

## 2023.004 340B Patient Eligibility

Policy Number	2023.004
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Revision Date	
Subject Matter Expert	340B Program Coordinator
Approval Authority	HIV/STD Section Director
Signed by	<i>Josh Hutchison</i>

### 1.0 Purpose

The Department of State Health Services (DSHS) ensures covered entities only provide, dispense, prescribe, or administer 340B drugs to eligible patients. DSHS Pharmacy Branch participates in a Central Distribution Model (CDM) for distributing medication and 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.

### 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.

**Dangerous Drug** – Any drug or device not included in [Penalty Groups 1-4 of the Controlled Substances Act](#) which is unsafe for self-medication, or any drug or device bearing or required to bear the legend: "Caution: federal law prohibits dispensing without prescription" or "Rx only." [\[1\]](#)

**Dispense** – Preparing, packaging, compounding, or labeling for delivery of a prescription drug or device during professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner. [\[1\]](#)

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

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

**Provide** – To supply one or more units of use of a nonprescription drug or dangerous drug to a patient. [\[1\]](#)

**Uninsured Patient** – A patient who experiences any circumstance which might influence or restrict access to necessary preventive health care services or medication. These circumstances might include, but are not limited to, patients concerned about privacy when using their insurance or having a financial burden due to high deductibles or co-pays, any patient whose provider would not be able to provide timely treatment, or any partner of a contact identified through disease intervention specialist (DIS) or contact tracing.

### 3.0 Persons Affected

Programs who participate in 340B, including recipients of 340B medication.

### 4.0 Responsibilities

DSHS ensures patient eligibility as defined by the Health Resources and Services Administration (HRSA) in the [Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992](#) Patient and Entity Eligibility.

#### 4.1 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.

#### 4.2 Supervisors

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

#### 4.3 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.

## 5.0 Policy

### 5.1

The policy of DSHS reflects the [Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992](#) Patient and Entity Eligibility; CEs only provide 340B drugs to individuals eligible to receive them. DSHS ensures the patient meets the definition as follows: An individual is a “patient” of a CE (with the exception of state-operated or funded AIDS drug purchasing assistance programs) only if:

- The CE has 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 responsibility for the care provided remains with the CE; and
- The individual receives a health care service or range of services from the CE which is 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.

### 5.2

A CE considers an individual a “patient” for the purposes of this definition if the CE is registered in a state-operated or funded AIDS Drug Purchasing Assistance Program receiving financial assistance under Title XXVI of the Public Health Service (PHS) Act and eligible for the state program.

### 5.3

A CE does not consider an individual a “patient” of the entity for purposes of 340B 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.

### 5.4

Any 340B medication provided to an ineligible patient is considered diversion and a violation of the [Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992](#) Patient and Entity Eligibility. See Policy 2023.006, Prevention of Diversion of 340B Medication for details on handling patient eligibility violations.

## 6.0 Procedures

### 6.1 Determine patient status

**\*\*\*This step is only for patients seeking treatment for sexually transmitted diseases under the DSHS sexually transmitted disease (STD) program. Skip to step 6.2 for patients getting care or services for any program other than STD.\*\*\***

6.1.1 Each patient must meet the DSHS uninsured definition for STD program patients. Each clinic must maintain documentation of the patient's uninsured status.

### 6.2 Maintain records of an individual's health care

**6.2.1** CE staff establish a patient chart.

**6.2.2** Determine whether the individual receives a health care service or range of services from the CE consistent with the service or range of services for which a DSHS program has provided grant funding to the CE.

### 6.3 Determine provider eligibility

**6.3.1** CE employs a provider or provider provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the CE.

**6.3.2** Follow standing delegation orders.

### 6.4 Determine the patient's Medicaid status

**6.4.1** Refer to [Policy 2023.007, Prevention of Duplicate Discounts](#)

## 7.0 Associated Policies

Policy Number	Policy Title
2023.007	<u><a href="#">Prevention of Duplicate Discounts</a></u>

## 8.0 Revision History

Date	Action	Section
5/30/2023	Policy Issued	All

## Notes

1 - [Texas Administrative Code; Title 22, Part 15, Chapter 291, Subchapter E; Rule §291.91](#):  
Definitions