2023.008 Covered Entity Ordering and Inventory Tracking

Policy Number	2023.008
Effective Date	June 5, 2023
Revision Date	
Subject Matter Expert	340B Program Coordinator
Approval Authority	HIV/STD Section Director
Signed by	*Josh Hutchison*

1.0 Purpose

The Department of State Health Services (DSHS) Pharmacy Unit ensures the proper procurement and inventory management of 340B-purchased medication. DSHS Pharmacy Unit participates in a Central Distribution Model (CDM) for distributing medication and testing supplies, which allows eligible program partners to use the Pharmacy Inventory and Ordering System (PIOS) to order 340B medication and testing supplies for their facility. This procedure describes the requirements for participating covered entities (CEs) to maintain accurate inventory within the scope of the 340B drug discount program.

The Pharmacy Unit provides medication and testing supplies to authorized CEs to prevent the spread of disease. The Pharmacy Unit receives, processes, and tracks orders using PIOS.

CEs receiving medications from the DSHS Pharmacy Unit are by default participating in the CDM and must meet the requirements outlined in Policy 2023.005, Covered Entity and Central Distribution Model Participation.

The DSHS Pharmacy Unit procures and manages medications purchased with the 340B discount for the following programs: the Sexually Transmitted Disease (STD) program, the Tuberculosis (TB) program, the Human Immunodeficiency Virus (HIV) program, and the Texas AIDS Drug Assistance Program (ADAP).

CEs registered in OPAIS using a DSHS grant ID always order medications at 340B pricing or sub-340B pricing, when available, whether they order the medications through their distributor or from the DSHS Pharmacy Unit.

CEs maintain accurate documentation of medication(s) ordered, received, provided, dispensed, administered, and wasted. CEs conduct internal reviews of inventory, including medication tracking documentation, to ensure the appropriate use of medication and 340B compliance at least quarterly.

DSHS monitors and oversees the inventory of 340B medication distributed by the DSHS Central Pharmacy to CEs. This may include site visits and inventory audits.

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 procedure refers to the 340B program.

Central Distribution Model – When a covered entity purchases medications under one account to send to multiple eligible locations. Each of the locations has its own 340B ID, except for DSHS Regional Clinics and pharmacies participating in the THMP program.

3.0 Persons Affected

- DSHS Pharmacy Unit Staff
- CE Staff

4.0 Responsibilities

DSHS Pharmacy Unit Staff – Oversee and adhere to the processes described within this procedure. Ensure accurate inventory processes and maintain records of transactions.

CE Staff – Adhere to the processes described within this procedure. Ensure inventory and maintain records of transactions.

5.0 Procedures

5.1 Eligible Entity Ordering Process

Each individual clinic ordering medication from the Pharmacy Unit within the CDM maintains a physical inventory of both 340B and non-340B drugs.

5.1.1 Clinics order medication using the PIOS portal.

5.1.1.1 Entities complete ordering, which is location-specific.

5.1.1.2 Each employee ordering medication uses an individual login (see Policy 2023.005, Covered Entity Eligibility and Central Distribution Model Participation).

5.1.2 Clinics confirm receipt of medication via the PIOS portal and document it on their Medication Tracking Log.

5.1.3 Clinics reconcile inventory in the PIOS portal no later than 30 days from the last documented reconciliation date for the specific clinic. Clinics complete inventory reconciliation prior to ordering additional medication.

5.2 Covered Entity Tracking Process

5.2.1 CEs document all medications received from the DSHS Pharmacy Unit on the Medication Tracking Log. CE creates a separate page of the log for each National Drug Code (NDC).

5.2.2 CEs document all medications dispensed, administered, provided, or wasted.

5.2.2.1 CEs use an auditable medication tracking log (electronic or manual). Medication tracking logs include the following information:

5.2.2.1.1 Medication name with NDC, lot number, and expiration date.

5.2.2.1.2 For each provision of the medication (e.g., medication CE receives; each time CE dispenses, administers, or provides the medication; medication expired; etc.), CE staff document the following information:

- Date of provision (e.g., date CE receives, dispenses, administers, or provides medication; date medication expired; etc.),
- Description of provision (e.g., medication received, medication administered, medication expired, etc.). For all provisions involving dispensing, administering, or providing to a client, the description includes the client's name and date of birth (DOB),
- Amount of medication units received or removed from inventory (e.g., tablet, vial, etc.),
- Remaining balance of inventory, and
- Personnel initials for the individual handling the provision. ***For DSHS Class D pharmacies, this individual must be a registered nurse***

5.2.3 CEs complete the monthly reconciliation form on the PIOS portal. For questions, please contact the Pharmacy Unit help desk at 340B@dshs.texas.gov.

5.3 THMP Participating Pharmacy Ordering and Tracking Process

See Policy 700.004, HIV Medications Ordering Process for Pharmacies.

5.4 Wasted 340B Medication Process

CE staff remove wasted medications from active inventory.

5.4.1 Pharmacies participating in THMP send medication back to the DSHS central pharmacy no less than 90 days prior to the expiration date.

5.4.2 CE staff document wasted medications on the medication tracking log.

5.4.3 Disposal of wasted medication from inventory

5.4.3.1 CE should dispose of wasted medications based on applicable policies and procedures established for their entity.

5.5 Discrepancies

CEs report discrepancies they cannot reconcile electronically to DSHS Pharmacy Unit. See Policy 2023.006, Prevention of Diversion of 340B Medication.

6.0 Associated Policies

Policy Number	Policy Title
700.004	HIV Medications Ordering Process for Pharmacies
2023.005	Covered Entity Eligibility and Central Distribution Model Participation
2023.006	Prevention of Diversion of 340B Medication

7.0 Revision History

Date	Action	Section
6/7/2023	Policy Issued	All