2023.009 340B Material Breach Policy

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Revision Date	
Subject Matter Expert	340B Program Coordinator
Approval Authority	HIV/STD Section Director
Signed by	*Josh Hutchison*

1.0 Purpose

The purpose of this policy is for the Texas Department of State Health Services (DSHS) to define a material breach of 340B compliance and the self-disclosure process. Covered entities are responsible for contacting the Health Resources and Services Administration (HRSA) as soon as reasonably possible if there is a material breach by the covered entity (CE) or instance of noncompliance with the 340B Program requirements. HRSA recommends each CE establish and document criteria signifying when a material breach of compliance has occurred.

The DSHS Central Pharmacy participates in a Central Distribution Model (CDM) for distributing 340B medications. CEs receiving medications from the DSHS Central Pharmacy are by default participating in the CDM and must meet the requirements outlined in this policy.

2.0 Definitions

340B Covered Entity (CE) – A program or facility participating in the 340B medication program. This includes DSHS as a direct recipient of federal funds as well as DSHS's CEs receiving federal funds or in-kind services from DSHS and utilizing a DSHS grant number for registering their program in the 340B Office of Pharmacy Affairs Information System (OPAIS) database.

340B Program – Refers to the 340B drug pricing program, which reduces the cost of covered outpatient drugs for certain federally supported entities and eligible health care organizations. The use of the term "340B" throughout this policy refers to the 340B program.

Diversion – Providing 340B medication to an ineligible patient or entity.

Duplicate Discount – Prohibited by the 340B statute, a duplicate discount occurs when a CE obtains a 340B discount on a medication and a Medicaid agency obtains a discount in the form of a rebate from the manufacturer for the same medication.

Materiality – A convention within auditing or accounting pertaining to the importance or significance of an amount, transaction, or discrepancy.

Material Breach – A breach of 340B compliance requirements which includes an adverse event which results in diversion, duplicate discounts, or both.

Office of Pharmacy Affairs (OPA) – The office within the Health Resources and Service Administration (HRSA) responsible for administering the 340B drug pricing program.

Office of Pharmacy Affairs Information System (OPAIS) – The system used to verify entity eligibility. The use of the term "OPAIS database" throughout this policy refers to this system.

Program – The specific program that awarded a contract or provided in-kind services to an entity such as Tuberculosis (TB), Sexually Transmitted Diseases (STD), or Human Immunodeficiency Virus (HIV).

Reconcile Inventory – The process in which staff from the ordering clinic compare the information in their tracking logs with the total number of units in their possession to ensure the numbers match, indicating they have accurately tracked the medication they ordered, received, and utilized.

3.0 Persons Affected

- DSHS 340B Pharmacy Unit Staff
- DSHS Regional Office Staff
- CE Staff

4.0 Responsibilities

DSHS 340B Pharmacy Unit Staff – Review incoming self-disclosures of material breaches from CEs. Verify calculations of materiality submitted by DSHS clinics and submit self-disclosures to HRSA and affected manufacturers. Identify and notify which clinics DSHS is responsible for submitting self-disclosure on their behalf.

DSHS Regional Office Staff – Comply with the expectations in this policy for reporting inventory discrepancies to central office staff.

CE staff – Adhere to the processes described within this policy. Report instances of materiality to HRSA and DSHS.

5.0 Policy

5.1

It is the policy of DSHS to define a material breach of 340B compliance as a combined violation of duplicate discount and diversion exceeding five percent of the total 340B inventory (units dispensed).

5.2

An entity with multiple locations under the same name calculates violations of diversion and duplicate discounts for each location separately. It is possible for one location to meet or exceed the material breach threshold, while the other locations do not meet the definition of materiality and therefore do not need to report violations as described in the Procedures section below.

5.3

Material breaches of 340B compliance violations meeting or exceeding the threshold defined in this policy require self-disclosure to HRSA, DSHS, and applicable pharmaceutical manufacturers. CEs participating in DSHS's CDM have the right to create their own material breach policy to follow in lieu of the DSHS material breach policy if the threshold established in their policy is less than the 5 percent threshold established in this policy.

5.4

The material breach threshold is applicable to each location of a 340B-eligible entity, except DSHS regional clinics and the CEs described below.

5.5

CEs participating in the DSHS CDM ordering less than 500 units (tablet, capsule, vial, etc.) per quarter from the DSHS central pharmacy should report violations of duplicate discount and diversion to DSHS 340B Pharmacy Unit staff at 340B@dshs.texas.gov. The DSHS Pharmacy Unit is responsible for calculating the material breach threshold and reporting instances of material breach to HRSA for these entities.

5.6

DSHS regional offices should report inventory tracking to 340B Pharmacy Unit staff at 340b@dshs.texas.gov, including instances of violations. 340B Pharmacy Unit staff manage reporting instances of material breaches to HRSA and affected manufacturers.

Type of Covered Entity	**Where to report Material Breach**
DSHS Regional Offices	Report to DSHS 340B Pharmacy Unit staff. 340B Pharmacy Unit staff report to HRSA.
CEs who receive less than 500 units (tablets, capsules, vials, etc.) per quarter from DSHS Central Pharmacy	Report to DSHS 340B Pharmacy Unit staff. 340B Pharmacy Unit staff report to HRSA.
CEs who receive more than 500 units per quarter	Report to DSHS central office AND HRSA to self-disclose a material breach.

6.0 Procedures

Determining Material Breach

Within the first two weeks following the end of each quarter (January 1–14, April 1–14, July 1–14, and October 1–14), use findings from internal self-audits, independent external audits, or otherwise that identify violations of duplicate discount, diversion, or both and that remain non-correctable within the quarter for which CE conducted the audit. See Policy 2023.008, Covered Entity and Inventory Tracking.

6.1

Gather all documentation (tracking logs, reports, etc.) that provides the medication name, National Drug Code (NDC), and quantity involved in violations.

6.2

DSHS and CEs must calculate the total quantity of medication they provided in violation of diversion, duplicate discounts, or both. See Policy 2023.006, Prevention of Diversion of 340B Medication, and Policy 2023.007, Prevention of Duplicate Discounts.

6.3

Calculate the percentage of materiality to determine if the threshold was met or exceeded [(quantity of violations/total quantity ordered within the quarter of audit) x 100].

6.4

If a CE determines they have met or exceeded the five percent threshold, they notify DSHS and HRSA as soon as possible and begin a Corrective Action Plan (CAP). The CE must complete the CAP within six months of reporting the material breach to HRSA.

6.5

DSHS and CEs must report to HRSA at 340Bselfdisclosure@hrsa.gov and applicable manufacturers using the Self-Disclosure to HRSA and Manufacturer Template and copy the 340B program staff as soon as possible at 340B@dshs.texas.gov.

6.6

DSHS stores and retains reported instances of material breaches and completed CAPs according to the agency retention schedule.

7.0 Associated Policies

Policy Number	Policy Title
2023.006	Prevention of Diversion of 340B Medication
2023.007	Prevention of Duplicate Discounts
2023.008	Covered Entity Ordering and Inventory Tracking

8.0 Revision History

Date	Action	Section
6/5/2023	Policy Issued	All