Definitions

Can/May-Indicates suggestions for consideration by individual provider agencies.

Confidential Services-Services provided to clients without the knowledge or involvement of any other person or entity.

Drug Diversion-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.

Duplicate Discount Prohibition-42 USC 256b(a)(5)(A)(i) prohibits duplicate discounts; that is, manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. Covered entities must have mechanisms in place to prevent duplicate discounts.

Family Planning Program-Under the WV DHHR, Bureau for Public Health, Office of Maternal, Child and Family Health, the FPP is the entity that manages all components of the Title X grant for WV.

Family Planning User-A client who has a face-to-face visit at a Family Planning service site and is seeking to achieve or prevent pregnancy, regardless of visit payor source.

Federal Poverty Level (FPL)-Income levels used for determination of financial eligibility for FPP services and reflected in the annual FPP sliding fee scale; undated annually based upon the last calendar year's increase in prices as measured by the Consumer Price Index.

Group Purchasing Organization (GPO) Exclusion-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.

Individual Entities-Entities within the WV FPP project certified through the 340B Program. This term indicates individual responsibilities of the sub grantee, grantee, and/or service site.

Memorandum of Understanding (MOU)-A formal agreement between two or more parties. Companies and organizations can use MOUs to establish official partnerships.

Must-Indicates mandatory program policy.

Service Sites-Locations where clinical services are provided.

Should-Indicates recommended program policy relating to components of family planning and program management that the service provider is urged to utilize in order to fulfill the intent of Title X and 340B.

Sub Grantee-The delegate/contact agency that provides clinical family planning services with Title X funds and/or supplies under a negotiated, written agreement with the FPP.

The Project-Term used to encompass the FPP as a whole including the grantee's sub recipients and service sites under these sub grantees.

Title X-U.S. Public Health Service, Family Planning Program; authorizes grants to assist in the establishment and operation of family planning clinics.

Title X Covered Client-A client who has a face-to-face visit at a family planning service site, is seeking to achieve or prevent pregnancy, and whose visit and/or drugs/supplies are covered by Title X funds. These clients are typically uninsured/underinsured, at or below 250% of the FPL, and/or have requested confidential services.

XIV. Appendix II: References and Resources

The following references and resources can be accessed by entities within The Project to help with 340B program self-audit, training, and program requirements.

340B Drug Pricing Program: Program Requirements. (n.d.). Retrieved from Health Resources and Services Administration (HRSA): https://www.hrsa.gov/opa/programrequirements/

Apexus. (2015). *Getting Started with 340B Compliance.* Retrieved from 340B Prime Vendor Program: https://docs.340bpvp.com/documents/public/resourcecenter/GettingStartedWith340BCompliance.pdf

Apexus. (2017). *340B Tools*. Retrieved from 340B Prime Vendor Program: https://www.340bpvp.com/education/340b-tools/

Apexus. (2017). *340B University OnDemand*. Retrieved from 340B Prime Vendor Program: https://www.340bpvp.com/education/340b-u-ondemand/

Sec. 340B PUBLIC HEALTH SERVICE ACT. (n.d.). Retrieved from Health Resources and Services Administration (HRSA): https://www.hrsa.gov/opa/programrequirements/phsactsection340b.pdf

XV. Appendix III: Contract Pharmacy Compliance Elements

HRSA has provided essential covered entity compliance elements as guidance for the contractual provisions expected in all Contract Pharmacy arrangements.

Excerpt from: https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf

(a) The covered entity will purchase the drug, maintain title to the drug and assume responsibility for establishing its price, pursuant to the terms of an HHS grant (if applicable) and any applicable Federal, State and local laws. A ''ship to, bill to'' procedure is used in which the covered entity purchases the drug; the manufacturer/wholesaler must bill the covered entity for the drug that it purchased, but ships the drug directly to the Contract Pharmacy. In cases where a covered entity has more than one site, it may choose between having each site billed individually or designating a single covered entity billing address for all 340B drug purchases.

(b) The agreement will specify the responsibility of the parties to provide comprehensive pharmacy services (e.g., dispensing, recordkeeping, drug utilization review, formulary maintenance, patient profile, patient counseling, and medication therapy management services and other clinical pharmacy services). Each covered entity has the option of individually contracting for pharmacy services with a pharmacy(ies) of its choice. Covered entities are not limited to providing comprehensive pharmacy services to any particular location and may choose to provide them at multiple locations and/or ''in-house.''

(c) The covered entity will inform the patient of his or her freedom to choose a pharmacy provider. If the patient does not elect to use the contracted service, the patient may obtain the prescription from the covered entity and then obtain the drug(s) from the pharmacy provider of his or her choice. When a patient obtains a drug from a pharmacy other than a covered entity's contract pharmacy or the covered entity's in-house pharmacy, the manufacturer is not required to offer this drug at the 340B price.

(d) The Contract Pharmacy may provide other services to the covered entity or its patients at the option of the covered entity (*e.g.,* home care, delivery, reimbursement services). Regardless of the services provided by the Contract Pharmacy, access to 340B pricing will always be restricted to patients of the covered entity.

(e) The Contract Pharmacy and the covered entity will adhere to all Federal, State, and local laws and requirements. Both the covered entity and the Contract Pharmacy are aware of the potential for civil or criminal penalties if either violates Federal or State law. [The Department reserves the right to take such action as may be appropriate if it determines that such a violation has occurred.]

(f) The Contract Pharmacy will provide the covered entity with reports consistent with customary business practices (e.g., quarterly billing statements, status reports of collections and receiving and dispensing records).

(g) The Contract Pharmacy, with the assistance of the covered entity, will establish and maintain a tracking system suitable to prevent diversion of section 340B drugs to individuals who are not patients of the covered entity. Customary business records may be used for this purpose. The covered entity will establish a process for periodic comparison of its prescribing records with the contract pharmacy's dispensing records to detect potential irregularities.

(h) The covered entity and the Contract Pharmacy will develop a system to verify patient eligibility, as defined by HRSA guidelines. The system should be subject to modification in the event of change in such guidelines. Both parties agree that they will not resell or transfer a drug purchased at section 340B prices to an individual who is not a patient of the covered entity. See 42 U.S.C. 256b(a)(5)(B). The covered entity understands that it may be removed from the list of covered entities because of its participation in drug diversion and no longer be eligible for 340B pricing.

(i) Neither party will use drugs purchased under section 340B to dispense Medicaid prescriptions, unless the covered entity, the contract pharmacy and the State Medicaid agency have established an arrangement to prevent duplicate discounts. Any such arrangement shall be reported to HRSA, by the covered entity.

(j) The covered entity and Contract Pharmacy will identify the necessary information for the covered entity to meet its ongoing responsibility of ensuring that the elements listed herein are being complied with and establish mechanisms to ensure availability of that information for periodic independent audits performed by the covered entity.

(k) Both parties understand that they are subject to audits by outside parties (by the Department and participating manufacturers) of records that directly pertain to the entity's compliance with the drug resale or transfer prohibition and the prohibition against duplicate discounts. See 42 U.S.C. 256b(a)(5)(c). The Contract Pharmacy will assure that all pertinent reimbursement accounts and dispensing records, maintained by the pharmacy, will be accessible separately from the pharmacy's own operations and will be made available to the covered entity, HRSA, and the manufacturer in the case of an audit. Such auditable records will be maintained for a period of time that complies with all applicable Federal, State and local requirements.

(l) Upon written request to the covered entity, a copy of the contract pharmacy service agreement will be provided to the Office of Pharmacy Affairs.

XVI. Appendix IV: 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 FPP recommends annual completion of the self-audit tool for all individual entities—including audit of FPP's own central distribution warehouse—and additional self-audits upon issuance of updated guidance by HRSA. All results should be documented with notes for areas of strength and improvement. All areas of improvement should be addressed by a corrective action plan. The signature on this page, indicates the member of the staff who completed the audit and the date of completion. Results of audits will be kept onsite and are recommended to be kept on file with this manual.

Staff Name and Title (please print): _____

Signature: _____ **Date:** _____

Staff Name and Title (please print): _____

Signature: _____ **Date:** _____

Staff Name and Title (please print): _____

Signature: _____ **Date:** _____

Staff Name and Title (please print): _____

Signature: _____ **Date:** _____

Staff Name and Title (please print): _____

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Signature: _____ **Date:** _____