

Instructions for Creating Sample Policy and Procedure Manual

Purpose: The purpose of this tool is to provide an example 340B Program policy and procedure (P&P) manual that exhibits high program integrity to assist participating Title X family planning (FP) leaders in the preparation of their own unique, site-specific P&P manual that supports placing compliant policy into practice.

Introduction: Policies and procedures (1) promote compliance with regulations and statute requirements; (2) standardize practice throughout the organization; and (3) serve as a resource for new team members. In addition, policies and procedures allow covered entities to establish and educate staff on key expectations for practice and procedures.

There are typically three parts of a P&P manual: policies, purpose, and procedures.

1. Policies: guidelines (or rules) to be followed under a given set of circumstances.
2. Purpose: a high-level statement that indicates what an entity plans to do (i.e., the objective of the policy).
3. Procedures: step-by-step instructions to assist the entity in completing a task in a consistent manner to ensure an appropriate result (or outcome). Procedures outline:
 - a. When the activity or task is triggered
 - b. What steps are performed
 - c. Who performs each step
 - d. When each step is performed
 - e. How the steps are performed

Instructions:

1. Identify team members to participate in the development, review, and approval process of the 340B Program P&P manual.
2. Review the sample 340B Program P&P manual and, based on the elements presented in the sample, customize a draft P&P manual specific to the covered entity.
 - a. This sample is not intended to be “cut and pasted.” It is intended to provide structure and content that entities may choose to include in the implementation of a 340B-compliant program.
 - b. Entities are expected to delete or add new language, customizing their P&P manual as applicable to their unique practice settings and 340B Program requirements.
 - c. There are many possibilities for structuring a 340B P&P manual. This sample represents just one option.
 - d. If you have specific questions, contact Apexus Answers (ApexusAnswers@340bpvp.com), who will provide assistance or connect you with a resource that can provide help.
3. Approve the 340B Program P&P manual according to organizational policy.
4. Regularly review and update the 340B Program P&P manual.
 - a. Revisions should be done in a timely manner whenever there is a clarification or policy change in the 340B Program or other regulatory requirements.
 - b. Review frequency according to established organizational policy.
5. Maintain all previous versions of 340B Program P&P manuals.

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Purpose: This document contains the written policies and procedures that [Entity] uses to oversee 340B Program operations, provide oversight of contract pharmacies, and maintain a compliant 340B program.

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 Health and Human Services.

- a. This agreement limits the price that manufacturers may charge certain covered entities for covered outpatient drugs.

The 340B Program is administered by the federal Health Resources and Services Administration (HRSA) in the Department of Health and Human Services (DHHS).

Upon registration in the 340B Office of Pharmacy Affairs Information System (340B OPAIS), [Entity]:

- a. Agrees to abide by specific statutory requirements and prohibitions.
- b. May access 340B drugs.

340B Policy Statements

1. [Entity] complies with all requirements and restrictions of Section 340B of the Public Health Service Act 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](#).)
2. [Entity] uses any savings generated from 340B in accordance with 340B Program intent.

i Reference location of 340B savings document or include as Appendix [#]. Consider using [“Calculating 340B Program Value and Use of Savings”](#) as a resource when creating this document.

3. [Entity] has systems/mechanisms and internal controls in place to reasonably ensure ongoing compliance with all 340B requirements.
4. [Entity] maintains auditable records demonstrating compliance with the 340B Program.
 - a. These reports are reviewed by [Entity] every [insert entity-specific frequency interval here] as part of its 340B oversight and compliance program.

Definitions: Definitions of terms may be found in (Appendix: [340B Glossary of Terms](#)).

References: Each section includes other references to P&Ps, 340B Glossary of Terms, HRSA website, etc.

Policy Review, Updates, and Approval: These written policies and procedures will be updated and approved by [Entity] staff/committee whenever there is a clarification or change to the 340B Program requirements. Otherwise, the policy will be reviewed and approved annually.

	Covered Entity Eligibility		
		Revision History	
		Effective Date:	XX-XX-XX
Departments Affected:		Original Issue Date:	XX-XX-XX
		Last Reviewed:	XX-XX-XX
		Last Revision:	XX-XX-XX

Policy: [Entity] must meet the requirements of 42 USC §256b(a)(4)(C) to be eligible for enrollment in, and the purchase of drugs through, the 340B Program.

Purpose: To ensure [Entity’s] eligibility to participate in the 340B Program.

Definitions: Covered outpatient drug: Defined in Section 1927(k) of the Social Security Act (https://www.ssa.gov/OP_Home/ssact/title19/1927.htm).

Procedure:

1. [Entity’s] basis for 340B eligibility is determined by the receipt of federal grant dollars (Title X) awarded by the Office of Population Affairs.
2. [Entity] has identified locations where it dispenses or prescribes 340B drugs (e.g., within the four walls of the covered entity or entity-owned outpatient pharmacy).
 - a. Covered entities should maintain auditable records, policies, and procedures related to the definition of covered outpatient drug that is consistent with the 340B statute and Social Security Act.
 - b. Define covered outpatient drugs based on section 1927(k) of the Social Security Act. [Insert entity-specific details here].

i Include a listing of drugs that are exclusions to the definition of covered outpatient drugs (e.g., bundled drugs) or include as Appendix [#].

3. [Entity] ensures that 340B OPAIS is complete, accurate, and correct for all 340B eligible locations and contract pharmacy(ies). [Refer to [Entity’s] Policy and Procedure “340B Program Enrollment, Recertification, and Change Request” [Insert [Entity’s] specific policy and procedure reference number here]].
 - a. All off-site locations that use 340B drugs are registered on [Entity’s] 340B OPAIS record.
 - b. All main addresses, billing and shipping addresses, the authorizing official, and the primary contact information are correct and up to date.
 - c. [Entity] regularly reviews its 340B OPAIS records [Refer to [Entity’s] Policy and Procedure “340B Program Compliance Monitoring and Reporting” [Insert [Entity’s] specific policy and procedure reference number here]].
 - d. [Entity] informs HRSA immediately of any changes to its Medicaid information by updating the 340B OPAIS Medicaid Exclusion File [Insert entity’s definition of a reasonable timeframe for this notification to take place]. The data included in the Medicaid Exclusion File is provided by covered entities for drugs billed under Medicaid fee-for-service and does not apply to Medicaid managed care organizations.

i Include Medicaid Exclusion File information as Appendix [#]: download from 340B OPAIS with version date.

- [Entity] annually recertifies [Entity’s] information on 340B OPAIS. [Refer to [Entity’s] Policy and Procedure “340B Program Enrollment, Recertification, and Change Request” [Insert [Entity’s] specific policy and procedure reference number here]].

Approvals (per organizational policy):

Executive /Authorizing Official Approval:		Date:	
Pharmacy/Primary Contact Approval:		Date:	
Health Information Management Approval:		Date:	
Compliance/Risk Management Approval:		Date:	
IT Department Approval:		Date:	
Legal Counsel Approval:		Date:	

	340B Program Enrollment, Recertification, and Change Requests		
		Revision History	
		Effective Date:	XX-XX-XX
Departments Affected:		Original Issue Date:	XX-XX-XX
		Last Reviewed:	XX-XX-XX
		Last Revision:	XX-XX-XX

Policy: Eligible entities must maintain the accuracy of 340B OPAIS and be actively registered to participate in the 340B Program.

Purpose: To ensure that [Entity] is registered appropriately on 340B OPAIS and maintains accurate records.

References: 340B Drug Pricing Program: Grantee Registration Instructions (<https://www.hrsa.gov/opa/registration/index.html>)

Registration dates:

- 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
- October 1–October 15 for an effective start date of January 1

340B Contract Pharmacy Guidelines (<https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf>).

Procedures:

Enrollment

1. [Entity] is eligible to participate in the 340B Program [Refer to [Entity’s] Policy and Procedure “Covered Entity Eligibility” [Insert [Entity’s] specific policy and procedure reference number here]].
2. [Entity] identifies upcoming registration dates and deadlines.
3. [Entity] identifies [Entity’s] authorizing official and primary contact.
4. [Entity] has available the [required documents/contracts](#).
- a. Include federal grant number (e.g., “FPHPA-----” for FP).
5. [Entity] completes registration on 340B OPAIS (<https://340bopais.hrsa.gov/>).

Recertification Procedure

1. [Entity] annually recertifies [Entity’s] information on 340B OPAIS.
 - a. [Entity’s authorizing official] completes the annual recertification by following the directions in the recertification email sent from HRSA to [Entity’s authorizing official] prior to the stated deadline.
 - b. [Entity] submits specific recertification questions to 340b.recertification@hrsa.gov.

Enrollment Procedure: New Contract Pharmacy(ies)

1. [Entity] has a signed contract pharmacy services agreement between the entity and contract pharmacy prior to registration on 340B OPAIS.
<https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf>
 - a. [Entity’s] legal counsel has reviewed the contract and verified that all federal, state, and local requirements have been met.
2. [Entity] has contract pharmacy oversight and monitoring policy and procedure developed, approved, and implemented. [Refer to [Entity’s] Policy and Procedure “Contract Pharmacy Oversight Management” [Insert [Entity’s] specific policy and procedure reference number here]].
3. [Entity’s] authorizing official or designee completes the online registration during one of four registration windows.
 - a. Within 15 days from the date of the online registration, the authorizing official certifies online that the contract pharmacy registration request was completed.
4. [Entity] begins using the contract pharmacy services arrangement only on or after the effective date shown on 340B OPAIS.

Procedure for Changes to [Entity’s] Information in 340B OPAIS

1. [Entity] notifies HRSA immediately of any changes to [Entity’s] grant status or other such changes within the [Entity].
 - a. [Entity] will stop the purchase of 340B drugs as soon as [Entity] loses 340B Program eligibility (e.g. through a grant status change)
 - b. [Entity’s] authorizing official will complete the online change request as soon as a change in eligibility is identified.
 - i. [Entity] will expect changes to be reflected within two weeks of submission of the changes/requests.
2. [Entity] will notify HRSA immediately of any changes to [Entity’s] information on 340B OPAIS. [Refer to [Entity’s] Policy and Procedure “Covered Entity Eligibility” [Insert [Entity’s] specific policy and procedure reference number here]].
3. [Entity’s] authorizing official will complete the online change request as soon as a change in eligibility is identified.
 - a. [Entity] will expect changes to be reflected within about [insert time interval (weeks)] of submission of the changes/requests.

Approvals (per organizational policy):

Executive/Authorizing Official Approval:		Date:	
Pharmacy/Primary Contact Approval:		Date:	
Health Information Management Approval:		Date:	
Compliance/Risk Management Approval:		Date:	
IT Department Approval:		Date:	
Legal Counsel Approval:		Date:	

	Patient Eligibility/Definition		
		Revision History	
		Effective Date:	XX-XX-XX
Departments Affected:		Original Issue Date:	XX-XX-XX
		Last Reviewed:	XX-XX-XX
		Last Revision:	XX-XX-XX

Policy: According to the Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 340B drugs are to be provided only to individuals eligible to receive 340B drugs from covered entities.

Purpose: [Entity] ensures that 340B drugs are dispensed/administered/prescribed only to eligible patients.

Definitions:

Administer: Give a medication to an individual, typically in a clinic, based on a health care provider’s order.

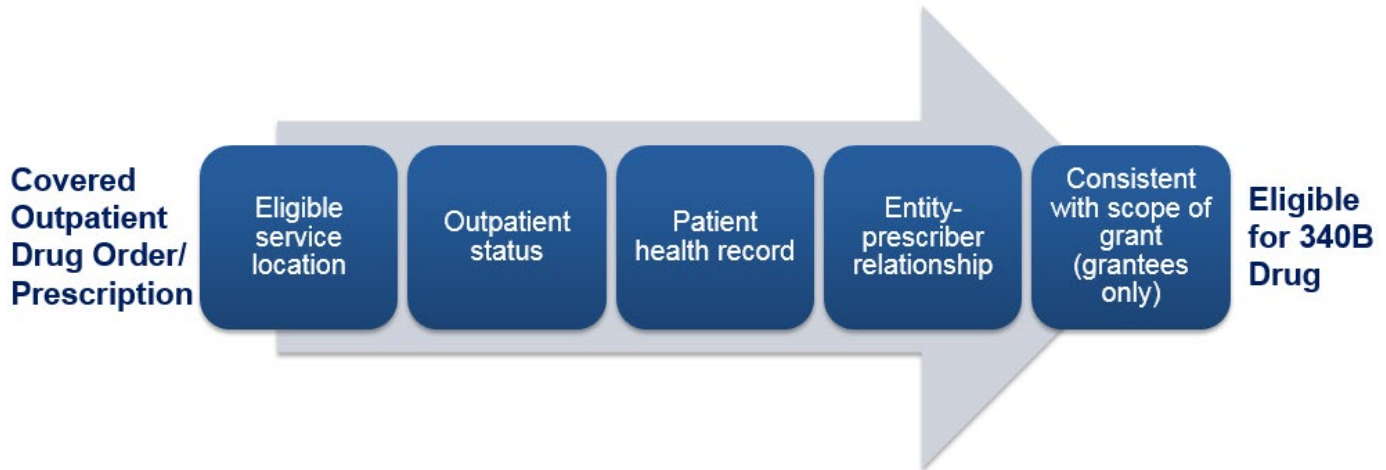
Dispense: Provide a medication, typically in a clinic, based on a health care provider’s order to be administered to a patient.

Outpatient status: [Entity’s definition of outpatient status including how the entity determines that patients have an outpatient status [Insert entity specific data set/method of determination].

Prescribe: Provide a prescription for a medication to an individual to be filled at an outpatient pharmacy.

Procedure:

Note: Covered entities need to ensure that the following 340B eligibility determination filters are implemented:



1. [Entity] validates site/service eligibility.
 - a. Refer to [Entity's] Policy and Procedure "Covered Entity Eligibility" [Insert [Entity's] specific policy and procedure reference number here].
2. [Entity] determines patient status.
 - a. Patient is outpatient status at the time the medication is dispensed/administered (depending on the outpatient status definition in [Entity's] policies and procedures).
 - b. Outpatient status is determined by [Insert entity-specific process here].
3. [Entity] maintains records of individual's health care.

i Include a description of the entity's medical record systems or include in Appendix [#] and any applicable screen shots of the medical record.

4. [Entity] determines provider eligibility.
 - a. Provider is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity.

i Describe entity-specific processes, including the relationship between the entity and provider, verification of provider eligibility, maintenance of an eligible provider list, and/or sharing of the provider list with contract pharmacy 340B management vendor (if applicable).

Identify the location of the eligible provider list, frequency of updates, and the process for uploading into the electronic health record (EHR), pharmacy operating system, and 340B split-billing software (if applicable).

5. [Entity] determines that the individual receives a health care service or range of services from the covered entity consistent with the service or range of services for which grant funding has been provided to the entity.

6. [Entity] determines patient’s Medicaid status [Refer to [Entity’s] Policy and Procedure “Prevention of Duplicate Discounts”] [Insert [Entity’s] specific policy and procedure reference number here].

Approvals (per organizational policy):

Executive/Authorizing Official Approval:		Date:	
Pharmacy/ Primary Contact Approval:		Date:	
Health Information Management Approval:		Date:	
Compliance/Risk Management Approval:		Date:	
IT Department Approval:		Date:	
Legal Counsel Approval:		Date:	

	Prevention of Duplicate Discounts		
		Revision History	
		Effective Date:	XX-XX-XX
Departments Affected:		Original Issue Date:	XX-XX-XX
		Last Reviewed:	XX-XX-XX
		Last Revision:	XX-XX-XX

Policy: 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.

Purpose: To ensure that [Entity] is preventing duplicate discounts.

References:

i Reference state policy(ies) for 340B reimbursement/billing/duplicate discount prevention (e.g., state Medicaid manual) for both Medicaid fee-for-service (FFS) and managed care organization (MCO) or include in Appendix [#].

Procedure: [Entity] has elected to [choose one] dispense 340B drugs to its Medicaid patients (carve in) OR purchase drugs for its Medicaid patients through other mechanisms (carve out).

Medicaid Carve-In (FFS)

1. [Entity] dispenses or administers 340B purchased drugs to Medicaid patients (carve in).
 - a. [Entity] has answered “yes” to the question, “Will the covered entity dispense 340B purchased drugs to Medicaid patients?” on 340B OPAIS.
2. [Entity] bills Medicaid according to state Medicaid reimbursement requirements [Insert entity-specific processes here for billing physician-administered medications and outpatient prescriptions filled at entity-owned (in-house) retail pharmacies, including application of actual acquisition cost (ACC), etc.].

i List Medicaid provider numbers on 340B OPAIS for all state Medicaid agencies billed and applicable National Provider Identifiers (NPIs) for the parent, each registered off-site location (aka child sites), and entity-owned retail pharmacies dispensing/administering 340B drugs to Medicaid patients to be listed in the Medicaid Exclusion File.

Describe the Medicaid agency 340B policy, if applicable, specifically including the agency’s(ies’) 340B requirements for both medications administered during services (e.g., UD modifier) and retail pharmacy dispenses billed to Medicaid (e.g., specific code in the cost basis determination field).

Include in the appendix:

- A list of entity’s Medicaid information from the Medicaid Exclusion File (MEF) for all sites and all states billed.
- State Medicaid contact information for any state Medicaid agency billed.
- Most recent policy documentation from contact at state Medicaid agency or identify location where documentation is maintained in the state Medicaid policy manual.

3. [Entity] informs HRSA immediately of any changes in its MEF information by updating 340B OPAIS before the 15th of the month prior to the quarter when the changes take effect (note that this is a different timeframe than quarterly registration).
For example, changes made to 340B OPAIS before March 15 would become effective on April 1.
4. [Entity] regularly reviews its 340B OPAIS Medicaid Exclusion File records [Refer to [Entity's] Policy and Procedure "340B Program Compliance Monitoring and Reporting" [Insert [Entity's specific policy and procedure reference number here]].
5. Medicaid reimburses [Entity] for 340B drugs per state policy and does not seek rebates on drug claims submitted by [Entity].

or

Medicaid Carve-Out (FFS)

1. [Entity] does not dispense or administer 340B purchased drugs to Medicaid patients AND [Entity] provides non-340B drugs instead and subsequently bills Medicaid for those non-340B drugs (carve out).
 - a. [Entity] has answered "no" to the question, "Will the covered entity dispense 340B purchased drugs to Medicaid patients AND subsequently bill Medicaid for those dispensed 340B drugs?" on 340B OPAIS.

Medicaid Managed Care (MCO)

Covered entities are required to ensure that drugs purchased under the 340B Program are not subject to a rebate claim by the state Medicaid agency. Covered entities are encouraged to work closely with their state to prevent duplicate discounts for Medicaid managed care claims.

i Reference location of document(s) identifying process for preventing MCO duplicate discounts or include as Appendix [#].

Contract Pharmacies

1. [Entity's] contract pharmacies carve out Medicaid FFS.

or

2. [Entity's] contract pharmacies carve in Medicaid FFS.
 - a. [Entity] has an arrangement with the state Medicaid agency to prevent duplicate discounts.
 - b. [Entity] has reported this arrangement to HRSA.

i Reference location of supporting document(s) or include as Appendix [#].

3. [Entity] has worked with the states billed on a process to prevent duplicate discounts for Medicaid MCO.

i Reference location of document(s) identifying process or include as Appendix [#].

Sample Policy and Procedure Manual

Grantees – Title X Family Planning (FP)

Approvals (per organizational policy):

Executive/Authorizing Official Approval:		Date:	
Pharmacy/Primary Contact Approval:		Date:	
Health Information Management Approval:		Date:	
Compliance/Risk Management Approval:		Date:	
IT Department Approval:		Date:	
Legal Counsel Approval:		Date:	

	340B Program Roles and Responsibilities		
		Revision History	
		Effective Date:	XX-XX-XX
Departments Affected:		Original Issue Date:	XX-XX-XX
		Last Reviewed:	XX-XX-XX
		Last Revision:	XX-XX-XX

Policy: Covered entities participating in the 340B Program must ensure program integrity and compliance with 340B Program requirements.

Purpose: To identify [Entity’s] key stakeholders and determine their roles and responsibilities in maintaining 340B Program integrity and compliance.

Procedure:

1. [Entity’s] key stakeholders involved with [Entity’s] 340B Program are [Insert entity specifics here].
2. [Entity’s] key stakeholders’ roles and responsibilities with [Entity’s] 340B Program are [Insert entity specifics here].
3. [Entity] has established a 340B Oversight Committee that is responsible for the oversight of the 340B Program, or other similar oversight process, including that the committee: [Insert entity specifics here].
4. [Entity’s] 340B Oversight Committee:
 - a. Meets on a regular basis [Insert entity specifics here].
 - b. Reviews 340B rules/regulations/guidelines to ensure consistent policies/procedures/oversight throughout the entity.
 - c. Identifies activities necessary to conduct comprehensive reviews of 340B compliance.
 - i. Ensures that the organization meets compliance requirements of program eligibility, patient definition, 340B drug diversion, and duplicate discounts via ongoing multidisciplinary teamwork.
 - ii. Integrates departments such as information technology, legal, pharmacy, compliance, and patient financial services to develop standard processes for contract/data review to ensure program compliance.
 - d. Oversees the review process of compliance activities, as well as taking corrective actions based on findings.
 - i. 340B Oversight Committee assesses whether the results are indicative of a material breach (Refer to [Entity’s] Policy and Procedure “340B Noncompliance/Material Breach” [Insert [Entity’s specific policy and procedure reference number here]).
 - e. Reviews and approves work group recommendations (process changes, self-monitoring outcomes, and resolutions).

The following [Entity] staff are potential key players in the 340B Program, including governance and compliance, and should be standing members of the 340B Oversight Committee. [Entity] will identify who serves as the entity's authorizing official and primary contact for the 340B Program. These individuals should be the sponsors of the 340B Oversight Committee.

Note: The following roles and responsibilities are not specific for all entities and are not all-inclusive.

1. Chief Executive Officer (CEO)
 - Responsible as the authorizing official in charge for the compliance and administration of the program
 - Responsible for attesting to the compliance of the program through recertification
2. Chief Financial Officer (CFO)
 - Responsible as the authorizing official in charge for the compliance and administration of the program in many cases
 - Potentially responsible for attesting to the compliance of the program through recertification
3. Chief Pharmacy Officer/Director of Pharmacy
 - Accountable agent for 340B compliance
 - Agent of the CEO or CFO responsible to administer the 340B Program to fully implement and optimize appropriate savings and ensure that current policy statements and procedures are in place to maintain program compliance
 - Maintains knowledge of the policy changes that affect the 340B Program, including, but not limited to, HRSA rules and Medicaid changes
 - Monitors any changes in clinic eligibility/information
 - Often responsible as the primary contact for the 340B Program
4. Pharmacy 340B Coordinator/Program Specialist
 - Accountable agent for 340B compliance
 - Day-to-day manager of the 340B Program
 - Responsible for maintenance and testing of tracking software
 - Responsible for documentation of policies and procedures
 - Maintains system databases to reflect changes in the drug formulary or product specifications
 - Manages purchasing, receiving, and inventory control processes
 - Continually monitors product minimum/maximum levels to effectively balance product availability and cost-efficient inventory control
 - Ensures appropriate safeguards and system integrity
 - Performs annual inventory and monthly [or other interval] cycle counts
 - Ensures compliance with 340B Program requirements for qualified patients, drugs, providers, vendors, payers, and locations
 - Reviews and refines 340B cost savings report, detailing purchasing, and replacement practices as well as dispensing patterns
 - Monitors ordering processes, integrating most current pricing from wholesaler, and analyzes invoices, shipping, and inventory processes
5. Corporate Compliance Officer or Director of Internal Audit
 - Designs and maintains an internal audit plan of the compliance of the 340B Program
 - Designs the annual plan to cover all changes in the 340B Program from the preceding year

6. Finance/Reimbursement Controller
 - Responsible for communication of all changes to Medicaid or other reimbursement for pharmacy services/products that affect 340B status
 - Responsible for modeling all managed care contracts (with/without 340B)
 - Engages pharmacy in conversations that affect reimbursement
7. Director of Accounting
 - Responsible for annual or semiannual physical inventory of pharmacy items (if applicable)
8. Chief IT Officer/Pharmacy Informatics Person
 - Supports the pharmacy software selection of tracking software to manage the 340B Program
 - Defines process and access to data for compliant identification of outpatient utilization for eligible patients
 - Archives the data to make them available to auditors when audited
9. Medication Procurement/Inventory Manager
 - Responsible for ordering all drugs from the specific accounts as specified by the process employed
 - Responsible for segregation, removal, and/or return of 340B drugs, including reverse distributor transactions
 - Aware of products covered by 340B and Prime Vendor Program pricing

Approvals (per organizational policy):

Executive/Authorizing Official Approval:		Date:	
Pharmacy/Primary Contact Approval:		Date:	
Health Information Management Approval:		Date:	
Compliance/Risk Management Approval:		Date:	
IT Department Approval:		Date:	
Legal Counsel Approval:		Date:	

	340B Program Education and Competency		
		Revision History	
		Effective Date:	XX-XX-XX
Departments Affected:		Original Issue Date:	XX-XX-XX
		Last Reviewed:	XX-XX-XX
		Last Revision:	XX-XX-XX

Policy: Program integrity and compliance are the responsibility of all 340B key stakeholders. Ongoing education and training are needed to ensure that these 340B key stakeholders have the knowledge to guarantee compliant 340B operations.

Purpose: To establish 340B education and competency requirements for [Entity's] 340B key stakeholders based on their roles and responsibilities in the 340B Program.

Procedure:

1. [Entity] determines the knowledge and educational requirements for each 340B Program role (Refer to [Entity's Policy and Procedure "340B Program Roles and Responsibilities" [Insert Entity's specific policy and procedure reference number here]]).
2. 340B key stakeholders complete initial basic training upon hire.
 - a. Watch "[Introduction to the 340B Drug Pricing Program](#)".
 - b. Complete OnDemand modules on the PVP website.
 - c. Attend 340B University.
3. 340B key stakeholders complete additional training as identified in #1 above.

i Insert specific 340B education and competency requirements in 340B key stakeholders' job descriptions.
Reference location of additional specific 340B educational documents or include as Appendix [#].

4. [Entity] provides educational updates and training, as needed [Insert entity-specific examples here (e.g., 340B policy changes, updates in HRSA guidance)].
5. [Entity] conducts annual verification of 340B Program competency [Insert entity specifics here].
6. Training and education records are maintained according to organizational policy and available for review.

Approvals (per organizational policy):

Executive/Authorizing Official Approval:		Date:	
Pharmacy/Primary Contact Approval:		Date:	
Health Information Management Approval:		Date:	
Compliance/Risk Management Approval:		Date:	
IT Department Approval:		Date:	
Legal Counsel Approval:		Date:	

	Inventory Management		
		Revision History	
		Effective Date:	XX-XX-XX
Departments Affected:		Original Issue Date:	XX-XX-XX
		Last Reviewed:	XX-XX-XX
		Last Revision:	XX-XX-XX

Policy: Covered entities must be able to track and account for all 340B drugs to ensure the prevention of diversion.

Purpose: Ensure the proper procurement and inventory management of 340B drugs.

Background:

340B inventory is procured and managed in the following settings:

- Clinic site administration
- In-house pharmacy
- Contract pharmacy

Inventory methods for each of these areas within the entity shall be described within the inventory management policy and procedure.

i Reference locations of other procedures affecting inventory management or include as Appendix [#].
These may include establishment of a pricing policy, usual and customary charges, applying income-based discounts, third-party billing/reconciliation, and Medicaid procedures (physician-administered drugs, managed care, Medicaid as a secondary/tertiary payer).

[Entity] uses one of the following inventory methods:

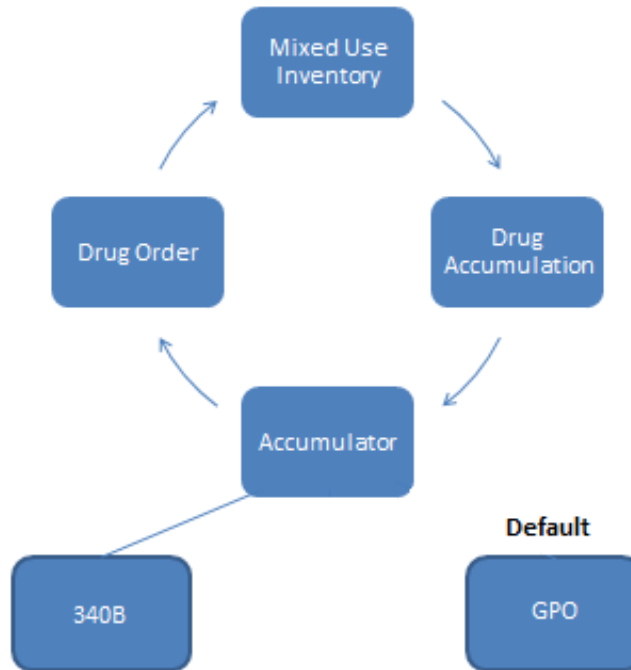
1. Physical 340B-only inventory
2. Physically separated 340B and non-340B inventory
3. Virtual mixed-use replenishment inventory (i.e., neutral)
4. Hybrid (physical and virtual) approach, stocking physically identifiable 340B inventory and maintaining a virtual mixed-use replenishment system

Pharmacists, technicians, and clinicians dispense 340B drugs only to patients meeting all the criteria in [Refer to [Entity’s] Policy and Procedure “Patient Eligibility/Definition” [Insert Entity’s specific policy and procedure reference number here]].

Procedure:

1. Physical inventory (both 340B and non-340B drugs) is maintained at [name(s) of site(s)]
 - a. [Entity] identifies all 340B and non-340B accounts used for purchasing drugs in each practice setting.
 - b. [Entity] separates 340B inventory from non-340B inventory. [Insert entity-specific process here].
 - c. [Entity] performs daily inventory reviews and shelf inspections of periodic automatic replenishment (PAR) levels to determine daily purchase order. [Insert entity-specific process here.]
 - d. [Entity] places 340B and non-340B drug orders. [Insert entity-specific process here.]
 - e. [Entity] receives shipment. [Insert entity-specific process here].
 - f. [Entity] verifies quantity received with quantity ordered. [Insert entity-specific process here]
 - i. Identifies any inaccuracies
 - ii. Resolves inaccuracies
 - iii. Documents resolution of inaccuracies
 - g. [Entity] maintains records of 340B-related transactions for [X period of time] in a readily retrievable and auditable format located [insert entity specifics here].
 - i. These reports are reviewed by the [entity] [interval] as part of its 340B oversight and compliance program. [Insert entity specifics here].
2. Physical inventory (340B only) is maintained at [name(s) of site(s)]
 - a. [Entity] identifies all accounts used for purchasing drugs in each practice setting.
 - b. [Entity] maintains inventory. [Insert entity-specific process here.]
 - c. [Entity] performs daily inventory reviews and shelf inspections of periodic automatic replenishment (PAR) levels to determine daily purchase order. [Insert entity-specific process here.]
 - d. [Entity] places 340B drug orders. [Insert entity-specific process here.]
 - e. [Entity] receives shipment. [Insert entity-specific process here.]
 - f. [Entity] verifies quantity received with quantity ordered. [Insert entity-specific process here].
 - i. Identifies inaccuracies
 - ii. Resolves inaccuracies
 - iii. Documents resolution of inaccuracies
 - g. [Entity] maintains records of 340B related transactions for a period of [interval] in a readily retrievable and auditable format located [Insert entity specifics here].
 - i. These reports are reviewed by [entity] [interval] as part of its 340B oversight and compliance program. [Insert entity specifics here.]

Mixed-use inventory replenishment system (340B/non-340B) is maintained at [name(s) of site(s)]



1. Identifies all accounts used for purchasing drugs in each practice setting for 340B and non-340B/GPO.
2. Purchases mixed-use inventory (according to eligible accumulations).
3. Administers/dispenses drugs to patients.
4. Split-billing software accumulates drug utilization based on patient status, patient location, and provider information. This accumulation occurs at the 11-digit NDC level and a full package size is accumulated before replenishment.

<u>340B</u>	<u>Non-340B/GPO</u>
Patients met 340B patient definition and received services on an outpatient basis in a 340B registered/participating clinic.	<ul style="list-style-type: none"> • Non-340B eligible outpatients, e.g.: <ul style="list-style-type: none"> ○ Administration or dispensing occurred at a clinic but not 340B eligible ○ Non-patient of the CE seen at an entity-owned retail pharmacy open to the public ○ Medicaid carve-out outpatients • Products that do not have an 11-digit NDC match on the 340B contract but are otherwise eligible for 340B purchase • Products that currently are not available (e.g., drug shortages) such that an 11-digit NDC match is not available • Lost charges or wasted product

5. Replenishment drug order(s) are placed according to eligible accumulations.

Mixed-Use Pharmacy Replenishment Sample Standard Process:

Reference:

i Insert split-billing detailed operations summary here and/or reference to operations manual to include as Appendix [#].

Key points to address appropriate access to wholesaler accounts and split-billing software include the following:

- The names and types of pharmacy ordering accounts.
 - The process the entity uses for determining how accumulations are identified as 340B eligible.
 - The eligibility filters process for mapping, maintenance, and updating (location eligibility, health care record, patient status; provider eligibility, scope of grant, Medicaid carve-in/-out status).
 - Basis for replenishment order (e.g., patient administration data to the 11-digit NDC); reporting elements (frequency).
 - Plan for accurate data capture (e.g., time stamps, conversions from “pharmacy system units” to “split-billing units”).
 - Grantee EHR–split-billing system interface; frequency of patient eligibility and order data updates; manual creation of purchase orders directly from manufacturer/incorporation of purchase data to the purchase history; PAR levels.
 - Procedures for accumulation when there are lost charges, procedures for decrementing accumulation for manufacturer and wholesaler returns and unused returns to stock, 340B priced product is not available, or waste.
 - Explanation of charge on dispensing vs. charge on administration and NDC match.
1. [Entity] identifies all pharmacy purchasing accounts.
 2. [Entity] identifies which accounts are used for each 340B-eligible location to purchase 340B drugs.
 3. [Entity] places 340B and non-340B/GPO drug orders based on orders created from the split-billing system. [Insert entity-specific process here.]
 - a. 340B drugs are ordered at an 11-digit NDC level.
 - b. Appropriate processes are in place to ensure proper ordering, tracking, and adjusting of accumulators for controlled substances [Insert entity specifics here.]
 4. [Entity] receives shipment. [Insert entity-specific process here.]
 5. [Entity] verifies quantity received with quantity ordered.
 - a. Identifies inaccuracies.
 - b. Resolves inaccuracies.
 - c. Documents resolution of inaccuracies.
 6. [Entity] documents manual manipulations to the 340B split-billing accumulator, including reason for manual manipulation. [Insert entity-specific process here.]
 7. [Entity] reconciles purchasing records with dispensing records [time interval] to ensure that covered outpatient drugs purchased through the 340B Program are used only for 340B-eligible patients. [Insert entity-specific process here.]
 - a. [Entity] resolves inventory discrepancies when 340B drugs are dispensed to ineligible patients. [Insert entity-specific process here.]
 8. [Entity] staff reports significant discrepancies (excessive quantities based on utilization or product shortages) to [Entity] management within [time interval].

9. [Entity] maintains records of 340B-related transactions for a period of [time interval] in a readily retrievable and auditable format located [Insert entity specifics here.]
 - a. These reports are reviewed by the [entity] [interval] as part of its 340B oversight and compliance program. [Insert entity specifics here.]

Wasted 340B Medication

1. [Entity] pharmacy/clinician staff documents destroyed or wasted drug not administered to the patient.
2. [Entity] pharmacy/clinician staff communicates wastage to the 340B coordinator.
3. [Entity] pharmacy staff adjusts 340B accumulator and documents adjustment with reason (if applicable).
4. [Entity] replaces medication through appropriate purchasing account.

Approvals (per organizational policy):

Executive/Authorizing Official Approval:		Date:	
Pharmacy/Primary Contact Approval:		Date:	
Health Information Management Approval:		Date:	
Compliance/Risk Management Approval:		Date:	
IT Department Approval:		Date:	
Legal Counsel Approval:		Date:	

	Contract Pharmacy Operations		
		Revision History	
		Effective Date:	XX-XX-XX
Departments Affected:		Original Issue Date:	XX-XX-XX
		Last Reviewed:	XX-XX-XX
		Last Revision:	XX-XX-XX

Policy: Covered entity remains responsible for ensuring that its contract pharmacy operations comply with all 340B Program requirements, such that the covered entity remains responsible for the 340B drugs it purchases and dispenses through a contract pharmacy.

Purpose: To ensure that [Entity] remains responsible for all 340B drugs used by its contract pharmacy(ies).

Reference:

Federal Register / Vol. 61, No. 165 / Friday, August 23, 1996 / Notices
<https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf>

Background:

[Entity] has obtained sufficient information from the contract pharmacy contractor to ensure compliance with applicable policy and legal requirements.

As a best practice, the signed contract pharmacy services agreement(s) should address the 12 contract pharmacy essential compliance elements: <https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf>.

Procedure:

- [Entity] contracts with [Vendor] to facilitate both the design and implementation of the 340B contract pharmacy program.

i Reference location of document or include as Appendix [#] copy of contract.

- [Entity] has a written contract is in place for each contract pharmacy location.

i List the name and addresses of the individual contract pharmacy locations identified in the executed contract pharmacy agreement (Appendix [#]).

- [Entity] registers each contract pharmacy location on [Entity’s] 340B OPAIS prior to the use of 340B drugs at that site.
- [Entity] uses a replenishment model at an 11-digit NDC level.
 - Non-replenishment 340B inventory is stored at [Contract Pharmacy], and clearly marked as belonging to the 340B entity (if applicable).

5. 340B-eligible prescriptions are presented to [Contract Pharmacy] via [e-prescribing, hard copy, fax, phone].
 - a. [Contract Pharmacy] verifies patient, prescriber, and outpatient clinic eligibility via [barcode, PBM eligibility file, other].
 - b. Updates are made to this mechanism by [Entity] at [time interval].
6. [Contract Pharmacy(ies)] dispense(s) prescriptions to 340B eligible patients using [Contract Pharmacy] non-340B drugs.
7. [Entity] implements a bill-to, ship-to arrangement with the contract pharmacy(ies).
 - a. [Contract Pharmacy] orders 340B drugs based on 340B eligible use as determined by [accumulator system or PBM], from [Wholesaler].
 - i. Orders are triggered by [package size used, etc.], placed by using [online system] at [X time interval], and communicated to [Entity] Staff via [email, wholesaler system, etc.]
 - b. Invoices are billed to [Entity].
8. [Contract pharmacy(ies)] receive shipment. [Insert Entity's contract pharmacy-specific process here].
9. [Contract pharmacy(ies)] verifies quantity received with quantity ordered. [Insert Entity's contract pharmacy-specific process here].
 - a. Identifies inaccuracies
 - b. Resolves inaccuracies
 - c. Documents resolution of inaccuracies
10. [Contract Pharmacy(ies)] notifies [Entity] if [Contract Pharmacy] doesn't receive 11-digit NDC replenishment order within [time interval] of original order fulfillment request.
11. [Entity] reimburses [Contract Pharmacy] at a pre-negotiated rate for such drugs.
12. [Entity] receives and reviews the invoice for drugs shipped to its contract pharmacy(ies).
13. [Entity] pays invoice to [Wholesaler] for all 340B drugs.
14. [Contract Pharmacy(ies)] provides a [time interval] report to [Entity]. [Insert entity specifics here.]
15. [Contract Pharmacy(ies)] adjusts claims when variance or discrepancy has occurred. [Insert entity specifics here.]
 - a. [Contract Pharmacy] uses approved methods with knowledge and agreement of [Entity] regarding reconciliation between inventory and invoices with adjustments as necessary to match changes.
 - b. Claim adjustments may occur only within [time interval, not more than 90 days] of original billing and not without prior notice and approval of [Entity].
16. [Entity] and [Contract Pharmacy] have agreed to a written procedure/agreement for inventory reconciliation if the relationship is terminated by either party. [Insert entity specifics here.]
 - a. [Entity] and [Contract Pharmacy] maintain auditable records to ensure that the process is transparent to manufacturers/wholesalers and in accordance with state law.
17. [Entity] will not use 340B drugs for Medicaid patients at its contract pharmacy(ies) (carve out). [Insert entity-specific process here including how contract pharmacy(ies) verifies that 340B drugs are not used or accumulated for Medicaid patients and prevents duplicate discounts.]
 - a. An entity may pursue the ability to use 340B drugs for Medicaid patients at its contract pharmacy(ies) if the entity, contract pharmacy, and state Medicaid agency have established an arrangement to prevent duplicate discounts and OPA has been notified and approves of the methodology used. 340B PVP Education Tool: [Contract Pharmacy Medicaid Carve-In Checklist](#).

Sample Policy and Procedure Manual

Grantees – Title X Family Planning (FP)

Approvals (per organizational policy):

Executive/Authorizing Official Approval:		Date:	
Pharmacy/Primary Contact Approval:		Date:	
Health Information Management Approval:		Date:	
Compliance/Risk Management Approval:		Date:	
IT Department Approval:		Date:	
Legal Counsel Approval:		Date:	

	340B Noncompliance/ Material Breach		
		Revision History	
		Effective Date:	XX-XX-XX
Departments Affected:		Original Issue Date:	XX-XX-XX
		Last Reviewed:	XX-XX-XX
		Last Revision:	XX-XX-XX

Policy: Covered entities are responsible for contacting HRSA as soon as reasonably possible if there is any material breach by the covered entity or any instance of noncompliance with any of the 340B Program requirements.

Purpose: To define [Entity’s] material breach of 340B compliance and self-disclosure process.

Definitions:

Materiality: A convention within auditing/accounting pertaining to the importance/significance of an amount, transaction, and/or discrepancy.

Threshold: The point that must be exceeded, as defined by the covered entity, resulting in a material breach. Examples of thresholds include:

- a. X% of total 340B purchases or impact to any one manufacturer.
- b. \$X (fixed amount), based on total outpatient or 340B spend, or impact to any one manufacturer.
- c. X% of total 340B inventory (units).
- d. X% of audit sample.
- e. X% of prescription volume/prescription sample.

Reference:

340B PVP Education Tool: Defining Material Breach Documentation Tool

<https://docs.340bpvp.com/documents/public/resourcecenter/establishing-material-breach-threshold.docx>

340B PVP Education Tool: Self-Disclosure to HRSA and Manufacturer Template

<https://docs.340bpvp.com/documents/public/resourcecenter/self-disclosure-to-hrsa-and-manufacturer-template.docx>

Procedure:

1. [Entity’s] established threshold of what constitutes a material breach of 340B Program compliance is [Insert entity specifics here].
 - a. [Entity] ensures that identification of any threshold variations occurs among all its 340B settings, including contract pharmacies (if applicable).
2. [Entity] assesses materiality [Insert entity specifics here].
 - a. [Entity] maintains records of materiality assessments.
3. [Entity] reports identified material breach immediately to HRSA and applicable manufacturers. [Insert entity specifics here.]
 - a. Maintain records of material breach violations, including manufacturer resolution correspondence, as determined by organization policy.

i Reference location of material breach policy/procedure or include as Appendix [#].

Approvals (per organizational policy):

Executive/Authorizing Official Approval:		Date:	
Pharmacy/Primary Contact Approval:		Date:	
Health Information Management Approval:		Date:	
Compliance/Risk Management Approval:		Date:	
IT Department Approval:		Date:	
Legal Counsel Approval:		Date:	

	340B Program Compliance Monitoring/Reporting		
		Revision History	
		Effective Date:	XX-XX-XX
Departments Affected:		Original Issue Date:	XX-XX-XX
		Last Reviewed:	XX-XX-XX
		Last Revision:	XX-XX-XX

Policy: Covered entities are required to maintain auditable records demonstrating compliance with 340B Program requirements.

Purpose: To provide an internal monitoring program to ensure comprehensive compliance with the 340B Program.

Note: Specify entity-specific processes for elements below, including the frequency of reviews and how the review and timely updates to 340B OPAIS are performed and documented.

Procedure:

1. [Entity] develops an annual internal audit plan approved by the internal compliance officer or as determined by organizational policy.
2. [Entity] reviews 340B OPAIS to ensure the accuracy of the information for all site locations and contract pharmacies (if applicable).
3. [Entity] reviews the Medicaid Exclusion File (MEF) to ensure the accuracy of the information for the site locations and contract pharmacies (if applicable).
4. [Entity] reconciles purchasing records and dispensing records to ensure that covered outpatient drugs purchased through the 340B Program are dispensed or administered only to patients eligible to receive 340B drugs and that any variances are not the result of diversion.
5. [Entity] reconciles dispensing records to patients’ health care records to ensure that all medications dispensed were provided to patients eligible to receive 340B drugs. [Entity] will select [Insert number here] records from a drug utilization file and preform the audit [Insert time period, e.g., monthly, quarterly, annually].
6. [Entity] reconciles dispensing records and Medicaid billing practices to demonstrate that [Entity’s] practice is following the Medicaid billing question on 340B OPAIS.
7. [Entity’s] 340B Oversight Committee reviews the internal audit results. [Insert entity-specific process here]
 - a. Assess whether audit results are indicative of a material breach [Refer to [Entity’s] Policy and Procedure “340B Noncompliance/Material Breach” [Insert [Entity’s specific policy and procedure reference number here]].
8. [Entity] maintains records of 340B-related transactions for a period of [time interval] in a readily retrievable and auditable format located [reference]. [Insert entity specifics here.]

Sample Policy and Procedure Manual

Grantees – Title X Family Planning (FP)

Approvals (per organizational policy):

Executive/Authorizing Official Approval:		Date:	
Pharmacy/Primary Contact Approval:		Date:	
Health Information Management Approval:		Date:	
Compliance/Risk Management Approval:		Date:	
IT Department Approval:		Date:	
Legal Counsel Approval:		Date:	

	Contract Pharmacy Oversight and Monitoring		
		Revision History	
		Effective Date:	XX-XX-XX
Departments Affected:		Original Issue Date:	XX-XX-XX
		Last Reviewed:	XX-XX-XX
		Last Revision:	XX-XX-XX

Policy: Covered entities are required to provide oversight of their contract pharmacy arrangements to ensure ongoing compliance. The covered entity has full accountability for compliance with all requirements to ensure eligibility and to prevent diversion and duplicate discounts. Auditable records must be maintained to demonstrate compliance with those requirements.

Purpose: To ensure that [Entity] maintains 340B Program integrity and compliance at its contract pharmacy(ies).

Reference:

Federal Register / Vol. 75, No. 43 / Friday, March 5, 2010 / Notices
(<https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf>)

Procedure:

1. [Entity] routinely conducts internal reviews of each registered contract pharmacy for compliance with 340B Program requirements. [Insert entity specifics here.] The following elements will be included when conducting self-audits of contract pharmacy(ies) to ensure program compliance:
 - a. Prescription is written from a 340B eligible site of care that provides health care services.
 - b. Patient eligibility: The episode of care that resulted in the 340B prescription is supported in the patient’s medical record and the service provided is consistent with the grant funding scope of services provided to the entity.
 - c. Provider eligibility: The prescribing provider is employed, contracted, or under another arrangement with the entity at the time of writing the prescription so that the entity maintains responsibility for the care.
 - d. The 11-digit NDC level is documented for accumulation and/or replenishment of a 340B dispensation or administration (if a virtual inventory is used).
 - e. [Entity] can document that no prescriptions were billed to Medicaid unless the contract pharmacy is listed as a carve-in contract pharmacy on 340B OPAIS.

2. [Entity] conducts independent audits of each registered contract pharmacy for compliance with the 340B Program requirements. [Insert entity specifics here.]

Note: It is HRSA’s expectation that covered entities will use annual independent audits as part of fulfilling their ongoing obligation of ensuring 340B Program compliance.

- a. Independent audits will include reviews of:
 - i. 340B eligibility
 - ii. 340B registration
 - iii. Documented policies and procedures
 - iv. Inventory, ordering, and record-keeping practices for all 340B accounts
 - v. Listing in the Medicaid Exclusion File and its reflection in actual practices

- vi. Testing of claims sample to determine any instance of diversion or duplicate discounts over a set period of time
- 3. [Entity] has mechanisms in place to demonstrate compliance with all state Medicaid billing requirements to prevent duplicate discounts at all sites, including off-site outpatient facilities. [Insert entity-specific process for all state Medicaid agencies that are billed.]
- 4. [Entity] follows all state practices consistent with state guidance and [Entity] Medicaid billing numbers/NPI numbers are properly reflected in the Medicaid Exclusion File.
 - a. The following state Medicaid programs are billed by [Entity]: [Insert entity specifics here.]
- 5. [Entity’s] 340B Oversight Committee reviews audit results. [Insert entity-specific process here.]
 - a. Assess if audit results are indicative of a material breach [Refer to [Entity’s] Policy and Procedure “340B Noncompliance/Material Breach” [Insert [Entity’s specific policy and procedure reference number here]].
- 6. [Entity] maintains records of 340B-related transactions for a period of [time interval] in a readily retrievable and auditable format located [reference]. [Insert entity specifics here.]

Approvals (per organizational policy):

Executive/Authorizing Official Approval:		Date:	
Pharmacy/Primary Contact Approval:		Date:	
Health Information Management Approval:		Date:	
Compliance/Risk Management Approval:		Date:	
IT Department Approval:		Date:	
Legal Counsel Approval:		Date:	

	Prime Vendor Program (PVP) Enrollment and Updates		
		Revision History	
		Effective Date:	XX-XX-XX
Departments Affected:		Original Issue Date:	XX-XX-XX
		Last Reviewed:	XX-XX-XX
		Last Revision:	XX-XX-XX

Policy: The purpose of the Prime Vendor Program (PVP) is to improve access to affordable medications for covered entities and their patients.

Purpose: Support [Entity’s] participation in the PVP to receive the best 340B product pricing, information, and value-added products.

Procedure:

Enrollment in PVP:

1. [Entity] completes online 340B Program registration with HRSA.
2. [Entity] completes online PVP registration (<https://www.340bpvp.com/register/apply-to-participate-for-340b/>).
3. PVP staff validates information and sends confirmation email to [entity].
4. [Entity] logs in to www.340bpvp.com, selects user name/password.

Update PVP Profile:

1. [Entity] accesses www.340bpvp.com.
2. [Entity] clicks Login in the upper right corner.
3. [Entity] inputs PVP log-in credentials.
 - a. In the upper right corner:
 - i. Click “My Profile” to access page.
<https://members.340bpvp.com/webMemberProfileInstructions.aspx>.
4. [Entity] clicks “Continue to My Profile” to access page:
<https://members.340bpvp.com/webMemberProfile.aspx>.
 - a. Find a list of your facilities.
 - i. Click on the 340B ID number hyperlink to view or change profile information for that facility.
 - b. Update HRSA Information:
 - i. Complete the 340B Change Form as detailed above.
 - a) After 340B OPAIS has been updated, the PVP database will be updated during the nightly synchronization.
5. [Entity] updates the 340B Prime Vendor Program (PVP) Participation Information:
 - a. Edit [Entity’s] DEA number, distributor and/or contacts.
 - b. Click submit.

Approvals (per organizational policy):

Executive/Authorizing Official Approval:		Date:	
Pharmacy/Primary Contact Approval:		Date:	
Health Information Management Approval:		Date:	
Compliance/Risk Management Approval:		Date:	
IT Department Approval:		Date:	
Legal Counsel Approval:		Date:	

Suggested Appendices

- i** Appendix [#]: 340B Savings document in accordance with 340B Program intent
- Appendix [#]: Listing of drug exclusions to covered outpatient drug definition (e.g., bundled drugs)
- Appendix [#]: Screen shots of all entity data on 340B OPAIS
- Appendix [#]: Screen shot of entity's medical record system
- Appendix [#]: Current eligible provider list
- Appendix [#]: State Medicaid policies for 340B reimbursement/billing/duplicate discount prevention (FFS, MCO)
- Appendix [#]: Entity's Medicaid information from the Medicaid Exclusion File for all sites and all state Medicaid agencies billed
- Appendix [#]: State Medicaid contact information for all state Medicaid agencies billed
- Appendix [#]: Last documentation from state's Medicaid contact for all state Medicaid agencies billed
- Appendix [#]: Communication with state Medicaid agency regarding the prevention of duplicate discounts if contract pharmacies are carving-in
- Appendix [#]: Communication with HRSA regarding arrangements with the state Medicaid agencies if contract pharmacies are carving-in
- Appendix [#]: Educational documents, including 340B competency requirements.
- Appendix [#]: Procedures impacting inventory management (e.g., income-based discounts, Medicaid billing)
- Appendix [#]: Copies of contract pharmacy agreement(s)
- Appendix [#]: List of the name and addresses of the individual contract pharmacy locations identified in the executed contract pharmacy agreement(s)
- Appendix [#]: Material breach policy/procedure

This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages each stakeholder to include legal counsel as part of its program integrity efforts.

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