	<b>DEPARTMENT OF CORRECTIONS AND REHABILITATION</b>		<b>EFFECTIVE DATE:</b>  <b>SEP 02 2025</b>	<b>POLICY NO.:</b> <b>COR.10.J.11</b>
	<b>CORRECTIONS ADMINISTRATION POLICY AND PROCEDURES</b>		<b>SUPERSEDES (Policy No. &amp; Date):</b> <b>**NEW**</b>	
	<b>SUBJECT:</b> <b>340B – PROGRAM COMPLIANCE AND MONITORING</b>			<b>Page 1 of 3</b>

## 1.0 PURPOSE

To establish an internal monitoring program to ensure full compliance with the 340B Program

## 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. 340B PVP Education Tool: Defining Material Breach Documentation Tool  
<https://docs.340bpvp.com/documents/public/resourcecenter/establishing-material-breach-threshold.docx>.
- c. 340B PVP Education Tool: Self-Disclosure to HRSA and Manufacturer Template  
<https://docs.340bpvp.com/documents/public/resourcecenter/self-disclosure-to-hrsa-and-manufacturer-template.docx>.
- d. Department of Corrections and Rehabilitation, Policy and Procedures, COR.10.J.10, 340B Noncompliance/Material Breach

## 4.0 POLICY

- .1 Covered entities must maintain clear, auditable records to demonstrate compliance with 340B Program requirements.

## 5.0 PROCEDURES

- .1 The Health Care Division creates an annual internal audit plan, which is proposed by the Registered Nurse V from the Public Health Nursing Office and approved by the 340B Program Oversight Committee.

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- .2 The Registered Nurse V from the Public Health Nursing Office conducts internal audits to review:
  - a. Policies and procedures.
  - b. Services provided to patients.
  - c. Patient eligibility at the time of dispensing.
  - d. Inventory balances compared to recorded dispensing.
  - e. Provider credentials.
  - f. Feedback from key stakeholders on program confidence and competency.
- .3 The Health Care Division reviews 340B OPAIS regularly to ensure accurate information for all site locations and contract pharmacies.
- .4 Clinical Services Section Administrators make sure copies of records for all patients receiving medications purchased through the 340B Program are sent to the Registered Nurse V of the Public Health Nursing Office, if not accessible through the electronic health record. These records include:
  - a. Relevant progress notes related to the scope of the grant.
  - b. Laboratory results.
  - c. Signed medication orders.
- .5 The Health Care Division reconciles purchasing and dispensing records to ensure that 340B drugs are dispensed or administered only to eligible patients and that any variances are not due to diversion.
  - a. The Registered Nurse V or their designee from the Public Health Nursing Office compares reports from the contract pharmacy with wholesaler purchase records to confirm accuracy.
- .6 The Health Care Division reconciles dispensing records with patients' health care records to confirm that all medications dispensed were provided to eligible 340B patients. Each month, the Registered Nurse V or their designee from the Public Health Nursing Office audits 10 records from the drug utilization file.

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- a. The Registered Nurse V or their designee reconciles reports from the contract pharmacy with the records maintained by the Public Health Nursing Office (refer to COR.10.J.11.5.4 above).
- .7 The Health Care Division does not bill Medicaid for any claims, so reconciliation of such claims against 340B purchases is not required. This ensures alignment with the Medicaid billing status on 340B OPAIS.
- .8 The Health Care Division's 340B Oversight Committee reviews internal audit results during its regular quarterly meetings.
  - a. The 340B Oversight Committee evaluates whether the audit results indicate a material breach. For more details, refer to the Policy and Procedure titled "340B Noncompliance/Material Breach" [COR.10.J.10].
- .9 The Health Care Division keeps records of 340B-related transactions for six years in an easily retrievable and auditable format, stored either at the Public Health Nursing Office or in the electronic health record system.


APPROVAL RECOMMENDED:


Sep 2, 2025  


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Deputy Director for Rehabilitation Services and Programs Date

APPROVED:


Sep 2, 2025  


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DIRECTOR Date

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