

DEPARTMENT OF CORRECTIONS AND REHABILITATION

CORRECTIONS ADMINISTRATION

SEP 0 2 2025

EFFECTIVE DATE:

POLICY NO.: COR.10.J.08

SUPERSEDES (Policy No. & Date):

NEW

POLICY AND PROCEDURES
SUBJECT:

340B - INVENTORY MANAGEMENT

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1.0 PURPOSE

To ensure the proper procurement and effective inventory management of 340B drugs.

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. Section 340B Public Health Service Act (1992): (https://www.hrsa.gov/sites/default/files/hrsa/rural-health/phs-act-section-340b.pdf)
- b. Department of Corrections and Rehabilitation, Policy and Procedures, COR.10.J.04, 340B Patient Eligibility/Definition

.2 Definitions

- a. Contract pharmacy: A 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.
- b. 340B-eligible patient: an individual qualifies as a 340B-eligible patient of a covered entity (except for state-operated or funded AIDS Drug Assistance Programs, or ADAPs) if the following criteria are met:
 - 1. Established Relationship: The covered entity has an established relationship with the individual, maintaining records of their healthcare.

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- Healthcare Provider Connection: The individual receives care from a healthcare professional who is either employed by the covered entity or working under a contractual or other arrangement (e.g., referral for consultation), ensuring the covered entity retains responsibility for the individual's care.
- Services Provided: The individual receives healthcare services from the covered entity that align with the services the entity is authorized to provide through grant funding or federally qualified health center look-alike status.

An individual will not be considered a patient of the covered entity if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

Exception: Individuals registered in a state-operated or funded AIDS Drug Assistance Program (ADAP) that receives federal Ryan White funding ARE considered patients of the participant ADAP if so registered as eligible by the state program.

- c. Replenishment (340B outpatient drug): Replenishment in the 340B Program happens when a non-340B drug is dispensed to a 340B-eligible patient, and the covered entity later replaces it with a 340B-purchased drug based on the patient's eligibility. While the replacement drug was purchased at a 340B price, it is no longer considered part of the 340B inventory because it replaces a previously dispensed non-340B drug. Replenishment operates on a neutral inventory model:
 - 1. The replenishment drug replaces a past dispensing or administration activity.
 - 2. Once the replenishment drug arrives, it becomes part of the neutral inventory, meaning it can be dispensed to any patient.
 - 3. This process effectively shifts the original dispensed drug into a 340B transaction, leaving the neutral inventory available for future use.

.3 Forms

a. DCR 0614, 340B Medication Tracking Log

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4.0 POLICY

- .1 Covered entities must track and account for all 340B drugs to prevent diversion and ensure compliance.
- .2 <u>340B inventory is procured and managed in the following settings:</u>
 - a. Clinic site administration.
 - b. Contract pharmacy.
- .3 The inventory management policy and procedure outlines the methods used to manage inventory in each area within the entity.
- .4 <u>The Health Care Division uses a physically separated inventory method to distinguish between 340B and non-340B inventory.</u>
- .5 Pharmacists, nurses, and clinicians dispense 340B drugs only to patients who meet all the criteria in the Department of Corrections and Rehabilitation's Policy and Procedure "Patient Eligibility/Definition" [COR.10.J.04].

5.0 PROCEDURES

.1 <u>Physical inventory, including both 340B and non-340B drugs, is maintained at the following Health Care Division sites:</u>

Oahu Community Correctional Center Hawaii Community Correctional Center Maui Community Correctional Center Kauai Community Correctional Center Women's Community Correctional Center Halawa Correctional Facility Waiawa Correctional Facility Kulani Correctional Facility

- a. The Health Care Division identifies all 340B and non-340B accounts used for purchasing drugs in each practice setting.
- b. The Health Care Division places 340B and non-340B drug orders through its contract pharmacy. For 340B drug orders, a bill-to/ship-to arrangement

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is established with the contract pharmacy and wholesaler. 340B medications cannot be ordered as stock medications

- c. The contract pharmacy receives the shipment.
 - Medications from the wholesaler are used exclusively for eligible patients of the Department of Corrections and Rehabilitation, based on orders from approved prescribers and dispensed in accordance with 340B Program rules.
 - 2. The contract pharmacy cross-checks the eligible patient list with medications ordered and ensures the use of 340B-purchased medications where applicable.
 - 3. The contract pharmacy packages and labels 340B medications, clearly identifying them as 340B-sourced on the medication label.
 - 4. 340B medications are shipped together with non-340B medications to the facility location.
- d. The Clinical Services Section Administrator or their designee verifies that the quantity of medications received from the contract pharmacy matches the quantity ordered. The Clinical Services Section Administrator:
 - 1. Identifies any discrepancies or inaccuracies.
 - 2. Resolves any discrepancies to ensure accurate inventory.
 - 3. Documents the resolution of discrepancies and submits a detailed report to the Registered Nurse V (Public Health Nursing Office).
- b. The Health Care Division keeps 340B inventory separate from non-340B inventory by placing 340B labels or stickers on individual patient medication storage areas within medication rooms and medication carts.
- c. Clinical Services Section Administrators or their designees review inventory and inspect shelves daily to keep 340B inventory separate from non-340B inventor.
- d. The Health Care Division keeps records of 340B-related transactions for six years in an easily accessible and auditable format, stored at the Public

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Health Nursing Office or within the electronic health record system.

1. The Registered Nurse V or their designee from the Public Health Nursing Office reviews these reports monthly as part of the 340B oversight and compliance program.

.3 Wasted 340B Medication.

APPROVAL RECOMMENDED:

DIRECTOR

- a. Nursing staff documents any destroyed or wasted drugs that were not administered to a patient.
- b. Prescribed 340B medications for an individual patient are never transferred or administered to another patient. These medications cannot be returned to the contract pharmacy, and the Division does not use a replenishment model at clinic sites.
- c. Nursing staff report medication wastage to the Registered Nurse V in the Public Health Nursing Office.
- d. The Clinical Services Section Administrator or designee updates the DCR 0614 340B Medication Tracking Log and documents the adjustment with a reason, if applicable.
- e. The Health Care Division replaces medications using the correct purchasing account.

Sep 2, 2025 Deputy Director for Rehabilitation Services and Programs APPROVED: Sep 2, 2025

Date