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Legal References (includes but is not limited to)  IC 11-8-2-5 IC 34-4-12.6 Public Law 102-585, Section 602	Related Policies/Procedures (includes but is not limited to)  01-02-101 01-02-106	Other References (includes but is not limited to)  340B Guidelines 340B Policy Guidelines
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I. PURPOSE:

This Health Care Services Directive (HCSD) describes the policies and procedures the Department utilizes to oversee the 340B program operations, oversight of the contracted 340B pharmacy, and maintain a compliant 340B program.

II. 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 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), the Indiana Department of Correction:

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

III. 340B POLICY STATEMENTS:

1. The Department and all Department facilities shall comply 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.
2. The Department uses any savings generated from 340B in accordance with

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340B Program Intent.

3. The Department has auditing processes in place to ensure 340B Compliance.
4. The Health Services Vendor has incorporated continuous quality improvement activities to ensure department facilities maintain program compliance.
5. The Department and the Health Services Vendor maintains readily available auditable records to demonstrate program compliance, and are reviewed by the Department every quarter during the Pharmacy and Therapeutics Committee.
6. This HCSD shall be reviewed, updated if necessary, and approved annually or whenever there is a change to the 340B Program requirements.

#### IV. DEFINITIONS:

For a full list of definitions used in this HCSD visit:

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

- A. **340B DRUG PRICING PROGRAM:** The federal drug discount program authorized under section 340B of the Public Health Service Act and established by Congress under the Veterans Health Care Act of 1992 (Public Law 102-585, codified at 42 USC § 256b). The 340B program requires drug manufacturers to enter into pharmaceutical pricing agreements with the HHS Secretary, under which manufacturers agree not to sell covered outpatient drugs to covered entities above 340B ceiling prices.
- B. **CONTRACT PHARMACY:** A pharmacy that enters into an agreement with a covered entity to provide services to the covered entity's patients, including dispensing entity-owned 340B drugs. Contract pharmacies must register for the 340B Program and be listed on the 340B OPAIS prior to dispensing 340B drugs on a covered entity's behalf. In addition, a contract pharmacy must have a written, signed contract pharmacy agreement in place with the covered entity prior to registering that pharmacy with the 340B Program. HRSA recommends that the written agreement include all essential elements of the contract pharmacy guidelines (75 Fed. Reg. 10272 [March 5, 2010]). Failure to have the contract pharmacy correctly listed in the 340B OPAIS may be cause for removal of the contract pharmacy from the 340B Program.
- C. **COVERED ENTITY (CE):** A facility or a program that is listed in the 340B statute as eligible to purchase drugs through the 340B Program and appears on 340B OPAIS.

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- D. **ELIGIBLE PATIENT:** Any patient or youth that resides in a Department Facility and receives care from an eligible provider.
- E. **HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA):** An agency of the U.S. Department of Health and Human Services, HRSA is the primary federal agency for improving access to health care services for people who are uninsured, isolated, or medically vulnerable.
- F. **IDOH:** Indiana Department of Health
- G. **OFFICE OF PHARMACY AFFAIRS INFORMATION SYSTEM (OPAIS):**  
The system that provides access to CE and manufacturer records, user accounts, change requests, recertification, and registrations.
- V. **GUIDELINES:**
- The Department and all Department facilities shall meet the requirement of the 340B Program as outlined in the 340B Policy Manual. All Department facilities shall utilize this directive to develop site specific operations, maintain readily auditable records, and ensure 340B program compliance.
- VI. **PROCEDURES:**
- A. **Patient Eligibility and Eligible Providers**
- To be eligible for inclusion in the 340B Program, a patient must reside in a Department facility, demonstrate an established relationship with eligible providers, and Department facilities shall maintain the Electronic Medical Record (EMR) for all patient health care needs including HCV treatment. Each participating Department facility shall maintain records of all eligible patients that have been or will be enrolled in the 340B program for a period of no less than 7 years. Records can be stored in roll over records as per facility management and in accordance with Policy and Administrative procedure 01-04-104, "Offender Records."
- Eligible providers are those that are employed or are contracted with the Department's Health Services Vendor ensuring that the care provided is maintained within Department facilities. All participating Department facilities shall keep active records of all eligible providers. The Health Services Vendor shall submit quarterly an updated roster of eligible providers to the Executive Director of Physical Health and to the contracted pharmacy to ensure program compliance.
- B. **Program Integrity and Compliance**

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The Department and all Department facilities shall ensure that program integrity is maintained. The Department shall accomplish this through the Pharmacy and Therapeutics Committee (P&T). The P&T Committee shall meet quarterly to discuss program requirements and compliance studies. The Department will conduct quarterly audits at each of the participating facilities and report findings to the P&T Committee and the Executive Director of Physical Health. The Health Services vendor shall also determine internal continuous quality improvement (CQI) studies to be completed no less than quarterly. All internal study results will be reported through the P&T Committee and discussed quarterly. For all audits, internal and external, and internal reviews any area that was noted to be deficient shall have a corresponding corrective action plan.

The Health Services Vendor's statewide CQI coordinator shall design and implement internal CQI activities and work with the P&T Committee to review compliance. All findings or deficiencies shall be reported to the Executive Director of Physical Health within 48 hours of finding. Corrective action plans shall be established and implemented with 72 hours of initial finding and monitored until 100% compliance is reached. The Health Services Vendor's P&T committee, Health Services Vendor's statewide CQI coordinator, or Executive Director of Physical Health shall report all CQI studies, internal, or external audits that fall below 100% compliance and remain non-correctable within one quarter of review to the Chief Medical Officer (CMO) or designee within 24 hours of found deficiency. The authorizing official shall report the compliance to the HRSA website or to the manufacturer. If a facility DON/HSA feel that there is a deficiency or have questions or concerns those should be shared with the state wide DON within 24 hours of noted concern. The Health Services Vendor's state wide DON shall report concerns to the P&T committee and the Executive Director of Physical Health.

The Health Services Vendor's statewide pharmacy director shall continuously monitor compliance practices at the site level, ensure that appropriate safeguards and practices are in place, and participate in reviews of the quarterly audits. The Department and all Department facilities shall maintain readily auditable records that demonstrate compliance with 340B program requirements for no less than 7 years.

#### C. 340B Program Purchasing, Procurement, and Inventory Management

1. The Department and all its facilities shall ensure the proper purchase, procurement, and inventory management of 340B medications to prevent diversion and duplicate discounts. All 340B medications shall be ordered in the electronic medical record (EMR) as with any other medications in

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accordance with HCSD 3.04A, “Management of Hepatitis C.” The Department utilizes a contract pharmacy and has agreements with a wholesaler to provide 340B medications in regard to Hepatitis C treatment. The contract pharmacy places medication orders with the wholesaler on behalf of the Department. The contract pharmacy will ship medications to the participating facility that will be administering medications.

- a. Weekly the Department will send a Hepatitis C dashboard to the Health Services Vendor to review all patients with an active diagnosis.
- b. Each week the Health Services Vendor shall review and prepare a list of patients that are eligible and ready to start receiving 340B medications.
- c. Weekly the infection control nurse compiles a list of patients that are ready to start treatment and forwards it to the Executive Director of Physical Health or designee for review.
- d. The Executive Director of Physical Health reviews all patients and provides an approval or request for more information. This review consists of verification of patient facility, earliest possible release date (ERPD), consent for treatment obtained, and that labs were obtained.
- e. Approval and list of patients are forwarded to the contracted pharmacy and the statewide infection control nurse.
- f. Orders for the medication are placed into the EMR for a start date in 14 days by the eligible provider.
- g. Contracted pharmacy will place an order with the wholesaler.
- h. The contracted pharmacy will send prescriptions to Department facilities where the eligible patients are housed.

## 2. Inventory Management

- A. Physical inventory is maintained at all participating facilities. Each facility shall keep a running count of medication notating each of the 84 doses that constitute a complete treatment. The licensed Health Services staff administering the 340B medications shall sign out each dose on the corresponding patient count sheet. Counts shall be verified weekly by the Director of Nursing (DON) or designee. The DON or designee shall

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complete a weekly review of all patients prescribed 340B medications to verify the physical inventory. All 340B medications shall be stored separately from all non-340B medications. All facilities shall perform daily inventory counts and review refill orders as required. 340B medication refills shall be electronically forwarded to the contracted pharmacy when a patient is down to the last nine pills as this allows the contracted pharmacy to obtain the supply necessary from the wholesaler.

Each facility shall maintain 340B Binders that include but not limited to the following documents:

- 1) List of eligible providers including license number and NPI numbers to be updated quarterly and as needed based on provider changes;
- 2) 340B ID of the participating facility;
- 3) All pharmacy manifest and delivery receipts;
- 4) Copies of Chronic Care Clinic visits, labs, and consent for treatment;
- 5) Copies of monthly medication administration records (MARs);
- 6) Chain of command if patient has transferred to or from a Department facility during treatment; and,
- 7) In a separate section keep all compliance activities (CQI, audits, DON weekly tool/sharps count, pharmacy audits, etc.).

#### B. Transfer of Medications

- 1) When a patient from one Department facility transfers to another Department facility while receiving 340B medications, the facilities must ensure that a chain of command form is utilized. The sending facility must confirm the current count of all of the patient's 340B medications on site and take a picture of the current stock, make a copy of the current count sheet, and notate the number of the doses that shall accompany the patient. The sending facility shall also complete the transfer sending document in the EMR notating how many doses of medication were sent with the patient, and the sending facility shall also copy all information in the patient's 340B binder to provide the receiving facility with the required documents. Once the patient has transferred, the sending facility shall transfer all binder documents into the historical binder for record keeping.

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The receiving facility shall verify all medication and documents received and start an active file for the newly received patient.

- 2) When a patient is released from a Department facility, all remaining doses shall be sent with the patient. This shall be documented in the count sheet noting that the patient has been released. The transfer sending screen shall be updated noting how many doses and indicate whether additional doses were provided at the time of release. Wrap around services shall be secured through Transitional Health Services in accordance with HCSD 3.04A, “The Management of Hepatitis C.” The patient documents stored in the active 340B binders shall be moved to the inactive binder and stored for a period of no less than 7 years. All release medications shall be handled according to the applicable policy and procedures. Early refills or extra doses may not be purchased via the 340B program to account for releases.

#### C. Unused 340B Medications

340B medication that has been refused or discontinued must be maintained on site until preparation to send to a reverse distributor can be arranged. No 340B medication shall be returned to the pharmacy or wholesaler, and 340B medications cannot be reused or repurposed into clinic stock. All excess medications shall be maintained at a participating facility until a return can be arranged. Each facility shall maintain on record all inactive prescriptions and maintain the daily inventory. The Health Services Vendor’s statewide DON shall work with the Executive Director of Physical Health to gather inventory and return to a reverse distributor.

The Health Services Vendor’s statewide DON shall maintain an active inventory of all unused medications along with all accompanying documents, such as copies of count sheets that will leave a facility with a count of zero for inactive patients. Once the return is ready a copy of the inventory sent to reverse distributor shall be forwarded to the Executive Director of Physical Health for record keeping.

The Executive Director of Physical Health shall ensure that the reverse distributor has access to updated NDC numbers.

#### D. Material Breach and Self Disclosure

The Department is responsible for contacting HRSA as soon as possible if there is any noncompliance or material breach by process of the

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program. A material breach for this directive is defined as a violation or occurrence of non-compliance that exceeds 10% of the total prescription volume of all Department facilities in a given month, or the impact to the wholesaler exceeds 10%. Any such violation shall require self-disclosure.

A violation identified through internal/external audits that meets the above threshold and cannot be self-corrected within 180 days after discovery of the violation, self-disclosure is required. The authorizing official and the primary contact will complete the disclosure as outlined in the 340B Policy Manual.

#### E. Training and Education

The Department shall provide training and education to all facility staff including those that do not have direct involvement with the program. Program integrity and compliance are the responsibility of all key stakeholders. Ongoing education and training are key components of a successful program. The RN Educator with the Health Services Vendor shall implement a training program that will be available to all current and new staff. Yearly training with post-test shall be implemented at every Department facility and for all Health Services Vendor's physical health staff. All training and education activities shall be maintained in the Health Services employee files.

#### VII. APPLICABILITY:

This HCSD is applicable to all facilities housing and providing health services to incarcerated adults.

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signature on file  
Adrienne Bedford, MD  
Chief Medical Officer

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1/30/2025  
Date