	DEPARTMENT OF CORRECTIONS AND REHABILITATION CORRECTIONS ADMINISTRATION POLICY AND PROCEDURES	EFFECTIVE DATE: SEP 0 2 2025	POLICY NO.: COR.10.J.01
		SUPERSEDES (Policy No. & Date): **NEW**	
	SUBJECT: 340B – OVERVIEW OF PROGRAM POLICY AND PARTICIPATION		Page 1 of 5

1.0 PURPOSE

To outline the written policies and procedures the Health Care Division uses to manage 340B Program operations, oversee contract pharmacies, and ensure compliance with 340B Program requirements.

2.0 SCOPE

This policy applies to the Health Care Division of the Department of Corrections and Rehabilitation .

3.0 REFERENCES, DEFINITIONS & FORMS

.1 References

a. 42 USC §256b

b. Section 340B Public Health Service Act (1992): (https://www.hrsa.gov/sites/default/files/hrsa/rural-health/phs-act-section-340b.pdf)

c. Public Law 102-585, Section 602: (https://www.hrsa.gov/opa/program-requirements/public-law-102-585#602)

d. 340B Federal Register Notices, Health Resources and Services Administration: (https://www.hrsa.gov/opa/program-requirements/federal-register-notices)

e. 340B Policy Releases, Health Resources and Services Administration: (https://www.hrsa.gov/opa/program-requirements/policy-releases)

f. Calculating 340B Net Financial Impact and Use of Savings, 340B Prime Vendor Program managed by Apexus.

.2 Definitions

a. 340B covered entity (CE): A facility or program eligible to purchase drugs through the 340B Program as specified in the 340B statute. These entities must be listed on the 340B Office of Pharmacy Affairs Information System (OPAIS).

b. 340B Drug Pricing Program (340B Program): The 340B Drug Pricing Program is a federal program that requires drug manufacturers, who participate in the Medicaid drug rebate program, to sell outpatient drugs to specific organizations called "covered entities" at or below a legally set maximum price, known as the ceiling price. This rule is based on Section 340B of the Public Health Service Act and is part of U.S. law under 42 USC §256b. The goal of the 340B Program is to help covered entities stretch limited federal funds to serve more eligible patients and provide broader healthcare services. This purpose was outlined in a Congressional report from 1992).

c. 340B ID: A unique identification number provided by HRSA to identify a 340B-eligible entity in 340B OPAIS. This 340B ID is used to purchase 340B drugs.

d. 340B OPAIS: The 340B OPAIS is a system that gives access to records for covered entities and manufacturers, manages user accounts, processes change requests, and handles recertification and registrations. It is designed to ensure the reliability and effectiveness of 340B program information by focusing on three main priorities: security, user accessibility, and accuracy .

e. 340B Prime Vendor Program (PVP): The Prime Vendor Program is operated by Apexus under an agreement with the Health Resources and Services Administration (HRSA), the federal agency that oversees the 340B Drug Pricing Program.

f. Contract pharmacy: 340B covered entity can partner with one or more pharmacies to serve its patients, including dispensing 340B drugs that the entity owns. This partnership requires a written agreement that follows compliance guidelines outlined in official guidance. The contract pharmacy must also be listed on the 340B OPAIS during a quarterly registration period. Usually, these arrangements operate under a "bill-to/ship-to" model, where the entity is billed, and the pharmacy receives the shipment.

g. Covered entity (CE): A covered entity is healthcare provider or organization that qualifies to participate in the 340B Program based on the eligibility criteria outlined in the 340B statute.

h. Covered outpatient drug (COD): medication defined under Section 1927(k) of the Social Security Act (SSA) as eligible for inclusion in the Medicaid Drug Rebate Program and, by extension, the 340B Program.

i. Duplicate discount: A duplicate discount, which is prohibited under the 340B statute, happens when a covered entity receives a 340B discount on a medication, and a Medicaid agency also receives a rebate for the same medication from the manufacturer.

j. Federal Register notice (FRN): Official announcements about guidelines, regulations, and other federal updates published in the *Federal Register*, a government journal.

k. Health Resources and Services Administration (HRSA): A key agency within the U.S. Department of Health and Human Services, HRSA focuses on improving healthcare access for uninsured, isolated, and medically vulnerable populations. It operates through five bureaus and ten offices, providing leadership and financial support to healthcare providers across all states and U.S. territories.

l. Office of Pharmacy Affairs (OPA): The division of HRSA that oversees and administers the 340B Drug Pricing Program.

m. Sexually transmitted disease clinic: The Centers for Disease Control and Prevention (CDC), part of the U.S. Department of Health and Human Services, manages and funds programs to prevent sexually transmitted diseases (STDs). Funding for these programs is authorized under Section 318 of the Public Health Service Act and is awarded to state and local health departments, as well as academic and public health organizations, to support STD prevention efforts.

n. Start date: 340B OPAIS uses the term "start date" to denote an entity's start date in the 340B Program. Entity start dates are updated quarterly.

o. Termination date: 340B OPAIS uses the term "termination date" to denote the date that the 340B entity is terminated from the 340B Program. The covered entity is no longer eligible to participate in the 340B Program on the day is terminated from the 340B Program or the day it becomes ineligible. The covered entity must stop purchasing, using, and administering 340B drugs once it is terminated from the 340B Program. Termination dates are updated on a quarterly basis.

.3 Forms

a. DCR 0613, 340B Net Financial Impact and Use of Savings

4.0 BACKGROUND

.1 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. The PPA sets a maximum price that manufacturers can charge certain covered entities for outpatient medications.

.2 The Health Resources and Services Administration (HRSA), under the Department of Health and Human Services (DHHS), administers the 340B Program

.3 To participate in the 340B Program, eligible organizations (covered entities) must register, enroll, and comply with all 340B program requirements. Upon enrollment, covered entities receive a unique 340B identification number, which vendors use to verify eligibility for 340B discounted drugs.

.4 Upon registering in the 340B Office of Pharmacy Affairs Information System (340B OPAIS), the Health Care Division:

a. Agrees to abide by specific statutory requirements and prohibitions.

b. May access 340B medication.

5.0 POLICY

.1 The Health Care Division follows all requirements and restrictions outlined in Section 340B of the Public Health Service Act, including regulations and guidelines. This includes prohibitions against duplicate discounts or rebates under Medicaid and transferring 340B-purchased drugs to anyone other than eligible patient.

.2 The Health Care Division uses any savings generated from the 340B Program in line with its purpose—to stretch limited federal resources, serve more eligible patients, and provide more comprehensive services

.3 The Health Care Division has systems, mechanisms, and internal controls in place to ensure ongoing compliance with all 340B Program requirements.

.4 The Health Care Division maintains clear, auditable records that demonstrate full compliance with the 340B Program.

5.0 PROCEDURES

.1 The Health Care Division reviews its eligibility for the 340B Program annually by verifying the status of the Department of Health's 318 grant. It updates the Memorandum of Agreement with the Department of Health as needed to avoid any gaps in eligibility.

.2 The 340B Oversight Committee completes DCR 0613 annually, and the Public Health Nursing Office maintains the document.

.3 The 340B Oversight Committee reviews audit reports quarterly as part of its oversight and compliance program.

.4 The 340B Oversight Committee updates and approves 340B policies and procedures whenever there are clarifications or changes to 340B Program requirements. If no changes occur, the committee reviews and approves the policies annually.

APPROVAL RECOMMENDED:

Sep 2, 2025

Deputy Director for Rehabilitation Services and Programs — Date

APPROVED:

Sep 2, 2025

DIRECTOR — Date

NOT CONFIDENTIAL

STATE OF HAWAII
DEPARTMENT OF CORRECTIONS AND REHABILITATION
HEALTH CARE DIVISION

Purpose: The purpose of this tool is to provide a sample 340B dispense tracking log for clinic and/or physician administered 340B drugs in a physical inventory **when an electronic tracking option is not available** to maintain auditable records.

Instructions: This tool includes data points needed to document key aspects of 340B Program compliance related to inventory management. It can be used to help document the 11-digit NDC record from point of purchase to point of use, including documentation of loss or waste. Covered entities who utilize this tool should tailor the log to meet their own unique needs for maintaining auditable records.

- Each row of this log represents a single inventory transaction (either product received and added to inventory or product removed from inventory for either patient use or expired/wasted items). Users should document as much information as possible about the source or use of the medication in order to accurately tie it to purchasing records or patient medical records.
- After each transaction, the amount remaining on the shelf is recorded. The last column is offered as an opportunity to document periodic verification of this process through inspection of the ledger captured within this document and the inventory remaining on the shelf. The timeframe for how often this task is completed is at the discretion of the site, but should be documented within policies and procedures.

STATE OF HAWAII
DEPARTMENT OF CORRECTIONS AND REHABILITATION
HEALTH CARE DIVISION

340B Medication Tracking Log

Eligible Patient Name: _____ **SID:** _____ **Facility:** _____

Medication Name/NDC: _____

Date of Transaction	Description of Transaction: -When adding medication to inventory, record invoice number -When removing medication from inventory, include patient ID/chart # or documentation of waste	Quantity Drug Received (+)	Quantity Dispensed / Wasted (-)	Ending amount on-hand	Lot # of Medication	Expiration Date	Nurse Documenting Transaction	Provider's Name	On-Hand Reconciliation Date and Initials