	DEPARTMENT OF CORRECTIONS AND REHABILITATION	EFFECTIVE DATE:	POLICY NO.: COR.10.J.03
		SEP 02 2025	
	CORRECTIONS ADMINISTRATION POLICY AND PROCEDURES	SUPERSEDES (Policy No. & Date): **NEW**	
	SUBJECT: 340B – PROGRAM ENROLLMENT, RECERTIFICATION, AND CHANGE REQUESTS		Page 1 of 4

1.0 PURPOSE

To ensure the Health Care Division is properly registered on 340B OPAIS and maintains accurate, up-to-date records

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. 340B Drug Pricing Program: Grantee Registration Instructions (<https://www.hrsa.gov/opa/registration/index.html>).

Registration dates:

- January 1–January 15 for an effective start date of April 1
- April 1–April 15 for an effective start date of July 1
- July 1–July 15 for an effective start date of October 1
- October 1–October 15 for an effective start date of January 1

- 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.02, 340B Covered Entity Eligibility
- d. Department of Corrections and Rehabilitation, Policy and Procedures, COR.10.J.12, 340B Contract Pharmacy Oversight and Monitoring

.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).

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- b. 340B OPAIS: The 340B Office of Pharmacy Affairs Information System 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.
- c. 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.

4.0 POLICY

- .1 Eligible covered entities must ensure the accuracy of their 340B OPAIS records and maintain active registration to participate in the 340B Program

5.0 PROCEDURES

- .1 Enrollment.
 - a. The Health Care Division is eligible to participate in the 340B Program. For more information, refer to the Department of Corrections and Rehabilitation's Policy and Procedure titled "Covered Entity Eligibility" [COR.10.J.02].
 - b. The Health Care Division tracks upcoming registration dates and deadlines to ensure timely participation in the 340B Program.
 - c. The Health Care Division designates the Corrections Health Care Administrator as its authorizing official and the Chief Nursing Officer as its primary contact.
 - d. The Health Care Division keeps the required documents and contracts readily available, including the federal grant number #6 NU51PS005155-01-0.

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- e. The Health Care Division completes its registration on 340B OPAIS at <https://340bopais.hrsa.gov/>.

.2 Recertification Procedure.

- a. The Health Care Division recertifies its information on 340B OPAIS annually.
1. The authorizing official, the Corrections Health Care Administrator, completes the annual recertification by following the instructions in the recertification email from HRSA and meeting the stated deadline.
 2. The Health Care Division submits any specific recertification questions to 340b.recertification@hrsa.gov.

.3 Enrollment Procedure: New Contract Pharmacy(ies).

- a. The Health Care Division ensures a signed contract pharmacy services agreement is in place between the entity and the contract pharmacy before registering on 340B OPAIS.
<https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf>.
1. The Department of Corrections and Rehabilitation's legal counsel reviews the contract to verify compliance with all federal, state, and local requirement.
- b. The Health Care Division develops, approves, and implements a policy and procedure for contract pharmacy oversight and monitoring. For details, refer to the Policy and Procedure document titled "Contract Pharmacy Oversight Management" [COR.10.J.12].
- c. The Health Care Division's authorizing official or designee completes the online registration during one of the four available registration windows.
1. The authorizing official certifies online that the contract pharmacy registration request is completed within 15 days of the online registration date.
- d. The Health Care Division starts using its contract pharmacy services arrangement only on or after the effective date listed on 340B OPAIS.


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.4 Procedure for Changes to the Health Care Division's Information in 340B OPAIS.


- a. The Health Care Division promptly notifies HRSA of any updates to the its 340B OPAIS information, including changes to its grant status or other significant updates. For more details, refer to the Policy and Procedure titled "Covered Entity Eligibility" [COR.10.J.02].
 1. The Health Care Division immediately stops purchasing 340B drugs if it loses 340B Program eligibility, such as through a change in grant status.
 2. The Health Care Division's authorizing official submits an online change request as soon as a change in eligibility is identified.
 - a) The Health Care Division expects the changes to be updated and reflected in 340B OPAIS within two weeks of submitting the request.

APPROVAL RECOMMENDED:


 Deputy Director for Rehabilitation Services and Programs

 Sep 2, 2025
 Date

APPROVED:


 DIRECTOR

 Sep 2, 2025
 Date

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