

# 2023.005 Covered Entity Eligibility and Central Distribution Model Participation

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Subject Matter Expert	340B Program Coordinator
Approval Authority	Associate Commissioner of Laboratory and Infectious Disease Services
Signed by	<i>Imelda Garcia</i>

## 1.0 Purpose

This policy explains the two options for purchasing medications and supplies available to covered entities (CEs) affiliated with the Texas Department of State Health Services (DSHS) and receiving direct funding or in-kind services, making them eligible to participate in the 340B drug pricing program.

This policy establishes the HIV/STD program partners eligible to participate in the 340B program using a DSHS federal grant number to purchase 340B discounted medication and supplies with their funds.

This policy establishes which partners are eligible to participate in the DSHS's 340B Central Distribution Model (CDM) for distributing medication and supplies. Allowing eligible program partners to use the Pharmacy Inventory and Ordering System (PIOS) to order 340B medication and testing supplies for their facility. This policy describes procedures for those program partners choosing to participate in DSHS's 340B CDM using PIOS.

Any program or facility receiving in-kind contributions or federal funding from DSHS is eligible to use a DSHS grant number to register as a CE for that program. CEs are eligible to order medication from the DSHS Central Pharmacy. Certain CEs can choose to order medications at 340B pricing with their funding.

## 2.0 Authority

Texas Health and Safety Code §81.002, §81.021, and §§85.061-85.065.

## 3.0 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.

**340B Program** – Refers to the federal Health Resources and Service Administration’s (HRSA) 340B drug pricing program, which reduces the cost of covered outpatient drugs for certain federally supported entities and eligible health care organizations. The term “340B” is used throughout this policy to refer to the 340B program.

**Central Distribution Model** – When a CE 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 Texas HIV Medication Program (THMP).

**Contract Pharmacy** – 340B-covered entities may contract with a pharmacy (or pharmacies) to provide services to the covered entity’s patients, including the service of dispensing the entity-owned 340B drugs. To engage in a contract pharmacy arrangement, the covered entity and pharmacy (or pharmacies) must have a written contract or a memorandum of understanding (MOU) aligning with 340B compliance elements. Typically, they use a bill-to-entity or ship-to-pharmacy arrangement. Covered entities must list the contract pharmacy on their 340B OPAIS account, which they can only be add or remove during a quarterly registration period.

**Direct Funding** – Funding provided to an organization directly from the federal government. Any funding received from DSHS is not considered direct funding for the purpose of this policy.

**Entity Owned Pharmacy** – A pharmacy owned by, and a legal part of, the 340B entity. Typically, entity-owned pharmacies are listed as shipping addresses for the entity. Also known as an “in-house pharmacy.”

**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. This system is referenced in this document as the “OPAIS database.”

**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).

## 4.0 Persons Affected

- DSHS Pharmacy Unit 340B Staff
- DSHS TB/HIV/STD Section Program Staff
- DSHS Pharmacy Unit Staff
- CE Staff

## 5.0 Responsibilities

**DSHS Pharmacy Unit 340B Staff** – Oversee and serve as the point of contact for requirements to participate in and maintain compliance with the CDM. Serve as the liaison between CE, DSHS program staff, and DSHS Pharmacy Unit staff to ensure the appropriate

parties complete and process documents and registrations. (e.g., MOUs, OPAIS registration, and PIOS account assistance).

**DSHS HIV/STD and TB Program Staff** – Oversee and enforce this policy to confer CE eligibility and grant access to PIOS for ordering 340B medications from the Pharmacy Unit.

**DSHS Pharmacy Unit Staff** – Reviews and verifies CE eligibility before allowing access to PIOS.

**Covered Entity (CE) Staff** – Understand the entity's relationship or contract(s) with DSHS and if or how their entity is eligible for the 340B medication program. If eligible and choosing to participate in DSHS's *CDM*, register the entity on OPAIS using the appropriate grant number. Submit a completed [PIOS Site Request Form](#) and then submit it to program staff for review.

## 6.0 Policy

### 6.1

The DSHS Central Pharmacy provides medication and supplies only to approved CEs, authorized pharmacies, and eligible patients for treating and preventing the spread of infectious diseases. The DSHS Central Pharmacy receives, processes, and tracks orders using PIOS.

### 6.2

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

### 6.3

DSHS 340B staff review and approve CEs requesting access to PIOS. See Sections 5 and 6 for eligibility criteria and exclusions.

### 6.4

Authorized CEs register in the OPAIS database as 340B CEs. Refer to Policy 2023.010, 340B Database Registration, Recertification and Review Process for details.

### 6.5

Eligibility to register in OPAIS as a 340B CE using a DSHS grant ID is site-specific. CEs with more than one location must determine CE eligibility for each site.

## 6.6

Suspension from PIOS occurs when CEs fail to maintain accurate information in the OPAIS database. CEs must correct the information, and DSHS confirms the reinstatement of access.

## 7.0 Covered Entity Exclusion Eligibility

If a CE receives direct federal funds for STD, HIV prevention, Ryan White, viral hepatitis, or TB and registers on OPAIS with their federal grant number (not a DSHS federal grant number), the CE is **not** eligible to utilize PIOS to receive 340B medications or testing supplies for that directly funded program(s).

## 8.0 Criteria for Determining Eligibility for Providing Entities Affiliated with DSHS's TB and HIV/STD Section Programs

### 8.1 Sexually Transmitted Disease (STD) Program

#### 8.1.1 Public Health Follow-Up (PHFU) contracted sites

- These sites receive funding from DSHS to carry out program operations, including surveillance and PHFU activities.
- These sites are also part of the Texas Infertility Prevention Project (TIPP) and receive in-kind services in the form of STD testing supplies and training for *Chlamydia trachomatis* (CT) or *Nisseria gonorrhoeae* (GC) or technical assistance.
- Texas Infertility Prevention Program (TIPP) Sites These sites receive in-kind services in the form of CT or GC testing supplies, training, or technical assistance.
- These sites are eligible to register in OPAIS with the DSHS STD grant number to order 340B medication through PIOS or using their funding.
- TIPP sites with multiple locations are only eligible for 340B at the site(s) receiving in-kind contributions from DSHS.

#### 8.1.2 HIV Prevention Program

- HIV Prevention Programs providing HIV prevention included in the scope of the CDC-funded HIV Prevention Grant.
- These sites are eligible to register in OPAIS with the DSHS HIV Prevention grant number to order 340B medication through PIOS or using their funding. PrEP and nPEP medications are not provided by DSHS.

Sites eligible under the STD Program *and* HIV Prevention Program should use only one grant number—either STD or HIV Prevention—for registration in the OPAIS database for participation in the CDM (the CE's decision). An entity which does not participate in the CDM may choose to register their eligible grant numbers, which are subject to DSHS verification. participate in the CDM, may choose to register their numbers, and are subject to DSHS verification.

## 8.2 Tuberculosis (TB) Program

**8.2.1** TB programs contracted with DSHS are eligible to register in OPAIS using the DSHS TB grant number to order 340B medications using PIOS.

## 8.3 HIV and Ryan White Care Services Program

**8.3.1** HIV Care Services works with seven administrative agencies (AAs) that subcontract out to entities working with clients. The sub-contractors are eligible to register in OPAIS using a DSHS grant number. They are not eligible to order medication through PIOS.

**8.3.2** The DSHS Central Pharmacy purchases 340B medications on behalf of the Texas HIV Medication Program (THMP) for the AIDS Drug Assistance Program (ADAP) and distributes these medications through the DSHS Central Pharmacy to a network of participating pharmacies.

## 8.4 DSHS Public Health Regions (PHR) (including Regional Clinics), Regional

**8.4.1** DSHS regional offices and clinics are an extension of the DSHS agency and are eligible for the 340B Program.

## 9.0 Procedures

### 9.1 Procedures for entities registered in OPAIS under a DSHS grant number that purchase medications and supplies using their funding

**9.1.1** Adhere to OPAIS registration and recertification requirements as outlined in Policy 2023.010, 340B Database and Registration, Recertification, and Review Process.

**9.1.2** Entities are responsible for ensuring their compliance with the 340B program.

### 9.2 Procedures for Entities Participating in the DSHS CDM

**9.2.1** PIOS Access for STD, HIV Prevention, or TB Program CEs.

#### 9.2.1.1 Covered Entities

- CE signs the PIOS MOU.
- Once DSHS executes the MOU, the CE registers on the OPAIS database. See Policy 2023.010, 340B Database Registration, Recertification, and Review Process.
- Submit a completed [PIOS Request Form Location](#) to the program contact person for the requested program (if requesting access for more than one program, submit it to the program contact person).

\*\*\*\*\* *PIOS accounts are for individual users. Each person placing medication or supply orders must have separate accounts. Do not share accounts or passwords.*

*The 340B team only grants access to PIOS after CE's eligibility is active on OPAIS, according to the OPAIS Open Registration Schedule. See Section 6.1 of [Policy 2023.010, 340B Database and Registration, Recertification, and Review Process](#), for the registration schedule.*

## **9.2.2 Suspension and Termination of PIOS Access**

### **9.2.2.1 Suspension**

The 340B team can suspend PIOS access due to:

- Failure to maintain registration in the OPAIS database. See Section 6.3 in Policy 2023.010, 340B Database and Registration, Recertification and Review Process.
- Failure to renew the PIOS MOU
- CE failure to maintain compliance with procedures and policies outlined in the 340B Provider Manual
- DSHS Pharmacy Unit 340B staff notifies CE's Authorizing Official (AO) and Primary Contact (PC) by email no later than one week prior to suspending PIOS access to inform them of the upcoming change in access due to failure to adhere to agency policies.
- The CE must address corrective actions to remove the suspension and reinstate PIOS account access.
- An individual with an PIOS account changes positions or leaves the agency and no longer uses the system.

### **9.2.2.2 Termination**

340B staff may terminate PIOS access at any time if or when:

- CE failure to maintain compliance with procedures and policies outlined in the 340B Provider Manual,
- Any change occurs to the CE's eligibility, such as the end of a contract or agreement with a participating DSHS program, or
- CE failure to implement and comply with non-complaint corrective actions.

## **9.3 Procedures for Ordering 340B Medications from DSHS Central Pharmacy for THMP Participating Pharmacies**

These procedures only apply to pharmacies contracted with DSHS to dispense medications for THMP.

**9.3.1** Each individual THMP-participating pharmacy must sign a THMP Contract Pharmacy MOU.

**9.3.2** When the THMP-participating pharmacy needs to order medications, they submit order requests to the THMP.

**9.3.3** THMP program staff verifies patient eligibility.

**9.3.4** After verification of patient eligibility, THMP program staff orders medications through PIOS.

**9.3.5** DSHS Central Pharmacy fills medication from 340B inventory and sends it to the THMP-participating pharmacy to dispense.

## **10.0 Associated Policies**

<b>Policy Number</b>	<b>Policy Title</b>
2023.010	<u>340B Database Registration, Recertification, and Review</u>

## **11.0 Revision History**

<b>Date</b>	<b>Action</b>	<b>Section</b>
<b>5/30/2023</b>	Policy Issued	All