A Guide for DSH 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 DSH leaders in the preparation of a unique, site-specific, P&P Manual that supports placing compliant guidance/policy into practice.

Instructions:

1. Identify which team members within the DSH 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.
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 in order to customize their P&P Manual to apply to their unique practice settings 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) and they will provide assistance, or connect you with a resource that can provide help.
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.

This tool, written to align with OPA policy, is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by the Office of Pharmacy Affairs 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 their program integrity efforts.

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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].

Additional definitions:

Covered outpatient drug: [Entity] interprets Section 1927 (k) of the Social Security Act to include the following drugs when used in the situations described (list) and exclude the following drugs when used in the situations described (list).

Inpatient status: [Entity] determines that patients have an inpatient status according to [data set/method of determination].

Outpatient status: [Entity] determines that patients have an inpatient status according to [data set/method of determination].

III. REFERENCES
Include other references to P&Ps, 340B Glossary of Terms, OPA 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 an agreement 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 Program. The program is administered by the Office of Pharmacy Affairs (OPA), a part of the federal Health Resources and Services Administration/Department of Health and Human Services.
Upon registration on the OPA database as a participant in the 340B Program, entities 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] OPA Database covered entity listing is complete, accurate, and correct. [Appendix: include screen shots of all entity data on the OPA Database]
  - [Select one bullet]
    - Is owned or operated by a unit of State or local government. [Appendix: provide source document demonstrating this criterion]
    - Is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government. [Appendix: provide source document demonstrating this criterion]
    - Is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under this title. [Appendix: provide contract or reference location of documentation demonstrating this criterion]
  - For the most recent cost reporting period that ended before the calendar quarter involved, [Entity] had a disproportionate share adjustment percentage greater than 11.75 percent. [Appendix I: Include copy of Worksheet E Part A, line 33 of most recently filed cost report or reference to location of documentation]
  - [Entity] does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement, except in accordance with GPO Policy Release.
  - [Entity] uses 340B only in outpatient clinics that are registered on the OPA database (or within the four walls of the parent), fully integrated into the DSH, and reimbursable on the most recently filed cost report. [Appendix: provide copy of Worksheet A of most recently filed cost report, and a schedule of all outpatient reimbursable clinics]
- [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.  


- [Entity] maintains auditable records demonstrating compliance with the 340B requirement described in the preceding bullet.
  - Prescriber is on the hospital’s eligible prescriber list as employed by the entity, or under contractual or other arrangements with the entity, and the individual receives a health care service 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]
  - 340B drugs are used in outpatient facilities that appear as reimbursable on the most recently filed CMS cost report and are registered on the OPA database (or within the four walls of the parent). [Appendix, documentation as above]
  - DSH maintains records of the individual’s health care. [Reference ADT policy or provide in Appendix a screen shot or description of medical record system]
  - Patient is an outpatient at the time medication is administered/dispensed. [Appendix: screen shot of status as indicated in the hospital ADT system or bed management system or other description]
  - [Entity] does not purchase covered outpatient drugs using a GPO (as described above)
  - [Entity] bills Medicaid per Medicaid reimbursement requirements, and as [Entity] has reflected its information on the OPA website/Medicaid Exclusion File
    - [Entity] informs OPA immediately of any changes to its information on the OPA website/Medicaid Exclusion File
    - Medicaid reimburses 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 OPA 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 and conducted annually. [Appendix:, also reference Section IX]
- [Entity] uses contract pharmacy services (if applicable), and the contract pharmacy arrangement is performed in accordance with OPA requirements and guidelines including, but
not limited to, that the hospital obtains sufficient information from the contractor to ensure compliance with applicable policy and legal requirements, and the hospital has utilized an appropriate methodology to ensure compliance (e.g., through an independent audit or other mechanism)

- Signed Contract Pharmacy Services Agreement(s) complies with 12 contract pharmacy essential compliance elements
  (http://www.hrsa.gov/opa/programrequirements/federalregisternotices/contractpharmacistservices030510.pdf). [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 OPA as soon as reasonably possible if there is any change in 340B eligibility or material breach by the hospital 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 upon 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 Office of Pharmacy Affairs
  - The 340B Prime Vendor Program, managed by Apexus
  - Any OPA contractors

VII. RESPONSIBLE STAFF, COMPETENCY
The following [Entity] Staff are engaged with 340B program compliance. Pharmacy staff members participating in the 340B Program complete initial basic training via webinar on the 340B and Prime Vendor Programs (https://docs.340bpvp.com/apps/public/gps/gps.html) and attend 340B University every [interval]. Comprehensive training is conducted on the 340B Program initially upon hire and competency is also verified annually by [STAFF] through verbal assessment and as part of the staff development plan (Reference Staff Development Policy, Hospital Compliance Policy). [The following staff are not specific for all hospitals and not all-inclusive.]

A. Chief Executive Officer
   - Responsible as the principal officer in charge for the compliance and administration of the program
   - Responsible for attesting to the compliance of the program in form of recertification
B. Chief Financial Officer
   • Responsible for above in many cases
   • Must account for savings and use of funds to provide care for the indigent under the indigent care agreement
C. 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 current policy statements and procedures are in place to maintain program compliance
   • Must maintain knowledge of the policy changes that impact the 340B program which includes, but not limited to, HRSA/OPA rules and Medicaid changes
   • Must coordinate constant knowledge of any change in clinic eligibility/information
D. Pharmacy 340B Coordinator
   • Accountable agent for 340B compliance
   • Day to day manager of the program
   • Responsible for maintenance and testing of tracking software
   • Responsible for documentation of policy and procedures
   • Maintain system databases to reflect changes in the drug formulary or product specifications
   • Manage purchasing, receiving and inventory control processes
   • Continuously monitor product min/max levels to effectively balance product availability and cost efficient inventory control
   • Assure appropriate safeguards and system integrity
   • Perform annual inventory and monthly [or other interval] cycle counts
   • Assure compliance with 340B program requirements of qualified patients, drugs, providers, vendors, payors, and locations
   • Review and refine 340B cost savings report detailing purchasing, and replacement practices, as well as dispensing patterns
   • Monitor ordering processes, integrating most current pricing from wholesaler, analyze invoices, shipping, and inventory processes
E. Corporate Compliance Officer or Director of Internal Audit
   • Designs and maintains an internal audit plan of the compliance of the 340B program
   • Design the annual plan to cover all changes in the program from the past year
F. Director of Hospital Reimbursement
   - Responsible for communication of all changes to the Medicare Cost report regarding clinics or revenue centers of the cost report
   - Responsible for communication of all changes to Medicaid reimbursement for pharmacy services/products that impact 340B status
   - Responsible for modeling all managed care contracts (with/without 340B)
   - Engage Pharmacy in those conversations that impact reimbursement

G. Director of Accounting
   - Responsible for annual or semi-annual physical inventory of pharmacy items
   - Responsible for establishment of “inventory average” process approved by the external audit firm (Reference policy or type of process used, i.e., FIFO)

H. Chief IT Officer/Pharmacy Informatics Person
   - Support the Pharmacy software selection of tracking software to manage the 340B program
   - Define process and access to data for compliant identification of outpatient utilization for eligible patients
   - Archive the data so as to be available to auditors when audited.

I. Clinical Pharmacy Coordinator
   - Be aware of products covered by 340B and Prime Vendor Program pricing
   - Work with the Medical Staff to use effective therapeutic classes that optimize savings with good clinical outcomes [Reference Pharmacy and Therapeutics Committee role]

J. Pharmacy Procurement/Inventory Manager
   - Responsible for establishing three distribution accounts and maintaining those accounts; i.e., non-GPO account, 340B account, and GPO account
   - Responsible for establishing and maintaining direct accounts for GPO (“own use”) class of trade as well as direct 340B accounts
   - Responsible for ordering all drugs from the specific accounts as specified by the process employed

VIII. 340B ENROLLMENT, RECERTIFICATION, CHANGE REQUESTS

Recertification Procedure

OPA requires entities to recertify their information as listed in the OPA database annually. [Entity’s Authorizing Official] annually recertifies [Entity’s] information by following the directions in the
recertification email sent from the OPA 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 if the location is eligible for participation in the 340B Program. The criteria used include: service area must be fully integrated into DSH, appear as a reimbursable clinic on the most recently filed cost report, have outpatient drug use, and have patients that 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). This includes submitting cost report information, as required by OPA. [http://www.hrsa.gov/opa/eligibilityandregistration/index.html](http://www.hrsa.gov/opa/eligibilityandregistration/index.html)

**Enrollment Procedure: New Contract Pharmacy(ies)**

1. The [Entity Staff] ensures 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 submission to OPA. This staff ensures the [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 process here: [http://opanet.hrsa.gov/opa/CERegister.aspx?isnew=true](http://opanet.hrsa.gov/opa/CERegister.aspx?isnew=true) 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 fifteen days from the date the online registration was completed. Pharmacy: 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 OPA website.
Changes to [Entity’s] Information in OPA Database Procedure

It is [Entity]’s ongoing responsibility to immediately inform OPA of any changes to its information or eligibility. As soon as [Entity] is aware that it loses eligibility, it will notify OPA immediately and stop purchasing (or may be required to repay manufacturers).

An online change request will be submitted to OPA by [Entity’s Authorizing Official] for changes to [Entity’s] information outside of the annual recertification timeframe. Change form will be submitted to OPA as soon as the entity is aware of the need to make a change to its database entry. The entity will expect changes to be reflected within about 2 weeks of submission of the changes/requests.

IX. PRIME VENDOR PROGRAM ENROLLMENT, UPDATES

Enrollment in PVP:

1. Entity completes online 340B Program registration with OPA.
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.

Update PVP Profile:

To update your profile:

2. Click Login in the upper right corner
3. Input your log-in credentials
4. In the upper right corner, arrow by your name, and click My Profile to access page https://members.340bpvp.com/webMemberProfileInstructions.aspx
5. Click Continue to My Profile to access page https://members.340bpvp.com/webMemberProfile.aspx
6. You’ll find a list of your facilities; click on the 340B ID number hyperlink to view or change profile information for that facility
7. The My Profile Change Request form is divided into two categories: HRSA Information and 340B Prime Vendor Program (PVP) Participation Information
8. To update HRSA Information, complete the 340B Change Form on page http://opanet.hrsa.gov/OPA/CRPublicSearch.aspx, and submit it via e-mail to the Office of
Pharmacy Affairs at opastaff@hrsa.gov. After the HRSA database has been updated, the PVP database will be updated during the nightly synchronization.

9. 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:

- Outpatient pharmacy
- Hospital, Mixed-use
- 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, Medicaid (physician administered drugs, fee for service drugs, managed care, Medicaid as secondary payer).

**Outpatient Pharmacy, Separate Physical Inventory Sample Standard Processes:**

1. [Entity] uses physically separate 340B inventory as well as non-GPO/WAC inventory or (GPO, if appropriate). Pharmacists and technicians only dispense 340B drugs to eligible patients.

2. [Entity] Staff places 340B orders from [Wholesaler] through daily inventory reviews and shelf inspections of 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 in the outpatient pharmacy maintained with a security system. Only pharmacy employees have access to the pharmacy through a bar coded, badge-ID limited entry system.
Mixed-use Settings Sample Standard Processes

1. Purchase mixed-use inventory (according to eligible accumulations).
2. Administer/dispense drugs to patients.
3. Accumulator accumulates drug on an 11-digit NDC match until unit of use is met, prepares order, uses patient/clinic/prescriber information to determine the appropriate contract for ordering.

<table>
<thead>
<tr>
<th></th>
<th>GPO</th>
<th>Non-GPO/WAC</th>
<th>340B</th>
</tr>
</thead>
<tbody>
<tr>
<td>GPO/Inpatient class of trade: Inpatient status determined by hospital at the date/time of administration</td>
<td>Products that do not have an 11 digit NDC match on the 340B contract but are otherwise eligible for 340B purchase</td>
<td>Non-340B eligible outpatients, i.e.: Administration or dispensing occurred at a clinic within 4 walls of parent, but not 340B basis in a 340B registered/participating hospital clinic</td>
<td>Patients met 340B patient definition and received services on an outpatient basis in a 340B registered/participating hospital clinic</td>
</tr>
<tr>
<td>GPO/Outpatient class of trade: Offsite/unregistered outpatient clinics</td>
<td>eligible</td>
<td>In-house pharmacy open to public</td>
<td>Medicaid carve-out outpatients</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Lost charges or wasted product</td>
</tr>
</tbody>
</table>
4. Replenishment drug order(s) are placed according to eligible accumulations.
Pharmacy Replenishment Sample Standard Processes:
(Customize split-billing model description under mixed-use section of P&P Manual)

1. [Entity] Staff places 340B orders, based upon orders created from the split-billing system, from [Wholesaler] by using [system] at [time] interval. [Wholesaler 2] is a secondary wholesaler and used in the event of product shortages.

2. [Entity] Staff checks in 340B inventory by examining the wholesaler invoice against the order, and reports inaccuracies to the wholesaler.

3. [Entity] Staff reports significant discrepancies (excessive quantities based upon utilization or product shortages) to [Entity] Staff within [interval].

4. [Entity] Staff maintains records of 340B related transactions for a period of [interval] in a readily retrievable and auditable format located [reference].

5. Inventory is stored in the (inpatient pharmacy, automated dispensing cabinet, etc.), protected by a security system. Only pharmacy employees have access to the (inpatient pharmacy, automated dispensing cabinet, etc.) through a bar coded, badge-ID limited entry system. [Reference Pharmacy Security Policy]

6. [INSERT Split-billing detailed operations summary here, and/or reference to complete manual] Key points to address include the names and types of outpatient pharmacy ordering accounts, the process the entity uses for determining how accumulations are identified as eligible for each contract purchase, inpatient vs outpatient status, basis for replenishment order (i.e. patient administration data to the 11 digit NDC), reporting elements (frequency), plan for accurate data capture (time stamps, filters used to remove non-qualified patients, conversions from pharmacy system “units” to split-billing “units,” NDC-CDM crosswalk updates, hospital EMR-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 how accumulation is handled for lost charges/340B priced product is not available/waste, explanation of charge on dispensing vs. charge on administration and NDC match, etc.)

7. [Entity] Staff examines report in Appendix at [interval], and reports to [specify committee type] [interval].

Inventory

Physical Inventory Sample Standard Processes
[Entity] Staff (and/or external vendor) conducts a physical inventory [interval] by the process outlined [reference provided or include Appendix]. Due to the virtual inventory replacement model used, physical inventory is expected to be reduced. A material decrease in inventory value is calculated by an average cost per NDC, as detailed in [Appendix].
Transfer Sample Standard Processes

From non-340B to 340B
Transfers between non-340B and 340B inventory are only in rare circumstances, and according to the following procedure:

1. [Entity] Staff records the transaction on a borrow/loan transaction log.
2. [Entity] Staff reconciles the process by transfer back to the separated non-340B inventory area through a purchase on the borrowing area’s 340B account of the same NDC and quantity that was borrowed. Reconciliation is completed within [interval] of the original loan date.

From 340B to non-340B
Only in the case of an emergency medical situation will drugs be transferred from a 340B inventory to a non-340B inventory. In the case this happens, the following procedures will be used:

1. [Entity] Staff records the transaction on a borrow/loan transaction log.
2. [Entity] Staff reconciles the process by transfer back to the separated 340B inventory area through a purchase on the borrowing area’s non-340B account (non-GPO/WAC account) of the same NDC and quantity that was borrowed. Reconciliation is completed within [interval] of the original loan date.

Contract Pharmacy Sample Standard Processes:

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.
[Entity] uses a replenishment model for contract pharmacy services.
2. 340B eligible prescriptions may be presented to [Contract Pharmacy] via (e-prescribing, hardcopy, fax, phone). [Contract Pharmacy] verifies patient, prescriber, and outpatient clinic eligibility via (barcode, PBM eligibility file, other). Updates are made to this mechanism by [Entity] at [interval].
4. [Contract Pharmacy/Entity] Staff places 340B orders on behalf of [Entity], based upon 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. [Contract Pharmacy] Staff receives 340B replenishment order by examining the wholesaler invoice against the order, and reports inaccuracies to [Wholesaler] and [Entity] Staff within [interval].

8. Any non-replenishment 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.

9. [Contract Pharmacy] will provide a [interval] report to the [Entity]. (reference reporting section)

XI. RECOMMENDED MONITORING

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-NON-COMPLIANCE

Address the types of non-compliance that warrant a report to OPA/manufacturer, records kept, documentation, and plan for corrective action. [Reference existing hospital pharmacy compliance policy, Self-Reporting Non-Compliance Tool].

340B COMPLIANCE REVIEW

The 340B Compliance Review summarizes all activities necessary to ensure 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 upon findings.
<table>
<thead>
<tr>
<th>Activity</th>
<th>Frequency (suggested)</th>
<th>Entity Eligibility</th>
<th>No Diversion</th>
<th>No Duplicate Discount</th>
<th>GPO Prohibition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review of all OPA database information for [ENTITY], indigent care agreement with state/local government, and Medicare Cost Report (Worksheet E, Part A and Worksheet A), prior to recertification [Entity] Staff responsible:</td>
<td>Annual</td>
<td>√</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Review of 340B Self-Audit Reports (mixed-use, outpatient, contract pharmacy) [Entity] Staff responsible:</td>
<td>Monthly</td>
<td></td>
<td>√</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>Review of quarterly contract price load [Entity] Staff responsible:</td>
<td>Quarterly</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Update (minimum) of prescriber and patient eligibility files with PBM/contract pharmacy [Entity] Staff responsible:</td>
<td>Monthly</td>
<td></td>
<td></td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>3rd Party Vendor External Audit of Entity/Contract Pharmacy (optional) [Entity] Staff responsible:</td>
<td>Annual</td>
<td></td>
<td>√</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>Split-Billing software maintenance/auditing (CDM-NDC mapping, updates, etc.) [Entity] Staff responsible:</td>
<td>Daily or Weekly</td>
<td></td>
<td></td>
<td>√</td>
<td>√</td>
</tr>
</tbody>
</table>
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:

(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 the OPA, 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.