	DEPARTMENT OF CORRECTIONS AND REHABILITATION		EFFECTIVE DATE: SEP 02 2025	POLICY NO.: COR.10.J.12
	CORRECTIONS ADMINISTRATION POLICY AND PROCEDURES		SUPERSEDES (Policy No. & Date): **NEW**	
	SUBJECT: 340B – CONTRACT PHARMACY OVERSIGHT AND MONITORING			Page 1 of 4

1.0 PURPOSE

To ensure that the Health Care Division upholds the integrity and compliance of its 340B Program at its contract pharmacies.

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. Federal Register / Vol. 75, No. 43 / Friday, March 5, 2010 / Notices
(<https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf>)
- b. 340B Contract Pharmacy Guidelines
(<https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf>).
- c. Department of Corrections and Rehabilitation, Policy and Procedures, COR.10.J.06, 340B Program Roles and Responsibilities
- d. Department of Corrections and Rehabilitation, Policy and Procedures, COR.10.J.10, 340B Noncompliance/Material Breach

.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. Duplicate discount: A duplicate discount, which is prohibited under the 340B statute, happens when a covered entity receives a 340B discount on

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a medication, and a Medicaid agency also receives a rebate for the same medication from the manufacturer.

4.0 POLICY

- .1 Covered entities must oversee their contract pharmacy arrangements to ensure continuous compliance with 340B Program requirements.
- .2 The covered entity remains fully accountable for meeting all requirements, ensuring eligibility, and preventing drug diversion and duplicate discounts.
- .3 Auditable records are maintained to demonstrate compliance with these requirements.

5.0 PROCEDURES

- .1 The Health Care Division conducts regular internal reviews of each registered contract pharmacy to ensure compliance with 340B Program requirements. The Public Health Nursing Office performs these internal reviews quarterly. Self-audits of the contract pharmacy include the following elements to verify program compliance:
 - a. Prescription Eligibility: The prescription originates from a 340B-eligible site of care that provides health care services.
 - b. Patient Eligibility: The episode of care leading to the 340B prescription is supported in the patient's medical record and aligns with the grant-funded scope of services provided by the entity.
 - c. Provider Eligibility: The prescribing provider is employed, contracted, or operating under another arrangement with the entity at the time of prescription, ensuring the entity is responsible for the patient's care.
 - d. NDC Documentation: The 11-digit NDC is recorded for accumulation and/or replenishment of a 340B dispensation or administration (if a virtual inventory system is used)
 - e. Medicaid Billing: The Health Care Division and its contracted pharmacy do not bill Medicaid for medications provided to its patient.

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- .2 The Health Care Division conducts annual independent audits of each registered contract pharmacy to ensure compliance with 340B Program requirements.
 - a. Independent audits will include reviews of the following areas:
 1. 340B Eligibility: Verifying that all criteria for program eligibility are met.
 2. 340B Registration: Ensuring accurate and current registration of the contract pharmacy.
 3. Policies and Procedures: Reviewing documented policies and procedures for adherence to program requirements.
 4. Inventory and Record-Keeping: Assessing inventory, ordering practices, and record-keeping for all 340B accounts.
 5. Medicaid Exclusion File: Confirming the contract pharmacy's listing in the Medicaid Exclusion File aligns with its actual practices.
 6. Claims Testing: Sampling claims to identify any instances of diversion or duplicate discounts during a defined review period.
- .3 The Health Care Division has mechanisms to ensure compliance with all state Medicaid billing requirements, preventing duplicate discounts at all locations, including off-site outpatient facilities. The Department does not use Medicaid services or collect drug rebates from Medicaid.
- .4 The Health Care Division adheres to all state practices in line with state guidance and ensures that its Medicaid billing numbers and NPI numbers are accurately listed in the Medicaid Exclusion File.
 - a. The Health Care Division does not bill state Medicaid programs.
- .5 The Health Care Division's 340B Oversight Committee reviews audit results to ensure compliance. For details, refer to the Policy and Procedure titled "340B Program Roles and Responsibilities" [COR.10.J.06]
 - a. The committee evaluates whether the audit results indicate a material breach. For guidance, refer to the Policy and Procedure titled "340B Noncompliance/Material Breach" [COR.10.J.10].

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- .6 The Health Care Division keeps records of 340B-related transactions for six years in an easily accessible and auditable format. These records are stored at the Public Health Nursing Office, the Health Care Division office, facility clinical services sections, and within the electronic health record system.

APPROVAL RECOMMENDED:


 Sep 2, 2025
 Deputy Director for Rehabilitation Date
 Services and Programs

APPROVED:


 Sep 2, 2025
 DIRECTOR Date

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