DIVISION OF ADULT INSTITUTIONS **POLICY AND PROCEDURES**	**DAI Policy #:** 500.80.28	**Page** 1 of 10
	Original Effective Date: 01/11/21	**New Effective Date:** 01/11/21
	Supersedes: N/A	**Dated:** N/A
	Administrator's Approval: Makda Fessahaye, Administrator	
	Required Posting or Restricted: [X] **Inmate** [X] **All Staff** [ ] **Restricted**	
Chapter: 500 Health Services		
Subject: 340B Compliance		

POLICY

All Division of Adult Institution facilities shall maintain written policies and procedures that oversee 340B Program operations and maintain a compliant 340B Program.

REFERENCES

Public Law 102-585, Section 602
Section 340B of the Public Service Act and Notices
340B Policy Releases
Wisconsin Statutes s. 302.38 – Medical Care of Prisoners

DEFINITIONS, ACRONYMS AND FORMS

340B Covered Entity – 340B covered entities are facilities/programs that are listed in the 340B statute as eligible to purchase medications through the 340B Program and appear on 340B OPAIS.

340B Drug Pricing Program (340B Program) – Section 340B of the Public Health Service (PHS) 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 that manufacturers may charge certain covered entities for covered outpatient medications. The resulting program is the 340B Drug Pricing Program.

340B – Eligible Patient – An individual is a patient of a covered entity (with the exception of state-operated or state-funded AIDS medication purchasing assistance programs) only if:

1. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care;
2. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity; and
3. The individual receives a health care service or range of services from the covered entity that is consistent with the service or range of services for which grant funding has been provided to the entity either directly or in-kind.

An individual will not be considered a patient of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of

a medication or medications for subsequent self-administration or administration in the home setting.

Authorizing Official – BHS Director of Healthcare Administration or designee responsible for maintaining 340B eligibility.

BHS – Bureau of Health Services

CPS – Central Pharmacy Services

DAI – Division of Adult Institutions

HRSA – Health Resources and Services Administration

HSU – Health Service Unit

OPA – Office of Pharmacy Affairs.

OPAIS – Office of Pharmacy Affairs Information System. The 340B registration and pricing databases

Primary Contact – BHS Central Pharmacy Director/designee

PROCEDURE

I. General Guidelines

A. 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 medications purchased under 340B to anyone other than a patient of the DOC shall be adhered to.

B. Any savings generated from 340B in accordance with 340B Program shall be used for the intent by expanding treatment for hard to reach populations, and be used for further expansion of programs for DOC justice-involved populations.

C. Auditable records shall be maintained demonstrating compliance with the 340B Program and to maintain systems, mechanisms, and internal controls to reasonably ensure ongoing compliance with all 340B requirements.

II. Eligibility for 340B Program

A. The DOC DAI is a sub recipient of in-kind services from the Wisconsin Division of Public Health STD Control Section here after known as (DPH).

B. A Memorandum of Understanding (MOU) outlining the in-kind services and program participation between the DOC and DPH shall be established and maintained.

C. DAI shall maintain auditable records, policies, and procedures related to the definition of covered outpatient medication that is consistent with the 340B statute and Social Security Act.

D. The authorizing official or designee shall annually recertify DAI information on 340B OPAIS.

E. For an individual to receive a 340B medication, the covered entity shall meet all the following requirements for the definition of an eligible patient by HRSA which has the following main three requirements:
   1. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care.
   2. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity.
   3. The individual receives health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or services in-kind has been provided to the entity.

III. Registration in the 340B Program

A. The authorizing official shall enroll DAI facilities in the 340B OPAIS in order to participate in the 340B Program.

B. The authorizing official shall monitor registration dates and deadlines.

C. The authorizing official shall update OPAIS with authorizing official and primary contact information.

D. The authorizing official shall annually recertify DAI information on 340B OPAIS.

IV. Changes to Division of Adult Institution Information in 340B OPAIS:

A. The authorizing official or primary contact shall notify HRSA immediately of any changes to Division of Adult Institution's grant status or other such changes within the Wisconsin Department of Corrections, Division of Adult Institutions.
   1. CPS will stop the purchase of 340B medications as soon as DAI facilities loses 340B Program eligibility (i.e. through a grant status change).
   2. DOC authorizing official will complete the online change request as soon as a change in eligibility is identified.

B. The authorizing official or primary contact will notify HRSA immediately of any changes to DAI information on 340B OPAIS.

V. Prevention of Duplicate Discounts

A. The Wisconsin DOC shall not seek reimbursement from Medicaid for the cost of medications obtained under the 340B program. Medicaid shall not pay for the cost of medication prescribed to an incarcerated individual when the medication is obtained under the 340B program**.**

VI. 340B Program Roles and Responsibilities

A. The Authorizing official shall be designated to oversee the 340B program.
   1. Responsible as the authorizing official in charge for the compliance and administration of the program.
   2. Responsible for attesting to the compliance of the program through recertification.

B. The Primary contact shall be designated to communicate with and receive communications from OPAIS regarding the covered entities status.
   1. Responsible as the official in charge for the compliance and administration of the program in many cases
   2. Potentially responsible for attesting to the compliance of the program through recertification
   3. Account for savings and use of funds to provide care for the indigent under the indigent care agreement
   4. Reviews and refines 340B cost savings report, detailing purchasing, and replacement practices as well as dispensing patterns

C. The Medical Director shall be a designated agent for 340B compliance
   1. Maintain knowledge of the policy changes that affect the 340B Program, including, but not limited to, HRSA rules and Medicaid change
   2. Monitor any changes in department eligibility/information
   3. Responsible to administer the 340B Program to fully implement and optimize appropriate savings and ensure that current policy statements and procedures are in place to maintain program compliance

D. The Assistant Pharmacy Director shall be designated as the day to day manager of the 340B program and act as the Pharmacy 340B Coordinator
   1. Responsible for maintenance and testing of tracking software
   2. Responsible for documentation of policies and procedures
   3. Maintains system databases to reflect changes in the drug formulary or product specifications
   4. Manages purchasing, receiving, and inventory control processes
   5. Continually monitors product minimum/maximum levels to effectively balance product availability and cost-efficient inventory control
   6. Ensures appropriate safeguards and system integrity
   7. Performs inventory and monthly cycle counts
   8. Ensures compliance with 340B Program requirements for qualified patients, medications, providers, vendors, payers, and locations

9. Monitors ordering processes, integrating most current pricing from wholesaler, and analyzes invoices, shipping and inventory processes.

E. The BHS Pharmacy and Therapeutics Committee shall serve as the 340B oversight committee and shall:
1. Meet at least on a quarterly basis.
2. Annually review 340B rules/regulations/guidelines to ensure consistent participation in accordance with 340B regulations.
3. Conduct necessary reviews of 340B compliance.
    i. Ensure that the organization meets compliance requirements of program eligibility, patient definition, 340B drug diversion, and duplicate discounts via ongoing multidisciplinary teamwork.
    ii. Integrate departments such as information technology, legal, pharmacy, compliance, and patient financial services to develop standard processes for contract/data review to ensure program compliance.
4. Oversees the review process of compliance activities, as well as taking corrective actions based on findings.
5. Be made aware of a material breach.
6. Review and approve work group recommendations (process changes, self-monitoring outcomes and resolutions).

VI 340B Co-Payment and Reimbursement Procedures

A. Prescriptions, changes, or renewals of 340B medications shall be exempt from charges to DOC patients.

B. 340B medications shall not be eligible for medication return reimbursement.

VII 340B Inventory and Procurement Procedures

A. CPS shall use the following methods for separating 340B inventory:
1. Physically separated identifiable 340B and non-340B inventory.
2. Maintaining a virtual mixed-use replenishment system for inventory not readily identifiable as 340B stock.
3. CPS staff dispense 340B medications only to patients meeting all the criteria in this Policy and Procedure.

B. Physical inventory (both 340B and non-340B medications) is maintained at CPS.

C. CPS identifies all 340B and non-340B accounts used for purchasing medications.

D. CPS separates 340B inventory from non-340B inventory.

E. CPS performs monthly inventory reviews and shelf inspections of periodic automatic replenishment (PAR) levels to determine monthly purchase order.

F. Only CPS staff shall place 340B medication orders. CPS shall receive the shipment of all 340B-priced medications purchased.

G. CPS pharmacist or designee verifies quantity received with quantity ordered.
1. Identifies any inaccuracies.
2. Resolves inaccuracies.
3. Documents resolution of inaccuracies.

H. CPS shall maintain records of 340B-related transactions for two years in a readily retrievable and auditable format located in the DOC central pharmacy.
1. These reports are reviewed by the Pharmacy and Therapeutics Committee as part of its 340B oversight and compliance program.

VIII Diversion Prevention Procedures for 340B priced medications

A. DOC shall maintain a separate wholesaler ordering account for 340B priced medications.

B. Medications are identified as 340B eligible when at least one of the following criteria are documented:
1. The patient for whom the medication is prescribed has received STD screening, counseling, or treatment during the incarceration in which the medication is prescribed.
2. The diagnosis for which the medication is prescribed is a sexually transmitted disease.
3. The treatment plan for which the medication is prescribed is part of an STD prevention strategy.

E. Records demonstrating eligibility for 340B-priced medication shall be stored in the DOC electronic health record of patient's receiving a qualifying medication.

F. CPS shall maintain records of 340B-priced product orders, inventory, and returned of unused supply.

E. CPS shall maintain a physical inventory of medications purchased for 340B eligible patients. This inventory shall be maintained separate from the inventory of medications purchased for non-340B eligible patients.
1. Medications purchased at the 340B pricing shall be dispensed only to 340B eligible patients.
2. Purchase orders for 340B eligible medications shall be billed to a separate wholesaler account.
3. PAR levels for 340B priced medications shall be maintained separate from non-340B priced medications.

G. Eligibility shall be verified by the prescriber and the receipt of STD screening, prevention, counseling, or treatment shall be documented in the electronic health record.

H. Data regarding the inventory and dispensing of 340B medications shall be maintained in the electronic health record pharmacy medication database.

I. CPS shall maintain records of unused 340B-priced medication that is returned or destroyed.

J. CPS Pharmacist Duties
   1. The CPS pharmacist or designee shall receive all shipments of 340B-priced medication and perform the following:
      a. Verify quantity received with quantity ordered.
      b. Identify inaccuracies.
      c. Resolve inaccuracies.
      d. Document resolution of inaccuracies.
   2. The CPS pharmacist or designee shall reconcile purchasing records with dispensing records to ensure that covered outpatient medications purchased through the 340B Program are used only for 340B eligible patients.
   3. The CPS pharmacist or designee shall resolve inventory discrepancies when 340B medications are dispensed to ineligible patients by replacing the 340B stock with the equivalent amount of the same medication acquired through the wholesaler at non-340B pricing.

K. HSU staff shall report significant discrepancies (excessive quantities based on utilization or product shortages) to the DOC pharmacist within 24 hours of identification of the discrepancy.

L. CPS shall maintain records of 340B-related transactions for a period of two years in a readily retrievable and auditable format.
   1. These reports are reviewed by the BHS Pharmacy and Therapeutics Committee quarterly as part of its 340B oversight and compliance program.

IX Wasted 340B medication

A. HSU staff shall document destroyed or wasted medication not issued or administered/delivered to the patient.

B. CPS staff shall report wastage to the pharmacist and the 340B administrator.

C. CPS shall replace destroyed or wasted 340-B-priced medication through appropriate purchasing account if necessary.

X 340B Noncompliance/Material Breach

A. The Division of Adult Institutions has defined an established threshold of what constitutes a material breach of 340B Program as non-compliance of > 5% of 340B purchases.

B. DAI ensures that identification of any threshold variations occurs among all its facilities.

C. The BHS Pharmacy and Therapeutics Committee assesses materiality the dispensing record of 340B-priced medications on a quarterly basis.

D. CPS maintains records of inventory and ensures 340B-priced medications are only dispensed to eligible patients.

E. The 340-B administrator or designee reports identified material breach to HRSA and applicable manufacturers upon discovery.

F. DAI maintains records of material breach violations, including manufacturer resolution correspondence.

G. In the event that a finding does not meet the requirements of a Material Breach, but could lead to a Material Breach if not corrected, a Corrective Action Plan (CAP) shall be created and filed with the Pharmacy and Therapeutics Committee. If the CAP would require a policy change, that must also be reported to the BHS Health Care Administrator. The CAP should be implemented as soon as possible to prevent future potential Material Breaches.

H. In the event that a Material Breach occurs, the Authorizing Official shall:
1. Notify HRSA and follow their instructions regarding the Self-Disclosure Process.
2. Contact Apexus Answers for any additional Guidance.
3. Notify the Manufacturer(s) involved.
4. Coordinate repayment of manufacturer:
   a. Request preferred method of repayment with receipt requested mail.
   b. If no response in 90 days, send a second notice.
   c. Repay the Manufacturer the negotiated repayment amount.
5. Retain a copy of all communications, and a signed/dated overview of all relevant conversations associated with the Material Breach.

XI 340B Program Compliance Monitoring/Reporting

A. The Division of Adult Institutions shall follow an annual internal audit plan approved by the internal compliance officer or as determined by organizational policy.

B. The DAI 340B administrator or designee reviews 340B OPAIS to ensure the accuracy of the information for DAI.

C. CPS reconciles purchasing records and dispensing records to ensure that covered outpatient medications purchased through the 340B Program are dispensed or administered only to patients eligible to receive 340B medications and that any variances are not the result of diversion.

M. A BHS Pharmacy and Therapeutics Committee sub-committee or designee(s) reconciles dispensing records to patients' health care records to ensure that all medications dispensed were provided to patients eligible to receive 340B medications. The sub-committee or designee(s) will select a minimum of ten and maximum of thirty records from a 340B-priced medication utilization file and preform the audit quarterly.

N. The BHS Pharmacy and Therapeutics Committee (340B Oversight Committee) reviews internal audit results at quarterly meetings.

O. CPS shall maintain records of 340B-related transactions for a period of two years in a readily retrievable and auditable format.

Bureau of Health Services: _____ **Date Signed:** _____
Michael A. Rivers, Director of Healthcare Administration

_____ **Date Signed:** _____
Vacant, Medical Director

_____ **Date Signed:** _____
Mary Muse, Nursing Director

Administrator's Approval: _____ **Date Signed:** _____
Makda Fessahaye, Administrator

DIVISION OF ADULT INSTITUTIONS FACILITY IMPLEMENTATION PROCEDURES

Facility: Name		
Original Effective Date: 00/00/00	**DAI Policy Number:** 500.80.28	**Page** 10 of 10
New Effective Date: 00/00/00	**Supersedes:**	**Dated:** 00/00/00
Chapter: 500 Health Services		
Subject: 340B Compliance		
Will Implement ☐ As written ☐ With below procedures for facility implementation		
Warden's/Center Superintendent's Approval:		

REFERENCES

DEFINITIONS, ACRONYMS AND FORMS

FACILITY PROCEDURE

I.

A.

B.

1.

2.

a.

b.

c.

3.

C.

II.

III.

RESPONSIBILITY

I. Staff

II. Inmate

III. Other