NH DEPARTMENT OF CORRECTIONS POLICY AND PROCEDURE DIRECTIVE Pursuant to RSA21-H:8 (III) Internal Practices and Procedures	CHAPTER Medical & Forensic Svcs STATEMENT NUMBER 599
SUBJECT: **FEDERAL 340B DISCOUNT DRUG PROGRAM PROCEDURES** PROPONENT: Director *Title* Medical & Forensic 271-3707 *Office* *Phone #*	EFFECTIVE DATE 10/21/2021 REVIEW DATE 10/21/2024 SUPERSEDES PPD# NEW DATED
ISSUING OFFICER: *Helen E. Hanks, Commissioner*	DIRECTOR'S INITIALS DATE APPENDIX ATTACHED: YES NO
REFERENCE NO: See reference section on last page of PPD.	

(a) PURPOSE:
To provide guidance for the New Hampshire Department of Corrections' (NHDOC) proper management of the Federal 340B Drug Discount program (340B) in its entirety.

(b) APPLICABILITY:
To all staff involved in implementation of the 340B program.

(c) POLICY:
It is the policy of the NHDOC to oversee and maintain systems/mechanisms and internal controls to ensure ongoing compliance with all 340B discount drug program requirements, pursuant to 42 USC §256b, Public Health Services Act, Section 340B.

(d) DEFINITIONS: As used in this policy, the following definitions shall apply:

(1) 340B Covered Entity – facilities/programs that are listed in the 340B statute as eligible to purchase drugs through the 340B program, and appear on 340B Office of Pharmacy Affairs Information System (OPAIS).

(2) 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 drugs. The resulting program is the 340B Drug Pricing Program.

(3) 340B Oversight Committee – the NHDOC Pharmacy and Therapeutics Committee, as described in PPD 580 *Pharmaceutical Services*, that meets monthly to discuss a variety of issues, including the 340B program and compliance.

(4) HRSA – Health Resource & Services Administration, the federal entity that improves

1. NHDOC's compliance with and administration of the program;
2. Maintain knowledge of the external policy changes that affect NHDOC's implementation of the 340B Program, including but not limited to, HRSA rules and Medicaid changes; and,
3. Annual 340B program recertification.

c. A "primary contact" shall be designated by the Director to communicate with and receive communications from OPAIS regarding NHDOC's program status, and is responsible for:
   1. NHDOC's compliance and administration of the program in many cases;
   2. Attesting to the compliance of the program through recertification (when the authorizing official is unavailable or has delegated that responsibility);
   3. Accounting for savings and use of funds to provide care for the indigent under the indigent care agreement;
   4. Maintain knowledge of the external policy changes that affect NHDOC's implementation of the 340B Program, including but not limited to, HRSA rules and Medicaid changes; and,
   5. Reviewing and refining 340B cost savings report, detailing purchasing, and replacement practices, as well as dispensing patterns.

d. The Chief Pharmacist shall be designated as the day-to-day manager of the 340B program at NHDOC, and shall:
   1. Maintain knowledge of the external policy changes that affect NHDOC's implementation of the 340B Program, including but not limited to, HRSA rules and Medicaid changes; and,
   2. Monitor any changes in clinic eligibility/information.
   3. Maintaining the electronic health record (EHR) and pharmacy database to reflect changes in the drug formulary or product specifications, for 340B program drugs;
   4. Managing purchasing, receiving, and inventory control processes for 340B program drugs;
   5. Continually monitoring inventory levels;
   6. Ensuring compliance with 340B program requirements for qualified patients, drugs, providers, vendors, payers, and location; and,
   7. Monitoring ordering processes; integrating most current pricing from wholesaler(s); and, analyzing invoices, and shipping.

e. The Pharmacy and Therapeutics Committee, acting in its role as the 340B oversight committee, shall:
   1. Address 340B compliance as a regular part of its monthly agenda.
   2. Annually review 340B rules, regulations, and guidelines to ensure consistent compliance with 340B regulations.
   3. Conduct necessary reviews of 340B compliance, including:
      (i) Ensure that NHDOC meets compliance requirements of program eligibility, patient definition, 340B drug diversion, and duplicate discounts via ongoing multidisciplinary teamwork.
      (ii) Ensure communication and collaboration among divisions involved in 340B service delivery.
   4. Take corrective actions based on post audit findings, or internally identified issues.

(4) Registration in 340B Program.

a. The Director shall enroll the Department in 340B OPAIS in order to participate in the 340B Program.
b. The Director shall monitor registration dates and deadlines.
c. The Director shall update OPAIS with authorizing official and primary contact information.
d. The Director shall annually recertify Medical and Forensic Services information on 340B OPAIS.

Division of Administration.

(10) 340B Material Breach.

a. A material breach refers to an instance of non-compliance with any of the 340B Program requirements.
b. The 340B oversight committee shall review any indication of or actual material breach.
c. The 340B primary contact or designee reports identified material breaches to HRSA and applicable manufacturers upon discovery.
d. The 340B oversight committee shall maintain records of material breaches, including manufacturer resolution correspondence.
e. 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, action shall be taken by the 340B oversight committee to correct.
    1. If the corrective action would require a policy change, that must also be reported to the Director.
    2. The corrective action should be implemented as soon as possible to prevent future potential material breaches.
f. In the event that a material breach occurs, the primary contact 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 to manufacturer:
        (i) Request preferred method of repayment via USPS First Class receipt-requested letter;
        (ii) If no response in 90 days, send a second notice; and,
        (iii) Repay the manufacturer the negotiated repayment amount.
    5. Retain a copy of all communications associated with the material breach.

REFERENCES:
42 USC §256b, Public Health Services Act, Section 340B, Federal Drug Pricing Program

340B Drug Pricing Program
340B Guidelines
340B Policy Releases

Standards for Adult Correctional Institutions
Fifth Edition Standards
5-ACI-6A-43

Standards for Health Services in prisons (NCCHC)
Pharmaceutical Operations P-D-01

Other

PPD 580 *Pharmaceutical Services*

MATTIS/bc