	DEPARTMENT OF CORRECTIONS AND REHABILITATION CORRECTIONS ADMINISTRATION POLICY AND PROCEDURES	EFFECTIVE DATE: SEP 0 2 2025	POLICY NO.: COR.10.J.10
		SUPERSEDES (Policy No. & Date): **NEW**	
	SUBJECT: 340B – NONCOMPLIANCE/MATERIAL BREACH		Page 1 of 3

1.0 PURPOSE

To define the Health Care Division's process for identifying and addressing material breaches of 340B compliance and the self-disclosure procedures to ensure transparency and accountability.

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.

.2 Definitions

a. Materiality: In auditing and accounting, materiality refers to the importance or significance of an amount, transaction, or discrepancy. It determines whether the item is substantial enough to influence decisions or impact the overall financial statements.

b. Threshold: The point that must be exceeded, as defined by the covered entity, resulting in a material breach. Examples of thresholds include:

1. X% of total 340B purchases or impact to any one manufacturer.

2. $X (fixed amount), based on total outpatient or 340B spend, or impact to any one manufacturer.

3. X% of total 340B inventory (units).

4. X% of audit sample.

5. X% of prescription volume/prescription sample.

.3 Forms

a. Self-Disclosure to HRSA and Manufacturer Template, Apexus (2022)

4.0 POLICY

.1 Covered entities must contact HRSA as soon as reasonably possible if a material breach or any instance of noncompliance with 340B Program requirements occurs.

5.0 PROCEDURES

.1 The Health Care Division defines a material breach of 340B Program compliance as any instance where the total 340B spend variation exceeds $999.

a. The Health Care Division ensures that any threshold variations are identified across all its 340B settings, including contract pharmacies.

.2 The Health Care Division determines materiality by calculating the value of products using their current 340B price.

a. The Health Care Division keeps records of all materiality assessments for accountability and transparency.

.3 The Health Care Division reports any identified material breach of 340B compliance to HRSA and applicable manufacturers. A material breach is defined as any violation exceeding $999, including loss of inventory, duplicate discounts, dispensing medication to an ineligible patient, or similar situations, and requires self-disclosure. Violations identified through internal self-audits, independent external audits, or other means that meet or exceed this threshold and cannot be corrected within two weeks or by the next scheduled 340B Program Oversight Committee meeting (whichever is later) are reported immediately. Reports are sent to HRSA at 340Bselfdisclosure@hrsa.gov and applicable

manufacturers using the Self-Disclosure to HRSA and Manufacturer Template (Attachment A).

a. The 340B Program Oversight Committee manages the noncompliance and material breach process. It reviews potential violations, conducts materiality assessments, and determines if a material breach has occurred. The committee decides to whom the breach should be disclosed based on the materiality assessment and corrective action plan resolution.

b. The Health Care Division keeps detailed records of material breach violations, including all internal and external communication, corrective action plans, materiality assessments, and resolution correspondence with manufacturers and/or HRSA. These records are retained for six years from the date of identification.

.4 The 340B Oversight Committee reviews the Noncompliance/Material Breach policy annually. The committee evaluates the definition of a material breach, assesses the self-disclosure procedure, and implements any necessary changes to ensure compliance and effective governance.

APPROVAL RECOMMENDED:

Sep 2, 2025

Deputy Director for Rehabilitation Services and Programs — Date

APPROVED:

Sep 2, 2025

DIRECTOR — Date

Self-Disclosure to HRSA and Manufacturer Template

Purpose: This tool provides a comprehensive template for entities self-reporting 340B noncompliance to the Health Resources and Services Administration's (HRSA's) Office of Pharmacy Affairs (OPA) and/or pharmaceutical manufacturers.

Background/Instructions: Covered entities are responsible for correcting any instance of noncompliance with 340B Program requirements. Once an issue is identified, the entity should follow its material breach policy requiring self-disclosure to HRSA (see 340B PVP Education Tool: Establishing Material Breach Threshold); however, it is likely that the manufacturer will need to be contacted regardless of materiality for diversion and duplicate discount compliance issues:

1. Non-material breach: work with manufacturer(s) directly to resolve issue
2. Material breach: self-disclose to HRSA and work with manufacturer(s) to resolve. Covered entity should email letter to 340bselfdisclosure@hrsa.gov

This tool includes the following resources to support resolving noncompliance:

1. Sample letter for disclosure to HRSA OPA
2. Recommendations for disclosing noncompliance to manufacturers

NOTE: Transparency with all parties is critical. Best practice for covered entities is to disclose the full extent and duration of the breach of compliance. The covered entity is expected to work in good faith with any affected manufacturer to mutually agree on a plan to address all breaches of compliance and how restitutions should be made.

Sample Letter to HRSA OPA

[Place letter on covered entity letterhead]

Date: [Date]

Director, Office of Pharmacy Affairs
Health Resources and Services Administration

Re: [Entity Name; 340B ID Number]

Dear [Director, HRSA OPA]:
The purpose of this letter is to disclose a 340B compliance issue regarding [issue such as duplicate discount, patient definition, GPO Prohibition] and describe a plan for corrective action.

[Entity] ([340B ID Numbers]) discloses that the compliance issues presented in this letter occurred and that it is dedicated to achieving complete compliance with 340B requirements and prohibitions. [Entity] offers this letter to provide a summary of the circumstance and a transparent plan for corrective action.

I. Entity and Partner Background

[Entity] is a [340B Entity type] located in [City, State] and has participated in the 340B Program since [date]. (Include the following text if relevant: [Entity] contracts with [Vendor] to provide [describe services] at [Location(s) at issue].)

II. Summary of Noncompliance

[Brief description] occurred during [date range] and was caused by [description]. The issue was first identified on [date, method]. [Insert detailed description of the issue and scope] *(Examples of the types of details to provide include: If the issue deals with eligibility, then when did the covered entity believe it became ineligible? How does this date compare to the date in 340B OPAIS? Or, if the issue relates to diversion or patient definition, what time period was involved? If the issue affected only some covered entity sites, which sites? If the issue involved a particular vendor or vendors, which ones and why?)*

III. External Affected Parties

[Entity] has identified the following external parties that may have been affected: *(e.g., manufacturers, contract pharmacies, wholesalers. List should reflect level of detail known at time of disclosure/update; covered entity may be unable to identify all categories of external parties at the time of initial disclosure).*

II. Corrective Action Plan

A. Internal Corrective Action Plan (within entity/partners)

[Entity] has taken corrective actions including: [description, including dates, such as evaluation/change of software/vendor, changes to policy and procedure manual, contact/action with partners such as vendors/Medicaid, changes to 340B OPAIS/Medicaid Exclusion File information]

[Entity] plans to take the following corrective actions: [description, including, for example, dates/timeline, specific goals such as evaluation/change of software/vendor, changes to policy and procedure manual, contact/action with partners such as vendors/Medicaid, changes to 340B OPAIS/Medicaid Exclusion File information, billing identifiers]

B. External Corrective Action Plan (beyond entity/partners, including Medicaid, manufacturers, wholesalers, and so on)

[Entity] has taken corrective actions including: [description, including dates, such as contact with external parties such as manufacturers/wholesalers/Medicaid]

[Entity] plans to take the following corrective actions: [IMPORTANT NOTE: Best practice is that entities disclose the full extent of noncompliance on all NDCs and quantities as it relates to each manufacturer's products. The entity should work with each manufacturer prior to taking any corrective action to remedy noncompliance.] [Description, including, for example, dates/timeline, specific goals such as contact/action/letters with external parties such as manufacturers/wholesalers/Medicaid, refunds issued or planned to be issued to manufacturers, changes on 340B OPAIS]

III. Request for OPA Action

[Entity] respectfully presents this self-reported compliance issue and a plan for corrective action. We request that OPA contact [name, information] within 30 days of the date of this letter to discuss or amend this plan for corrective action. [Entity] will otherwise proceed with the corrective action plan as described in this letter on [date, 30 days from date of letter]. Thank you for your attention to this matter.

Sincerely,

[Signed, Entity Authorizing Official]
[Contact information for authorizing official: Name, title, phone number, and email address]

Name of person submitting form
Organization

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HRSA respectfully requests that manufacturer communications described in the following pages not be sent to HRSA.

Common recommendations from manufacturers regarding self-disclosing

1. **Transparency among all parties is critical.** Best practice includes fully disclosing all NDCs and quantities involved and working with the manufacturer to mutually agree on a corrective action plan including how any repayments should be made.

2. Manufacturers often require transaction-level data to validate against their internal data.

    a. If self-disclosing for diversion, the manufacturer may need the account number, invoice number, purchase date, quantity incorrectly purchased, price paid, and suggested restitution amount.

    b. If self-disclosing for duplicate discount violations, the manufacturer may need a list of dispenses, purchase date, dispense date, NPI/Medicaid provider numbers, states affected, quantities involved, and suggested restitution amount.

3. The entity should **not** send a check/payment, or attempt to offset ineligible 340B purchases with WAC purchases, without first discussing with the manufacturer.

4. Entities can search 340B OPAIS for the appropriate manufacturer contact information here: https://340bopais.hrsa.gov/SearchMfr.

    a. Manufacturers are expected to keep contact information up to date.

    b. It is suggested to send the notice to multiple contacts at the manufacturer, including "Attention: Government Pricing Programs and Price Reporting."

5. Sending a self-reporting letter, or receipt of such a letter by the manufacturer, does **not** waive any rights of the manufacturer, including audit rights.

Entities can use the "sample letter to HRSA" template (pp. 2–3) and modify it to be a letter to a manufacturer. Section V should most likely be replaced with the following:

V. Request for Manufacturer Action

[Entity] respectfully presents this self-reported compliance issue and plan for corrective action. We request that [manufacturer's name] contact [name, information] within 30 days of the date of this letter to discuss or amend this plan for corrective action. Thank you for your attention to this matter.

Include entity contact information on each page (name, title, address, phone number, and email)

Please check all that apply to this compliance issue:

____ Program eligibility ____ Duplicate discount

____ Diversion ____ GPO Prohibition

____ Other (please describe): _____

_____

_____

Table 1: Entity Data, Contract Pharmacy Data

340B ID	HIN (if known)	Wholesaler or Distributor Name and Account Number	Entity Name, Subdivision Name	Address 1	Address 2	City	State	Zip	HRSA Start Date	HRSA Term. Date

Ship-To or Contract Pharmacy Name	HIN (if known)	Wholesaler or Distributor Name	Wholesaler Account Number	Address 1	Address 2	City	State	Zip	Contract Start Date	Contract Term. Date

Table 2: [Manufacturer] Repayment/Credit Summary

11-Digit NDC	Pkg Units	Product Shipped to: (Name, address)	Number of Units (report at the NDC level)	[Entity] 340B Acquisition Costs per Unit Represented by NDC	WAC or Contract Price per Unit Represented by NDC	Contract Used to Purchase (Include Contract Number)	Invoice Date	Invoice Number	Chargeback Memo Number	Wholesaler	Total Refund/Credit (as agreed upon between the covered entity and manufacturer)
TOTAL											

This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.