	DEPARTMENT OF CORRECTIONS AND REHABILITATION	EFFECTIVE DATE:	POLICY NO.:
		SEP 02 2025	COR.10.J.02
	CORRECTIONS ADMINISTRATION POLICY AND PROCEDURES	SUPERSEDES (Policy No. & Date):	
		NEW	
SUBJECT:			
340B – COVERED ENTITY ELIGIBILITY		Page 1 of 4	

1.0 PURPOSE

To ensure the Health Care Division remains eligible to participate in 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. 42 USC §256b
- b. 42 USC §247c
- c. Section 1927(k) of the Social Security Act
(https://www.ssa.gov/OP_Home/ssact/title19/1927.htm)
- d. Section 340B Public Health Service Act (1992):
(<https://www.hrsa.gov/sites/default/files/hrsa/rural-health/phs-act-section-340b.pdf>)
- e. Department of Corrections and Rehabilitation, Policy and Procedures, COR.10.J.03, 340B Program Enrollment, Recertification, and Change Request
- f. Department of Corrections and Rehabilitation, Policy and Procedures, COR.10.J.11, 340B Program Compliance Monitoring and Reporting

.2 Definitions

- a. 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)

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- b. Covered outpatient drug: 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.
- c. 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.

4.0 POLICY

- .1 The Health Care Division must meet the requirements of 42 USC §256b(a)(4)(C) to qualify for enrollment and purchase drugs through the 340B Program.

5.0 PROCEDURES

- .1 The Health Care Division's 340B eligibility is based on receiving federal grant funds under Section 318 of the Public Health Service Act, awarded by the Centers for Disease Control and Prevention (CDC) through the Department of Health.
- .2 The Health Care Division identifies the locations where it dispenses or prescribes 340B drugs, such as within the covered entity's facilities or through a contract pharmacy.
 - a. Covered entities must maintain auditable records, policies, and procedures that align with the 340B statute and the Social Security Act's definition of a covered outpatient drug.
 - b. Covered outpatient drugs, as defined by section 1927(k) of the Social Security Act, include medications funded through grants to treat, monitor, and screen sexually transmitted diseases. This includes drugs used to treat Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV), which are part of the Department of Corrections and Rehabilitation's 340B program. Examples of covered outpatient drugs under section 1927(k) include, but are not limited to:
 - 1. Mavyret
 - 2. Zepatier


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
3. Genvoya
4. Biktarvy
5. Triumeq
6. Epclusa
7. Descovy
8. Tivicay
9. Odefsey
10. Truvada

- c. The above list is not exhaustive but serves as an example of medications that fall within the scope of the grant provided through 318 funds.
- .3 The Health Care Division ensures that the 340B OPAIS is complete, accurate, and correct for all eligible locations and contract pharmacies. For detailed guidance, refer to the Policy and Procedure document titled "340B Program Enrollment, Recertification, and Change Request" [COR.10.J.03].
 - a. All off-site locations using 340B drugs are registered in the Health Care Division's 340B OPAIS record.
 - b. The main addresses, billing and shipping addresses, authorizing official, and primary contact information are accurate and kept up to date.
 - c. The Health Care Division regularly reviews its 340B OPAIS records. For details, refer to the Policy and Procedure document titled "340B Program Compliance Monitoring and Reporting" [COR.10.J.11].
 - d. The Health Care Division notifies HRSA of any changes to its Medicaid information within 10 working days by updating the 340B OPAIS Medicaid Exclusion File. The data in the Medicaid Exclusion File applies to drugs billed under Medicaid fee-for-service and does not include Medicaid managed care organizations.
- .4 The Health Care Division recertifies its 340B OPAIS information annually. For detailed guidance, refer to the Policy and Procedure document titled "340B Program Enrollment, Recertification, and Change Request" [COR.10.J.03].

APPROVAL RECOMMENDED:

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

APPROVED:

 Sep 2, 2025
 DIRECTOR DATE

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