



INDIANA DEPARTMENT OF CORRECTION
340B PROGRAM POLICY AND PARTICIPATION
(Adult and Youth)

MARCH 1, 2023

TOPIC: GENERAL STATEMENT OF 340B PROGRAM POLICY AND PARTICIPATION

PURPOSE:

This document describes the policies and procedures to comply with all 340B Program requirements, ensure 340B program savings and revenue are used in a manner consistent with the intent of the 340B Program, and establish a process for regularly reviewing and updating as needed Indiana Department of Correction 340B policies and procedures.

POLICY STATEMENTS:

- The Department and all Department facilities complies with all requirements and restrictions of Section 340B of Public Health Service Act including, but not limited to, the rule against duplicate discounts or rebates under Medicaid, and the rule against transferring 340B medications to any other patient outside of the covered entity.
- The Department uses any savings generated from 340B in accordance with 340B Program Intent.
- The Department has auditing processes in place to ensure 340B Compliance.
- The Health Services Vendor incorporated continuous quality improvement activities to ensure department facilities maintain program compliance.
- The Department and the Health Services Vendor maintains readily available auditable records to monitor and ensure program compliance; and are reviewed by the Department every quarter during the Pharmacy and Therapeutics Committee. This directive will be updated and approved annually or whenever there is a change to the 340B Program requirements

BACKGROUD SOURCES:

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), Indiana Department of Correction.

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

Definitions: See Appendix A

For a full list of 340B definitions visit:

PROCEUDRES:

1. IDOH ensures its continued eligibility for the 340B Program by checking the status of its 21 grants or contracts on a semi-annual basis and updating the grant or contract as needed to prevent any gap in eligibility.
2. IDOH uses savings and revenue generated from its 340B Program participation to establish integrated health programs to expand jurisdictional surveillance for infectious diseases and facilitate development and implementation of plans to eliminate infectious diseases.
3. Additionally, use savings to increase access to prevention, diagnosis, and treatment of viral, bacterial, and fungal infectious disease consequences of drug use for Persons With Infectious Diseases in settings disproportionately affected by drug use. IDOH has systems in place to regularly check and ensure its compliance with 340B requirements that are described in detail in its 340B policies and procedures. IDOH reviews its 340B policies and procedures on an annual basis and updates them as needed to reflect changes in 340B Program requirements or operations.

Approvals:

Title	Signature	Approval/Revision Date

TOPIC: 340B Program Eligibility and Registration

PURPOSE:

The Department meets the requirements of 42 USC §256b(a)(4)(C) to be eligible for enrollment in the 340B Drug Pricing Program and registration in the 340B Office of Pharmacy Affairs Information System (OPAIS).

POLICY STATEMENTS:

The Department's basis for 340B eligibility is determined by the continuation of the in-kind services and program participation between IDOC and IDOH through the receipt of federal grant funding PS21-2103.

BACKGROUND/SOURCES:

The entities eligible for 340B pricing are set forth in statute and generally include certain hospitals and federally funded grantees. Recipients of funding under Section 318 of the Public Health Service Act are eligible for 340B pricing, including EHE (NOFO 20-2010) and PCHD (NOFO 19-1901) grantees and subgrantees. Although a 318 grantee or subgrantee may be eligible to participate in the 340B Program, it must register each health care delivery site that received the 318 funding (direct or in-kind or both) in 340B OPAIS before manufacturers will begin selling 340B drugs. HRSA has designated the first two weeks of every quarter for registering newly eligible entities with 340B discounts commencing the beginning of the following quarter.

- ♦ HRSA: <https://www.hrsa.gov/opa/eligibility-and-registration/index.html>

Definitions: See Appendix A

For a full list of 340B definitions visit:

<https://www.340bpvp.com/Documents/Public/340B%20Tools/340b-glossary-of-terms.pdf>

Procedures:

Eligibility

1. The Department meets the requirements of 42 USC §256b(a)(4)(C) to be eligible for enrollment in the 340B Program. The Department will maintain eligibility to participate in the 340B program.
 - a. The grant lists each participating facilities. A copy of the grant or contract is located at the main facility.
2. The Department has identified a contract pharmacy, eligible locations where 340B medications are administered, and eligible providers that may prescribe 340B medications.
 - a. All department facilities shall maintain readily auditable records, policies, and procedures that are consistent with the 340B statute and Social Security Act.

Registration

1. The Department understands 340B registration dates and has all of the information necessary, including the federal grant number and Notice of Funding Opportunity number, to register each eligible facility and any associated contract pharmacies in OPAIS.
2. The Department will ensure that 340B OPAIS is complete, accurate, and correct for all 340B eligible locations and contract pharmacy location(s) and ensure:
 - a. All department facilities that use 340B drugs are registered on the 340B OPAIS record.
 - b. All facility addresses, bill to ship
 - i. to location addresses, authorizing official, and primary contact information are correct and maintained when there are changes. The Authorizing Official is the Chief Medical Officer. The Primary Contact is the Deputy Commissioner of Administration.
 - c. The Department reviews 340B OPAIS records quarterly and will update when changes are made.
 - d. The Department will inform HRSA immediately if there would be any changes relating to Medicaid information.
 - e. The Department shall annually recertify information on 340B OPAIS.

Registration Dates	Effective Dates
January 1 – 15	April 1
April 1 – 15	July 1
July 1 – 15	October 1
October 1 – 15	January 1

Approvals:

Title	Signature	Approval/Revision Date

TOPIC: 340B Program Enrollment, Recertification, and Change Requests

Policy Purpose:

The Department meets the requirements of 42 USC §256b(a)(4)(C) to be eligible for enrollment in the 340B Drug Pricing Program and registration in the 340B Office of Pharmacy Affairs Information System (OPAIS).

Policy Statements:

The Department's basis for 340B eligibility is determined by the continuation of the in-kind services and program participation between IDOC and IDOH through the receipt of federal grant funding PS21-2103.

Background/Statements:

Each year, a 340B covered entity is required to annually recertify eligibility to participate in the 340B Program and continue purchasing drugs at discounted 340B prices. The covered entity's AO and PC will receive an email notification from HRSA before the recertification process begins. The recertification process requires the AO to ensure that all information in OPAIS is accurate and attest to the covered entity's compliance with 340B requirements. The covered entity can update information in OPAIS at any time during the year (not just during recertification) by submitting an online change request to HRSA for approval. HRSA: <https://www.hrsa.gov/opa/recertification/recertification.html>

Definitions:

For a full list of 340B definitions visit:

<https://www.340bpvp.com/Documents/Public/340B%20Tools/340b-glossary-of-terms.pdf>

Procedures:

Enrollment

1. The Department maintains a readily accessible fully executed pharmacy services agreement prior to registration on 340B OPAIS.
 - a. The Deputy Commissioner of Administration and Chief Legal Officer reviews the contract to verify all federal, state, and local requirements have been met.
2. The Department ensures and implements contract pharmacy oversight and ensures compliance practices are initiated and routinely performed as described later in this directive.
3. The authorizing official (Chief Medical Officer or Designee) completes the contract pharmacy registration(s) during the designated time frames set forth by HRSA and certifies online that the contract pharmacy registration request was completed.
4. The Department begins using the contracted pharmacy on or after the effective date as shown in the 340B OPAIS.

Recertification

1. Eligible entities must maintain the accuracy of the 340B OPAIS and be actively registered to

participate in the 340B Program. The Department will ensure this is maintained.

a. Registration dates are as follows:

Registration Dates	Effective Dates
January 1 – 15	April 1
April 1 – 15	July 1
July 1 – 15	October 1
October 1 – 15	January 1

2. The Department is eligible to participate in the 340B program and shall identify upcoming registration dates and deadlines.
3. The Department shall identify and update the authorizing official(s) and primary contact information when changes are made
4. The Department has readily available and accessible required documents and contacts including but not limited to the federal grant number, contract pharmacy agreements and DEA number and physical address.
5. The Department will maintain and keep OPAIS registration up to date.
6. The Department will annually recertify all information on 340B OPAIS.
 - a. The authorizing official (Chief Medical Officer) shall complete the recertification prior to set deadlines as set by HRSA. Any questions should be sent to 340b.recertification@hrsa.gov

Change Requests

1. The Department will notify HRSA immediately of any changes in the grant status or any pertinent changes dealing with eligibility.
 - a. The Department will stop purchases of 340B drugs immediately if Program Eligibility is lost due to grant status changes.
 - b. The authorizing official will complete the change request online.
 - c. Immediately when changes are identified. All change requests are expected to be reflected within two weeks of submission.
2. The Department will notify HRSA immediately of any changes made on 340B OPAIS.

Approvals:

Title	Signature	Approval/Revision Date

TOPIC: 340B Program Patient Eligibility Policy

Policy Purpose:

To ensure that IDOC and Boswell Pharmacy dispense or administer 340B drugs to eligible patients as defined by HRSA guidance.

Policy Statements:

STD (318 grantee) clinics that participate in the 340B Program may purchase 340B drugs (including prescribed contraceptives), for grantee patients that meet the patient definition criteria [61 Fed. Reg. 55156 (Oct. 24, 1996)]. The covered entity may purchase and dispense any 340B drugs associated with a service for which the covered entity is responsible, including contraceptives, to that patient, to the extent it aligns with patient definition and is consistent with the scope of the grant.

Procurement

IDOC uses contract pharmacy services. Currently, IDOC has a pharmacy service agreement with Boswell Pharmacy to dispense prescriptions for 340B eligible patients (hereinafter the “Contract Pharmacy”). Because of the scope of the current grant program, IDOC can only offer eligible inmate prescriptions through the Contract Pharmacy.

Purchasing

IDOC has wholesaler agreements and accounts with Cardinal Health for the purchase of medications priced at the 340B ceiling price or better. The Contract Pharmacy places drug orders on behalf of IDOC.

Inventory Management

1. Covered entities shall track and account for all 340B drugs to prevent diversion. The compliance committee shall ensure the proper procurement and inventory management of all 340B drugs through record keeping.
2. Physical inventory is maintained at each facility (covered entity).
3. Each facility will keep records in a separate file that includes all of the following documents for a period of seven years:
 - a. List of eligible providers including license number and NPI numbers.
 - b. 340B ID
 - c. Pharmacy Delivery Receipts/ Manifests
 - d. Copies of the CCC visit, labs, and consent for treatment
 - e. Copies of monthly medication administration records

- f. Chain of command (proof of transfer, # of meds sent, disposition etc)
- g. In a separate section: record of all internal and external reviews
- ◆ Facilities will keep separate 340B inventory from non-340B drug orders if applicable. Facilities perform daily inventory reviews and orders refills as required.
 - a. Facility to Facility Transfer of Medication - medications dispensed to patients in a home facility will transfer with the patient to the receiving facility. The home facility will remove the medication from its inventory and the receiving facility shall take custody of the medication and add to its inventory.
- 5. Weekly the department will run and send the Hepatitis C dashboard to the health services vendor. The contracted health services vendor will monitor patients through the Chronic Care program and work up and place all qualifying patients into treatment status each Friday according the HCSD 3.04A. All 340B medication orders will be reviewed and approved by the Executive Director of Physical Health. The registered pharmacy will receive orders through the EMR and will send all 340B medications ordered to the ordering facility. The facility will verify receipt of the medications by faxing/ or emailing a photocopy of the delivery receipt and scanning the barcode. The facility's health services staff shall then place the inventory onto the medication logbook and all required paperwork into the tracking folder. Executive Director of Physical Health maintains records of current National Drug Code (NDC) numbers and current pricing levels.
- 6. Wasted or refused 340B medications shall be returned to a 340B reverse distributor. Facilities will maintain any unused medications on site until ready for return. Returns will be completed at the Central office level with supervision of the compliance committee. Executive Director of Physical Health shall ensure that all updated NDC codes and pricing are available to the reverse distributor.

Approvals:

Title	Signature	Approval/Revision Date

TOPIC: 340B Contract Pharmacy Arrangements and Oversight

Policy Purpose:

To ensure that 340B contract pharmacy arrangements comply with applicable 340B Program requirements and that [Covered Entity] retains responsibility for such compliance.

Policy Statements:

- IDOC has a written arrangement with each contract pharmacy to dispense 340B drugs to IDOC's 340B eligible patients.
- IDOC ensures that its contract pharmacies comply with all applicable 340B Program requirements and IDOC retains responsibility for non-compliance.

Background/Statements:

A covered entity may contract with a pharmacy vendor or multiple pharmacy vendors to dispense medications to 340B eligible patients on the covered entity's behalf. HRSA requires these arrangements to be in writing and for each contract pharmacy to be registered in OPAIS. Covered entities retain full responsibility for contract pharmacy compliance with all 340B requirements, including the prevention of drug diversion and duplicate discounts. Covered entities are required to independently audit its contract pharmacy arrangements on an annual basis and maintain auditable and readily available records demonstrating 340B compliance. Covered entities often engage third-party administrators to help manage their contract pharmacy arrangements.

- ◆ NCSD: <https://www.ncsddc.org/resource/340b-and-ending-the-epidemics/> (select 340B Contract Pharmacy Toolkit)
- ◆ HRSA: <https://www.hrsa.gov/opa/implementation/contract/index.html>
- ◆ HRSA: [HRSA Guidance on contract pharmacy arrangements](#)
- ◆ Apexus: <https://www.340bpvp.com/resource-center/340b-tools> (Click on "Grantees", then select "Contract Pharmacy Medicaid Carve-in Checklist" or "Self- Audit: Contract Pharmacy")

Definitions:

For a full list of 340B definitions visit:

<https://www.340bpvp.com/Documents/Public/340B%20Tools/340b-glossary-of-terms.pdf>

Procedures:

Pharmacy Operations

1. The Department is responsible for ensuring that the contract pharmacy operations comply with all 340B requirements. The Department has secured a fully executed documented with

a contract pharmacy and is on record with OPAIS and HRSA as required. The Department has registered each eligible facility with the contracted pharmacy prior to the initiation of 340B medications.

2. The Department will provide oversight of the contract pharmacy to ensure ongoing compliance and shall routinely perform internal review of the contract pharmacy to include review of written prescriptions, patient is at a Department Facility, the health services vendor updates eligible prescribers routinely, and that the appropriate NDC code is ordered and supplied.
3. The Department is responsible for securing independent audits of the contract pharmacy and the eligible facilities annually. Independent audits shall include at a minimum the following information: 340B eligibility, 340B registration, documented policy and procedures, inventory, ordering, and record keeping practices for all 340B accounts, and testing of claims samples to determine any instance of diversion.
4. 340B eligible prescriptions are sent to the contracted pharmacy each Thursday after review and approval by the Executive Director of Physical Health and all orders are sent via EMR. Contract pharmacy verifies patient, prescriber, and patient eligibility.
5. Contract pharmacy orders medications from identified wholesaler, verifies quantity ordered and received, and dispenses medication to the ordering facility.
6. Contract pharmacy notifies the Department if they do not receive the replenishment order within time frame of original order. The Department receives and reviews invoices from the Contract Pharmacy and the wholesaler.
7. The Department and the Contract Pharmacy maintains auditable records to ensure program integrity.
8. Contract pharmacy shall send monthly reports as requested by the Department.
9. The P&T Committee reviews all audit and internal review results and maintains records of all 340B related transactions for a period of 7 years in a readily available and auditable format.

Approvals:

Title	Signature	Approval/Revision Date

TOPIC: 340B Program Compliance, Material Breach, Self-Disclosure

Policy Purpose:

To ensure IDOC compliance with 340B Program requirements.

Policy Statements:

- IDOC retains auditable records demonstrating compliance with 340B Program requirements.
- IDOC regularly monitors 340B Program operations and compliance at all its 340B qualified health care delivery sites and Boswell Pharmacy and is able to identify instances of material breach.
- IDOC contacts the relevant parties, as appropriate, if instances of 340B noncompliance are discovered in accordance with federal, state, and local law.
- IDOC has a definition of material breach of 340B Program requirements triggering HRSA's self-disclosure requirements.
- IDOC informs HRSA of instances of material breach, as required by 340B Program rules.

Background/Statements:

Covered entities are required to comply with all 340B Program requirements, including the prevention of drug diversion and duplicate discounts. Since 2012, HRSA has been conducting routine audits of covered entities in its attempt to improve the oversight and integrity of the 340B Program. Each year, HRSA has increased the number of audits of covered entities. HRSA recommends that covered entities have 340B policies and procedures that address 340B compliance and that they conduct internal audits on a regular basis to verify compliance. If a covered entity discovers any material breach of 340B Program requirements, it is required to implement a corrective action plan to prevent additional instances of non-compliance and report (or self-disclose) any such finding(s) to HRSA.NCSD: <https://www.ncsddc.org/resource/340b-and-ending-the-epidemics/> (select HRSA Audit Overview and Checklist)

- ◆ HRSA: 340B Peer-to-Peer Program, 340B Compliance Improvement Guide
- ◆ HRSA: Program Integrity/Audits - <https://www.hrsa.gov/opa/program-integrity/index.html>
- ◆ HRSA: Entity Self-Disclosure - <https://www.hrsa.gov/opa/self-disclosures/self-disclosure.html>
- ◆ Apexus: HRSA 340B Audit Overview
- ◆ Apexus: Sample HRSA 340B Audit Data Request
- ◆ Apexus: <https://www.340bpvp.com/resource-center/340b-tools> (Click on "Grantees", then select "Self-Disclosure to HRSA and Manufacturer Template" or "Establishing Material Breach Threshold")

Definitions:

For a full list of 340B definitions visit:

Procedures:

340B Monitoring

The Department is responsible for contacting HRSA as soon as possible if there is any noncompliance or material breach by process of the program. The compliance committee shall report any internal CQI studies, audits, or external audits that fall below 100% compliance and remain non-correctable within one quarter of review to ED of PH at time of deficiency. The CMO or designee shall report the noncompliance to the HRSA website and applicable manufacturers. Facility staff that feel there is a deficiency shall report to the Statewide Director of Nursing (SWDON) within 24 hours of noted concern. The SWDON shall report the concern to the compliance committee as outlined above.

Material Breach

Material Breach is defined as: a violation or occurrence of non-compliance that exceeds 10% of the total prescription volume of all IDOC facilities in a given month, or the impact to any one manufacturer exceeds 10%. Any such violation requires self-disclosure.

Self Disclosure

A violation identified through internal/external audit(s) that meets this threshold and cannot be self-corrected within 180 days after discovery of the violation, and self-disclosure is required, the Authorizing Official and Primary Contact will complete the self-disclosure document. In addition, IDOC will self-report violations deemed to be intentional or substantial in nature to HRSA at 340Bserlfdisclosure@hrsa.gov.

- a. The ED of PH shall notify the CMO and the Deputy Commissioner of Administration within 24 hours if pricing discrepancy is noted on the billing invoices as reviewed from the wholesaler or the contracted pharmacy.
- b. The Department and each of the covered entities (facilities) shall keep readily available records of all notifications and compliance activities.

Reporting

The Department and all Department Facilities shall maintain readily accessible auditable records that demonstrate compliance with 340B Program requirements for a period of 7 years.

Applicability

This Health Care Services Directive is applicable to all facilities providing Health Services to incarcerated adults.

Approvals:

Title	Signature	Approval/Revision Date

TOPIC: 340B Program Training and Education**Policy Purpose:**

This document describes the policies and procedures to comply with all 340B Program requirements, ensure 340B program savings and revenue are used in a manner consistent with the intent of the 340B Program, and establish a process for regularly reviewing and updating as needed Indiana Department of Correction 340B policies and procedures.

Policy Statements:

The Department and all Department facilities engages in training and education of staff that complies with the training and education requirements of Section 340B of Public Health Service Act to sustain and maintain the integrity of the 340B program and eligibility to participate as a covered entity.

Background/Statements:

Each year, a 340B covered entity is required to annually recertify eligibility to participate in the 340B Program and continue purchasing drugs at discounted 340B prices. The covered entity's AO and PC will receive an email notification from HRSA before the recertification process begins. The recertification process requires the AO to ensure that all information in OPAIS is accurate and attest to the covered entity's compliance with 340B requirements. The covered entity can update information in OPAIS at any time during the year (not just during recertification) by submitting an online change request to HRSA for approval.

Definitions:

For a full list of 340B definitions visit:

<https://www.340bpvp.com/Documents/Public/340B%20Tools/340b-glossary-of-terms.pdf>

Procedures:**Training & Education**

1. Program integrity and compliance are the responsibility of all key stakeholders. Ongoing education and training are required to ensure knowledge at all levels to ensure program integrity.
2. The compliance committee will oversee the training program to validate for current practices and the contracted Health Services vendor shall implement a training schedule to include all new staff and provide yearly updates.
3. The compliance committee will ensure annual verification of 340B Program Competency. All training and education records are maintained in the contracted health services employee files.

Approvals:

Title	Signature	Approval/Revision Date

APPENDIX
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340B Self-Auditing Tool	Appendix B

APPENDIX A

DEFINITIONS:

CMO: Chief Medical Officer

ED of PH: Executive Director of Physical Health

IDOH: Indiana Department of Health

IDOC: Indiana Department of Corrections

SWDON: Statewide Director of Nursing

340B Program Policy and Procedure Review	
1. Document the parent 340B ID	
2. Document the parent covered entity name	
3. Document the parent physical address	
4. Document the date of the LAST policy and procedure self-audit	
5. Document the completion date of THIS policy and procedure self-audit	
6. Document name and title of the individual completing this self-audit	
7. Signature of reviewer	
8. Summary of results:	

2. Actions to be taken:

Assessment Question	Yes	No	N/A	Unsure
<p>1. Do the Department policies and procedures describe its registration/recertification process?</p> <p>Document name of the policy and procedure:</p> <p>Document the section or page number that includes the following elements:</p> <ul style="list-style-type: none"> a. Process for ensuring that 340B OPAIS is up to date and accurate for primary site (and off-site locations, if applicable) b. Process for ensuring 340B-eligible grant designations (if applicable) c. Process for ensuring that 340B OPAIS is up to date and accurate for contract pharmacy (if applicable) d. Processes include frequency of regular reviews, how review is documented, and the timely update of 340B OPAIS records <p>Date last reviewed/updated/approved:</p> <p><i>If response is “No,” “N/A,” or “Unsure,” explain:</i></p>				
<p>2. Do the Department policies and procedures describe its process for determining eligible sites?</p> <p>Document name of policy and procedure:</p> <p>Document the section or page number that includes the following elements to address how eligibility of each service site that uses 340B drugs is determined:</p> <ul style="list-style-type: none"> a. Site must be one of Department’s 21 Correctional Facilities b. Registered on 340B OPAIS as a grantee <p>Date last reviewed/updated/approved:</p> <p><i>If response is “No,” “N/A,” or “Unsure,” explain:</i></p>				

Assessment Question	Yes	No	N/A	Unsure
<p>3. Do the Departments policies and procedures describe its procurement process?</p> <p>Document name of the policy and procedure:</p> <p>Document the section or page number that includes the following elements:</p> <ul style="list-style-type: none"> a. Identification of all accounts used for purchasing medications at the primary site b. Identification of all accounts used for purchasing medications at the off-site locations (if applicable) c. Identification of all accounts used for purchasing medications at the contract pharmacy (if applicable) d. Process for generating purchase orders in each environment <p>Date last reviewed/updated/approved:</p> <p><i>If response is "No," "N/A," or "Unsure," explain:</i></p>				
Assessment Question	Yes	No	N/A	Unsure
<p>4. Do the Department's policies and procedures describe its process for prevention of GPO Prohibition violations? (Applies to disproportionate share hospitals [DSH], children's hospitals [PED],</p>			XX	

and free-standing cancer hospitals [CAN])

Document name of the policy and procedure:

Document the section or page number that includes the following elements:

- a. Definition of “covered outpatient drugs”
- b. Process for handling self-negotiated contracts for individual entities and integrated delivery networks
- c. Process for handling-controlled substance ordering system (CSOS) orders

Date last reviewed/updated/approved:

If response is “No,” “N/A,” or “Unsure,” explain:

Assessment Question	Yes	No	N/A	Unsure
5. Do the hospital’s/grantee’s policies and procedures define any exclusions to the definition of covered outpatient drugs (e.g., bundled			X	

drugs, inpatient drugs, or orphan drugs) if applicable?

Document name of the policy and procedure:

Document the section or page number that includes the following elements:

3. Definition of a covered outpatient drug (consistent with section 1927(k) of the Social Security Act)
4. Exclusion list of covered outpatient drugs and procurement process for these non-covered drugs

Date last reviewed/updated/approved:

If response is “No,” “N/A,” or “Unsure,” explain:

Assessment Question	Yes	No	N/A	Unsure
<p>6. Do the Department’s policies and procedures describe its process for conducting oversight of its contract pharmacy operations?</p> <p>Document name of the policy and procedure:</p> <p>Document the section or page number that includes the following elements:</p> <ol style="list-style-type: none">a. Process used for internal auditsb. Process used for independent auditc. Processes include methodology, frequency, documentation, and process for resolving <p>Date last reviewed/updated/approved:</p>				

If response is “No,” “N/A,” or “Unsure,” explain:

Assessment Question

Yes

No

N/A

Unsure

7. Do the Department’s policies and procedures include inventory management procedures in place to prevent diversion of 340B drugs to ineligible patients?

Document name of the policy and procedure:

Document the section or page number that includes the following elements:

- a. Inventory process is outlined from the receipt of the medication to the dispensation/administration of the medication
- b. Routine inventory counts
- c. Reconcile inventory counts with inventory system
- d. Adjusting and reconciling variances (including documentation of outcome)

Date last reviewed/updated/approved:

If response is “No,” “N/A,” or “Unsure,” explain:

Assessment Question

Yes

No

N/A

Unsure

8. Do the Department's policies and procedures describe its process to track and account for all 340B drugs via accumulation in a virtual replenishment model?

Document name of the policy and procedure:

Document the section or page number that includes the following elements:

- a. Inventory process outlined from the receipt of the medication to the dispensation/administration of the medication
- b. Accumulator software settings criteria
- c. Reconciliation of accumulator counts with purchases and dispensations to identify variances
- d. Accumulator manual adjustment criteria (e.g., unused medication, return-to-stocks, outdated drug destruction)
- e. Replenishment with an 11-digit to 11-digit National Drug Code (NDC) number

Date last reviewed/updated/approved:

If response is "No," "N/A," or "Unsure," explain:

Assessment Question	Yes	No	N/A	Unsure
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9. Do the Department's policies and procedures describe its process for handling accumulations and replenishment at an 11-digit NDC level?

Document name of the policy and procedure:

Document the section or page number that includes the following elements:

- a. Use of charge description master (CDM) to NDC crosswalk
- b. Maintaining auditable records to demonstrate proper accumulation in a replenishment model

Date last reviewed/updated/approved:

If response is “No,” “N/A,” or “Unsure,” explain:

Assessment Question

Yes

No

N/A

Unsure

10. Do the Department’s policies and procedures describe its process for the prevention of diversion at the parent entity and its off-site locations?

Document name of the policy and procedure:

Document the section or page number that includes the following elements to address the eligibility determination system(s), including how:

- a. A 340B drug order/prescription is generated from an eligible service location
- b. Outpatient status is defined
- c. Changes in patient status from outpatient to inpatient affect the use of 340B drugs
- d. A patient health care record is defined, including which data in the health care record determine eligibility
- e. Provider eligibility is determined, along with a process for handling changes in provider eligibility
- f. It is determined that the responsibility for care remains with the hospital/grantee (including a referral process, if applicable)
- g. Service within the scope of grant is determined (grantees only)
- h. Process is used for accounting for destroyed or wasted drugs not administered to the patient

Date last reviewed/updated/approved:

If response is “No,” “N/A,” or “Unsure,” explain:

Assessment Question

Yes

No

N/A

Unsure

11. Do the Department's policies and procedures describe its process for monitoring the 340B split-billing software program to ensure the prevention of diversion at the parent entity and its off-site locations?

Document name of the policy and procedure:

Document the section or page number that includes the following elements:

- a. Type of self-auditing activities
- b. Frequency of self-auditing activities
- c. Maintenance of auditable records, including description of what constitutes an auditable record in both automated and manual processes

Date last reviewed/updated/approved:

If response is "No," "N/A," or "Unsure," explain:

Assessment Question	Yes	No	N/A	Unsure
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12. Do the Department's policies and procedures describe its process for the prevention of diversion at its contract pharmacy(ies)?

Document name of the policy and procedure:

Document the section or page number that includes the following elements to address the eligibility determination system(s), including how:

- a. A 340B drug prescription is generated from an eligible service location
- b. A patient health care record is defined, including which data in the health care record determine eligibility
- c. Provider eligibility is determined, along with a process for handling changes in provider eligibility
- d. It is determined that the responsibility for care remains with the hospital/grantee (including a referral process, if applicable)
- e. Service within the scope of grant is determined (grantees only)

Date last reviewed/updated:

If response is "No," "N/A," or "Unsure," explain:

Assessment Question	Yes	No	N/A	Unsure
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13. Do the Department's policies and procedures describe its process for monitoring the 340B split-billing software program of its contract pharmacy to ensure the prevention of diversion?

Document name of the policy and procedure:

Document the section or page number that includes the following elements:

- a. Process for performing self-audits
- b. Frequency of self-auditing activities
- c. Maintenance of auditable records

Date last reviewed/updated:

If response is "No," "N/A," or "Unsure," explain:

Assessment Question	Yes	No	N/A	Unsure
<p>14. Do the Department's policies and procedures describe its process used to prevent duplicate discounts at entity and off-site outpatient facilities?</p> <p>Document name of the policy and procedure:</p> <p>Document the section or page number that includes the following elements:</p> <ul style="list-style-type: none"> a. State Medicaid agency requirements for the prevention of duplicate discounts for both Medicaid fee-for-service (FFS) and Medicaid managed care organization (MCO), including multiple state Medicaid agencies, if applicable b. List of all Medicaid provider number(s) /NPI number(s) used to <i>carve in</i> 340B drugs in the Medicaid Exclusion File at each registered site. The data included in the Medicaid Exclusion File are provided by covered entities for drugs billed under Medicaid FFS and does not apply to Medicaid MCOs. c. Process used to prevent duplicate discounts for each Medicaid provider number/NPI number listed in the Medicaid Exclusion File d. Process used to ensure that 340B drugs are <u>not</u> billed to Medicaid for each Medicaid provider number/NPI number <u>not</u> listed in the Medicaid Exclusion File <p>Date last reviewed/updated/approved: <i>If response is "No," "N/A," or "Unsure," explain:</i></p>				
<p>15. Do the Department's policies and procedures describe its process used to prevent duplicate discounts at its contract pharmacy(ies)?</p>				

Document name of the policy and procedure:

Document the section or page number that includes the following elements:

- a. Process used to carve out Medicaid FFS *or* carve in Medicaid FFS, including the listing of a carve-in contract pharmacy arrangement on 340B OPAIS
- b. Process used to prevent duplicate discounts for Medicaid MCO claims based on state policy

Date last reviewed/updated/approved:

If response is “No,” “N/A,” or “Unsure,” explain:

Assessment Question	Yes	No	N/A	Unsure
<p>16. Do the Department’s policies and procedures describe how the hospital/clinic defines a material breach and the process for when and how it would self-disclose?</p> <p>Document name of the policy and procedure:</p> <p>Document the section or page number that includes the following elements:</p> <ol style="list-style-type: none">a. Definition of noncompliance material breach<ol style="list-style-type: none">i) Established threshold for what would constitute a material breach of compliance that would require self-disclosure is establishedb. Assignment of responsibility for material breach assessment<ol style="list-style-type: none">i) Articulates when, how, and by whomc. Process for self-disclosure<ol style="list-style-type: none">i) How is self-disclosure to HRSA and/or manufacturers accomplished?ii) How are corrective action plans submitted, approved, and completed?d. Maintenance of records of materiality assessments and violations <p>Date last reviewed/updated/approved:</p> <p><i>If response is “No,” “N/A,” or “Unsure,” explain:</i></p>				

APPENDIX B

340B Self Auditing Tool

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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APPLICABILITY:

This Policy Manual is applicable to all Department Facilities including Youth and Adult.

Kristen Dauss, MD
Chief Medical Officer

Date