2023.006 Prevention of Diversion of 340B Medication

Policy Number	2023.006
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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

Per the Final Notice regarding Section 602 of the Veterans Health Care Act of 1992 patient and entity eligibility, 340B drugs are only provided to individuals eligible to receive 340B drugs from covered entities (CEs).

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 covered entities 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.

Administer – The direct application of a prescription drug by injection, inhalation, ingestion, or any other means to the body of a patient by: (A) a practitioner or an authorized agent under his supervision; or (B) the patient at the direction of a practitioner.

Diversion – Providing 340B medication to an ineligible patient or entity. Examples (this is not an exhaustive list):

- Providing medication to an ineligible patient or CE
- Undocumented medication (e.g., failure to track or document)
- Sharing or transferring medication to any other location or clinic

Eligible patient – An individual is a patient of a 340B CE (with the exception of state-operated or state-funded AIDS drug purchasing assistance programs) only if: The CE established a relationship with the individual, such that the CE maintains records of the individual's health

care. The individual receives health care services from a health care professional who either the CE employs or who provides health care under contractual or other arrangements (e.g., referral for consultation) such that the responsibility for the care provided remains with the CE. The individual receives a health care service or range of services from the CE consistent with the service or range of services for which grant funding or federally qualified health center look-alike status has been provided to the entity. HRSA does not consider an individual a patient of the CE if the only health care service received by the individual from the CE is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting. Exception: HRSA considers individuals registered in a state-operated or state-funded AIDS Drug Assistance Program (ADAP) receiving federal Ryan White funding patients of the participant ADAP if the state program registers them are as eligible.

Provide – To supply one or more units of use of a nonprescription drug or dangerous drug to a patient.

Prescribe – Provide a prescription for a medication to an individual filled at an outpatient or retail pharmacy.

3.0 Persons Affected

- DSHS Pharmacy Unit 340B Staff
- CE Staff

4.0 Responsibilities

4.1

The DSHS Central Pharmacy only provides 340B medications to eligible CEs, as defined by Policy 2023.005, Covered Entity Eligibility and Central Distribution Model Participation.

4.2

CEs ensure they only provide, administer, or prescribe 340B drugs to eligible patients. See Policy 2023.004, 340B Patient Eligibility for further details on patients eligible to receive 340B medications.

4.3

DSHS and CE must maintain and follow state regulations, as defined in Section 158.002 (a) & (b) of the Texas Medical Act.

4.4

DSHS oversees 340B medication distribution and inventory as defined in Policy 2023.012, Central Pharmacy and Warehouse Inventory Ordering and Tracking and Policy 2023.008,

Covered Entity Ordering and Inventory Tracking.

4.5

CE reports each instance of diversion to DSHS and the affected manufacturer. Each entity is responsible for payback associated with diversion violations and works in good faith with manufacturers. DSHS reports violations meeting the material breach threshold as defined in Policy 2023.009, 340B Material Breach, to the Health Resources and Services Administration (HRSA).

4.6

DSHS regional offices immediately report instances of diversion identified to 340B Pharmacy Unit staff at 340B@dshs.texas.gov. 340B Pharmacy Unit staff handle reporting instances of diversion to affected manufacturers.

4.7 Division Heads (Laboratory and Infectious Disease Services and Regional and Local Health Operations Division Heads)

- Ensure agency policies and division operation procedures are in alignment with:
- Federal and state statutes, rules, and guidelines;
- DSHS and HHS policies; and
- Guidelines defined by external funding sources.

4.8 Supervisors

- Ensure the implementation of this policy;
- Communicate policies and procedures to employees; and
- Document instances of violations of this policy and report them to the section director and 340B coordinator.

4.9 DSHS and covered entity employees

- Understand and comply with this policy;
- Ask the supervisor to clarify responsibilities for complying with policies and procedures as necessary;
- Report perceived conflicts or discrepancies between different DSHS policies and procedures to the supervisor; and
- Report instances of violations of this policy to the supervisor.

4.10 CE Staff

- Ensure compliance with this policy by reporting identified instances of diversion not meeting the 340B material breach threshold to manufacturers and DSHS 340B Pharmacy Unit staff.

- Work in good faith with manufacturers to ensure repayment for violations.

5.0 Procedures

5.1 Procedures for preventing diversion

5.1.1 DSHS and its CEs confirm site and service eligibility.

5.1.1.1 DSHS and its CEs determine CE eligibility. Refer to Policy 2023.005, Covered Entity Eligibility and Central Distribution Model Participation.

5.1.1.2 DSHS and its CEs determine patient eligibility. Refer to Policy 2023.004, 340B Patient Eligibility.

5.2 Procedures for handling and reporting violations of diversion

5.2.1 Report violations of diversion to DSHS 340B Pharmacy Unit staff in writing. Submit the notification within 15 calendar days of identifying the violation. Include the following information with submission:

- Entity name
- Entity's 340B ID number
- Name of medication and National Drug Code (NDC)
- Quantity of medication in violation of diversion
- Description of violation—do not include personally identifiable information (PII)

5.2.2 Report violations of diversion to the affected manufacturer(s).

- Refer to Apexus for the reporting template: 340bpvp.com/education/340b-tools/
- Notify DSHS 340B Pharmacy Unit staff once you submit the report to the manufacturer(s)
- Work with manufacturers to determine the cost associated with violations

5.2.3 DSHS 340B Pharmacy Unit staff determine if a corrective action plan (CAP) is necessary after receiving reported incidents of diversion. If a CAP is required, DSHS works with the reporting entity to ensure the completion of the CAP.

If instances of diversion reach or exceed the Material Breach defined in Policy 2023.009, 340B Material Breach. See Section 7.0 of the policy for the reporting requirement.

6.0 Associated Policies

Policy Number	Policy Title
2023.004	340B Patient Eligibility
2023.005	Covered Entity Eligibility and Central Distribution Model Participation
2023.008	Covered Entity Ordering and Inventory Tracking

2023.009	340B Material Breach Policy

7.0 Revision History

Date	Action	Section
5/30/2023	Policy Issued	All