



Sample 340B Policy & Procedures Manual

A Guide for Family Planning Entity Leaders

Purpose: The purpose of this tool is to provide an example of a 340B policy and procedure manual (P&P manual) that exhibits high program integrity, to assist participating family planning entity leaders in the preparation of a unique site-specific P&P manual that supports compliant 340B practices.

Instructions:

1. Identify which team members within the family planning entity will be involved in the creation, review, and approval process of the P&P manual.
2. Meet to discuss the project and assign responsibilities and timelines.
3. Review the sample P&P manual.
4. Based on the topics presented in the sample, customize a draft P&P manual for the specific entity. This sample is not intended to be “cut and pasted”; rather, it is intended to provide structure and content that entities may want to address as part of creating a 340B compliant program. Entities are expected to delete or add new language to customize their P&P manual to apply to their unique practice setting and 340B program requirements. There are many possibilities for structuring a 340B P&P manual; this sample represents just one option.
5. 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.
6. Review and approve draft P&P manual with entity team members.
7. Regularly update the P&P manual and maintain all records of previous versions of P&P manuals and meeting minutes from P&P manual reviews.



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I. PURPOSE

This document contains descriptions of the policies and procedures used at [Entity] to maintain compliance with the 340B program.

II. DEFINITIONS

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

III. REFERENCES

Include other references to P&Ps, 340B Glossary of Terms, HRSA website, etc.

IV. POLICY REVIEW, UPDATES, AND APPROVAL

This policy will be reviewed, updated, and approved by [Entity] staff/committee at [interval] with documentation. [Reference P&P Committee Policy]

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 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. 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, [Entity's] policies are:

- [Entity] uses any savings generated from 340B in accordance with 340B program intent. [Appendix: include reference to 340B intent from 340B University Notes]
- [Entity] meets all 340B program eligibility requirements.
 - [Entity's] HRSA 340B Database covered entity listing is complete, accurate, and correct. [Appendix: include screen shots of all entity data on the HRSA 340B Database]
 - [Entity] receives a grant or designation consistent with that conferring 340B eligibility [Appendix: provide source document demonstrating this criterion]



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- [Entity] 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](#)]
- [Entity] 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 grant/designation for which 340B status was conferred) from this professional such that the responsibility for care remains with the entity. [Appendix: reference where to locate current prescriber list, include description of relationship between entity and prescribers and any supporting documentation]
 - [Entity] maintains records of the individual's health care. [Reference policy or provide in Appendix a screen shot or description of medical record system]
 - If [Entity] bills Medicaid for 340B drugs, billing follows state guidelines and [Entity] has reflected its information on the HRSA 340B Database/Medicaid Exclusion File:
 - [Entity] informs HRSA immediately of any changes to its information on the HRSA 340B Database/Medicaid Exclusion File.
 - Medicaid reimburses [Entity] for 340B drugs per state policy and does not collect rebates on claims from [Entity]. [Reference: State policy(ies) for 340B reimbursement/billing/duplicate discount prevention (State Medicaid Manual, etc.); Appendix: [Entity's] Medicaid information from the Medicaid Exclusion File for all sites, State Medicaid contact(s) information, last documentation from state contact.]
- [Entity] has systems/mechanisms and internal controls in place to reasonably ensure ongoing compliance with all 340B requirements.
- [Entity] has an internal audit plan adapted by the internal compliance officer or other and conducted annually, and an external audit plan, as appropriate (include details if 340B is addressed). [Appendix:, also reference Section IX]
- [Entity] 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:
 - [Entity] obtains sufficient information from the contractor to ensure compliance with applicable policy and legal requirements, and [Entity] has used an appropriate methodology to ensure compliance (e.g., through an independent audit or other mechanism).
 - Signed Contract Pharmacy Services Agreement(s) comply with [12 contract pharmacy essential compliance elements](#). [Appendix I: provide copy of agreement, compliance elements, reference where contract is maintained—i.e., department of pharmacy or compliance office, etc.]
- [Entity] acknowledges its responsibility to contact HRSA as soon as reasonably possible if there is any change in 340B eligibility or material breach by [Entity] of any of the foregoing policies.



- [Entity] acknowledges that if there is a breach of the 340B requirements, [Entity] 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.
- [Entity] 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 [Entity] staff are engaged with 340B program compliance. Pharmacy and other staff member(s) participating in the 340B program complete initial basic training via webinar on the 340B and Prime Vendor programs (<https://www.brainshark.com/apexus/TopFive340BBasics>) and attend 340B University every [interval] [suggested interval is every 1–2 years]. Comprehensive training is conducted on the 340B program initially upon hire and competency is also verified annually by [Entity staff] through verbal assessment and as part of the staff development plan [Reference Staff Development Policy, Family Planning Entity Compliance Policy]. [The following staff are not specific for all entities and not all-inclusive.]

- A. Primary Contact [Describe position title, general 340B responsibilities, or reference job description]
- B. Secondary Contact [Describe position title, general 340B responsibilities, or reference job description]

VIII. 340B ENROLLMENT, RECERTIFICATION, CHANGE REQUESTS

Recertification Procedure

HRSA requires entities to recertify their information as listed in the HRSA 340B Database annually. [Entity's authorizing official] annually recertifies [Entity's] information by following the directions in the recertification email sent from the HRSA to [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 [Entity staff] 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 grant/designation received by the entity that confers 340B status, have outpatient drug use, and have patients who meet the 340B patient definition.

If a new clinic meets these criteria, the [Entity] 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).

Enrollment Procedure: New Contract Pharmacy(ies)

1. The [Entity 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 [Entity's] legal counsel has reviewed the contract and verified that all federal, state, and local requirements have been met.

2. The [Entity 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. The [Entity 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 [Entity staff] begins the contract pharmacy arrangement only on or after the effective date shown on the HRSA 340B Database.

Procedure for Changes to [Entity's] Information in HRSA 340B Database

It is [Entity]'s ongoing responsibility to immediately inform HRSA of any changes to its information or eligibility. As soon as [Entity] is aware that it 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 [Entity's authorizing official] for changes to [Entity's] information outside of the annual recertification timeframe. 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. [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. The PVP staff validates information and sends a confirmation email to [Entity].
4. [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'll find a list of your 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 Prime Vendor Program (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 Prime Vendor Program (PVP) participation information, you can edit your DEA number, distributor and/or contacts, and click "Submit."

X. 340B PROCUREMENT, INVENTORY MANAGEMENT, DISPENSING

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

- Clinic administration
- In-house pharmacy or dispensary
- Contract pharmacy
- [Note: Entity may wish to establish a pricing policy addressing establishment of usual and customary charges, applying income-based discounts, third-party billing/reconciliation, and/or Medicaid (physician administered drugs, fee for service drugs, managed care, Medicaid as secondary payer).]

In-House Dispensary, Sample Standard Processes

1. [Entity] uses either only 340B inventory, or electronically or physically separate 340B and non-340B purchased inventory. Pharmacists, technicians, or designated clinical staff dispense 340B drugs only to patients meeting all the criteria in [reference P&P manual, section VI].
2. [Entity] Staff places 340B orders from [Wholesaler] through periodic inventory review and shelf inspections of periodic automatic replenishment (PAR) levels by using [system] at [time interval]. [Wholesaler 2] is a secondary wholesaler and used in the event of product shortages.
3. [Entity] staff checks in 340B inventory by examining the wholesaler invoice against the order, and reports inaccuracies to the wholesaler.
4. [Entity] staff maintains records of 340B-related transactions for a period of [interval] in a readily retrievable and auditable format located [reference].
5. 340B inventory is stored securely and access is limited to designated clinical staff.
6. [Entity] staff examines the report in [Appendix] at [interval], and reports to [specify committee name] [interval].

Clinic-Administered Drugs, Sample Standard Processes

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



Contract Pharmacy Sample Standard Processes (if applicable)

1. [Entity] has contracted with [Vendor] to facilitate both the design and implementation of the 340B contract pharmacy program. The entity is responsible for 340B compliance. The executed contract with [Vendor] appears in [Appendix].
2. [Entity] uses a replenishment model for contract pharmacy services.
3. 340B eligible prescriptions may be presented to [Contract Pharmacy] via [e-prescribing, hard-copy, fax, phone]. [Contract Pharmacy] verifies patient, prescriber, and clinic eligibility via [barcode, PBM eligibility file, other]. Updates are made to this mechanism by [Entity] at [interval].
4. [Contract Pharmacy] staff dispenses prescriptions to 340B-eligible patients using [Contract Pharmacy] non-340B drugs.
5. [Contract Pharmacy/Entity] staff places 340B orders on behalf of [Entity], based on 340B-eligible use as determined by [accumulator system or PBM] from [Wholesaler]. Orders are triggered by [package size used, etc.], placed by using [online system] at [time] interval, and communicated to [Entity] staff via [email, wholesaler system, etc.].
6. [Entity] pays invoice to [Wholesaler] for all 340B drugs.
7. [Contract Pharmacy] staff receives 340B inventory by examining the wholesaler invoice against the order, and reports inaccuracies to [Wholesaler] and [Entity] staff within [interval].
8. [Contract Pharmacy] notifies [Entity] if [Contract Pharmacy] does not receive 11-digit NDC replenishment orders within [interval] of original order fulfillment request. [Entity] will reimburse [Contract Pharmacy] at a pre-negotiated rate for such drugs.
9. Any nonreplacement 340B inventory is stored at [Contract Pharmacy], and clearly marked as belonging to the 340B entity. The inventory is protected by a security system. Only pharmacy employees have access to the pharmacy.
10. [Contract Pharmacy] will provide a [interval] report to the [Entity]. [Reference reporting section]

XI. REIMBURSEMENT

The entity obtains reimbursement for 340B drugs from [Medicaid, private insurers, etc.] according to [reference existing reimbursement policy or address in this section]. [Entity] requests Medicaid reimbursement from [list states] detailed here [reference document or source]. Note: Reimbursement policies are different depending on the state Medicaid program, and these policies are subject to change.

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 [list]:

Reporting 340B Noncompliance

Address the threshold and types of noncompliance that warrant a report to HRSA/manufacturer, records kept, documentation, and plan for corrective action. [Reference existing entity 340B compliance policy, [Self-Reporting Non-Compliance Tool](#)].

340B Compliance Review

The 340B Compliance Review summarizes activities necessary to ensure a comprehensive review of 340B compliance at [Entity]. [Entity] staff is responsible and accountable for overseeing this review process, as well as taking corrective actions based on findings.

Activity	Frequency (suggested)	Area of Focus		
		Entity Eligibility	No Diversion	No Duplicate Discount
Review of all HRSA 340B Database information for [Entity], indigent care agreement with state/local government. [Entity] Staff responsible:	Annually	X		
Review of 340B self-audit reports. [Entity] staff responsible:	Monthly		X	X
Review of quarterly contract price load. [Entity] staff responsible:	Quarterly		X	
Update (minimum) of prescriber and patient eligibility files with PBM/contract pharmacy. [Entity] staff responsible:	Monthly		X	
Third-party vendor external audit of [Entity/Contract Pharmacy] (optional). [Entity] staff responsible:	Annually		X	X



XIII. Appendix I: 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: <http://www.hrsa.gov/opa/programrequirements/federalregisternotices/contractpharmacyservices030510.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.



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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.

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 all stakeholders to include legal counsel as part of their program integrity efforts.

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