

## 2023.010 340B Database Registration, Recertification, and Review

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Subject Matter Expert	340B Program Coordinator
Approval Authority	HIV/STD Section Director
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### 1.0 Purpose

Describes the process by which Texas Department of State Health Services (DSHS) programs and covered entities (CEs) register and recertify on the [Office of Pharmacy Affairs Information System](#) (OPAIS) database to be eligible for 340B discounted medications. The Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA) requires registration and annual recertification for each unique 340B ID. DSHS's HIV/STD Section has four unique 340B IDs which must abide by these requirements: Tuberculosis (TB), Sexually Transmitted Disease (STD), HIV Services branch or HIV Medication Program, and Texas HIV Medication Program (THMP) AIDS Drug Assistance Program (ADAP). This policy also explains the expectations for reviewing the OPAIS database to ensure accuracy of information and to confirm the CEs associated with program-specific grant ID numbers in the database are comprehensive and correct.

Each CE has one unique 340B ID for each site registered (e.g., if a CE has more than one site receiving federal funding or in-kind services through DSHS, the CE needs to register each site, and each site has its own 340B ID).

Each DSHS program with a registered 340B ID number is responsible for reviewing the [OPAIS database](#) to ensure the completeness and accuracy of the information entered for their program. This review takes place in each quarter when the OPAIS database registration period is open to allow for edits if necessary. The registration periods are January 1–15, April 1–15, July 1–15, and October 1–15.

The DSHS HIV Prevention Program and the Ryan White HIV/AIDS Part B (RWHAP) Program do not register in the OPAIS database because they do not use grant funds to purchase medications. However, CEs that are recipients of the HIV Prevention and RWHAP Part B grant are eligible to register in OPAIS using a DSHS grant number to purchase medication at the 340B discounted price with their own funds if they meet the criteria outlined in [Policy 2023.005, Covered Entity Eligibility and Central Distribution Model Participation](#).

Each DSHS program is responsible for ensuring CEs register their 340B program in the OPAIS database and monitoring accuracy in their registration each quarter, as defined above.

Every program, including DSHS and CEs, must recertify annually to continue 340B eligibility using a DSHS grant number during the recertification period defined by the OPA.

CEs using a DSHS grant number for 340B registration must have a contract or memorandum of understanding (MOU) executed prior to registration on the OPAIS database.

## 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.

**340B ID** – Identification number used in the OPAIS system for 340B-specific activities; HRSA OPA assigns the 340B ID to a covered entity at the time of registration into the OPAIS database. A 340B ID is different from a grant number. Each program within DSHS has a unique 340B ID: Tuberculosis (TB), Sexually Transmitted Disease (STD), HIV Services Branch or HIV Medication Program, and Texas AIDS Drug Assistance Program (ADAP). Each covered entity also has one unique 340B ID for each location registered (e.g., if a covered entity has more than one location receiving federal funding or in-kind services through DSHS, the covered entity needs to register each location, and consequently each location has its own 340B ID).

**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. Use of the term "340B" throughout this policy refers to the 340B Program.

**Authorizing Official** – The person who has the legal authority to bind an organization to a contract. DSHS and covered entities must have an authorized official. For example, the authorizing official (AO) for DSHS is the Division of Laboratory and Infectious Disease (LIDS) Associate Commissioner. The AO for covered entities may be a chief executive officer, chief financial officer, chief operations officer, clinic administrator, or program manager.

**Contract Pharmacy** – 340B-covered entities may contract with a pharmacy or pharmacies other than the DSHS Pharmacy Unit 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 Memorandum of Understanding (MOU) aligning with the compliance elements and list the contract pharmacy on 340B OPAIS during a quarterly registration period. Typically, CE uses a bill-to (entity) or ship-to (pharmacy) arrangement.

**Direct Funding** – Funding provided to an organization directly from the federal government. This policy does not consider funding received from DSHS as direct funding.

**Grant Number** – The 10- or 12-character series consisting of the activity code, organization code, and serial number to identify federal grants. DSHS is the recipient of federal grants through the Federal Grant Program, which programs use to fund covered entities, and HRSA

assigns each of those federal grants a grant number. Each DSHS program and covered entity provides the federal grant number linking them to DSHS's funds when registering for the 340B Program.

**In-kind Services** – Contributions paid for by grant funds from Section 317 or 318 of the Public Health Service Act. In-kind contributions may be in the form of real property, equipment, supplies, and other expendable property, as well as goods and services directly benefiting and specifically identifiable to the project or program. The Public Health Service Act does not consider medication purchased with 340B discounts as in-kind contributions.

**Memorandum of Understanding (MOU)** – Contracts involving the exchange of promises, with or without the actual exchange of money. In general, MOUs are legally enforceable.

**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. Use of the term "OPAIS database" in this policy refers to this system.

**Primary Contact** – An employee of the organization or covered entity responsible for updating the OPAIS information and ensuring they make changes within the correct deadlines for their program. This person is the program contact for HRSA and is notified if or when HRSA plans to conduct an audit on their 340B program. Each registered program in DSHS's HIV/STD Section has a primary contact. Each covered entity registered in OPAIS under a DSHS grant ID number also designates a primary contact for their covered entity. The primary contact cannot be the same person as the authorizing official and cannot be an individual who is not directly employed by the organization (e.g., a contractor or outside consultant).

### 3.0 Persons Affected

- HIV/STD Section Staff
- Authorizing Officials (AOs)
- DSHS Primary Contacts
- CE Primary Contacts

### 4.0 Responsibilities

**HIV/STD Section Staff** – Monitor each program for compliance and ensure the CE Primary Contact is reviewing the OPAIS database each quarter.

**Authorizing Official (AO)** – Certifies compliance annually and monitors compliance within the program. The AO is the only person who can approve and submit a CE's registration in OPAIS. This person is responsible for keeping a CE's 340B status active and up-to-date.

**DSHS Primary Contacts (PC)** – Oversees and enforces this policy for 340B CEs included within their DSHS program and serves as the point of contact for each of their CEs. Reviews the OPAIS database on a quarterly basis for accuracy and ensures CEs associated with each program's grant ID numbers register in OPAIS with accurate information.

**Covered Entity Primary Contacts** – Registers their program in OPAIS, ensure information in the database is correct and complete, and review their own registration quarterly, as defined in this policy. Conducts a review of DSHS 340B ID information in OPAIS within the first two weeks of each quarter to ensure accuracy and completeness. DSHS PC then communicates with OPAIS to update incorrect information.

## 5.0 Procedures

### 5.1 Initial Registration for new 340B Programs

A new 340B program within DSHS or a new CE registers on the OPAIS database at the beginning of the next registration period. The registration periods are January 1–15, April 1–15, July 1–15, and October 1–15.

**5.1.1** The authorizing official (AO), primary contact (PC), or both need to create an account in OPAIS ([340bopais.hrsa.gov/home](https://340bopais.hrsa.gov/home)). Once created, the AO or PC follows the prompts to register a new site. The AO approves and submits registration, and they complete online registration in one session.

**5.1.2** Registration requires the completion of the following information:

- Name of organization
- Grant number (provided by DSHS for CEs)
- The Notice of Funding Opportunity (NOFO) number
- The date range for NOFO funding
- The type of in-kind support received (if applicable)
- Street address
- Billing address
- Shipping addresses (if different)
- AO contact information
- PC information
- Medicaid Billing tab (see [Policy 2023.007, Prevention of Duplicate Discounts](#))
- Contract pharmacies (if any, see below)

**5.1.3** Once each CE registers, HRSA sends a request to the DSHS PC for the corresponding DSHS grant number to confirm the CE. The DSHS PC reviews the submitted information and verifies if the CE receives federal funding or in-kind services from a DSHS program, then provides verification when they confirm the information. HRSA responds within five business days with an approval or denial of the registration.

**5.1.4** Once CE has completed the registration and HRSA OPA has approved it, CE receives notification from HRSA and is eligible to start ordering using the 340B discounts on the first day of the next quarter after registration. For example, if the registration is complete during the January 1–15 registration period, the entity is eligible on April 1.

**5.1.5** CEs receiving awards at multiple sites register each address location where they store or administer medications as a separate CE with its own 340B ID number, even if they use the same grant number.

**5.1.6** CEs receiving multiple awards must register each program separately, even if the address is the same. For example, if a CE receives HIV care services funding and STD funding, it registers using both grant numbers, which results in two unique 340B IDs.

**5.1.7** The exception to the above statement is for STD providers who also provide HIV prevention services: CEs use only one grant number, either STD or HIV prevention, for registration (CE decides).

**5.1.8** If the information is incorrect, the PC submits a change request through the OPAIS database. Once PC submits a change request, HRSA OPA sends it to the AO for approval.

## 5.2 Procedures for DSHS Programs to Review Information Entered in OPAIS for CEs

Each quarter, the DSHS PC reviews the information entered for each of the CEs using their program's DSHS grant number as follows:

- Process a 'search' request in OPAIS.
- Enter the DSHS program's grant number in the 'Grant or Provider Number' field.
- Review each active CE associated with the grant number to ensure the following:
  - ▶ The listed CE receives funding or in-kind services,
  - ▶ Review NOFO and ensure accuracy and completeness (e.g., number, date range of funding, type of in-kind support received, if applicable),
  - ▶ The name and address listed are the same names and addresses DSHS has on record, and
  - ▶ The CE PC is an active employee whom DSHS program staff may contact.
- If the information is incorrect, contact the CE's AO or PC to inform them of the required edits. During the next quarter's review period, confirm that CE's AO or PC completed the requested edits. If edits were not made within two quarters (i.e., six months), DSHS' AO or PC reports to HRSA for CEs not using Pharmacy Inventory and Ordering System (PIOS) or suspends access to PIOS for CEs ordering medications and supplies from the DSHS Central Pharmacy (refer to Section 9.2 in [Policy 2023.005, Covered Entity Eligibility and Central Distribution Model Participation](#) for guidance on PIOS suspension).

## 5.3 Procedures for Registering Contract Pharmacies

**5.3.1** CEs may use contract pharmacies to get 340B medication to eligible patients (see [Policy 2023.004, 340B Patient Eligibility](#)). To engage in a contract pharmacy arrangement, the CE and pharmacy (or pharmacies) must have a written contract or a MOU aligning with 340B compliance elements. Typically, CE uses a bill-to (entity) or ship-to (pharmacy) arrangement. CEs list the contract pharmacy on their 340B OPAIS account, and they can only add or remove it during a quarterly registration period.

**5.3.2** Prior to registering on OPAIS, CEs must have an executed contract or MOU in place with the pharmacy. Registering new pharmacies occurs during the registration dates listed above in Section 5.1.

**5.3.3** PC or AO navigate to the "Contract Pharmacy" tab once signed into OPAIS and enter the information required.

- Pharmacy name
- Pharmacy address
- Approval date (date of contract or MOU execution)

**5.3.4** HRSA may request verification of the executed contract at the time of registration.

## 5.4 Annual Recertification and Registration Review

### 5.4.1 Registration Review

At the time of annual recertification, the PC or AO first reviews the following information in the OPAIS database for their program to ensure accuracy and completeness:

- Name of organization
- Grant number
- Update the Notice of Funding Opportunity (NOFO) number (if applicable)
- Update the date range of NOFO funding (if applicable)
- Update the type of in-kind support received (if applicable)
- Street address
- Billing address
- Shipping addresses (if different than the billing address)
- AO's contact information
- PC's contact information
- Medicaid Billing tab

### 5.4.2 Annual Recertification

HRSA requires programs to complete annual recertification and an attestation of compliance via the OPAIS database. Each AO and PC receives an email from the OPAIS database for a designated timeframe based on their program designation. The AO completes the attestation and submits the recertification. Failure to recertify by the date provided results in termination from the 340B Program.

## 5.5 Terminating OPAIS Registration

### 5.5.1 Covered Entities

#### 5.5.1.1 When to Terminate OPAIS Registration

A CE must terminate registration in OPAIS if they are no longer receiving funds or in-kind contributions from DSHS, making them eligible for the 340B Program.

#### 5.5.1.2 How to Terminate Registration in OPAIS

- AO or PC login to their OPAIS account. Refer to the user manual for instructions on terminating a CE and for assistance.
- Once AC or PC submit termination in OPAIS, OPA sends the AO and PC an email with their termination date.

- CE, AO, or PC notify DSHS PC by email with the OPAIS termination date once received from OPA.

#### **5.5.1.3 Party Responsible for Terminating OPAIS Registration**

The CE, AO, and PC are responsible for terminating registration for their CE in OPAIS.

#### **5.5.1.4 Timeframe for Terminating OPAIS Registration**

A CE must terminate registration in OPAIS by the last day of the quarter in which the contract with DSHS that makes them eligible for 340B ends. The following table describes the timeframe for handling termination in OPAIS:

<b>Period in which contract with DSHS ends</b>	<b>Last Day CE can terminate registration in OPAIS</b>	<b>Termination Date (date when CE registration ends)</b>
January 1-March 31	March 31	April 1
April 1-June 30	June 30	July 1
July 1-September 30	September 30	October 1
October 1-December 31	December 31	January 1 (following year)

#### **5.5.1.5 Failure to Terminate OPAIS Registration**

If a CE does not terminate their registration within the appropriate timeframe described above, DSHS notifies HRSA that the CE is no longer eligible for 340B, and HRSA opens an investigation. The investigation could result in diversion findings and repayment to manufacturers at the expense of the CE.

### **5.5.2 Contracted Pharmacies**

#### **5.5.2.1 When to Terminate OPAIS Registration**

- A CE must terminate a contract pharmacy in OPAIS if the contract between them ends.
- If another company buys out a contract pharmacy, the CE must terminate the old contract pharmacy in OPAIS and register the new pharmacy upon execution of the new contract. This transition in OPAIS takes place during the registration period prior to the change in ownership to prevent a lapse in 340B eligibility.
- HRSA OPA does not terminate a contract pharmacy incurring a name or address change (but no new ownership) in OPAIS, and instead PC submits a change request with the updated information. These changes must happen within the quarterly registration periods: January 1–15, April 1–15, July 1–15, and October 1–15.

#### **5.5.2.2 How to Terminate Registration in OPAIS**



- AO or PC login to their OPAIS account. Refer to the OPAIS User Manual by clicking the “Help” button in the account for instructions on terminating a contract pharmacy for assistance.
- Once the AO or PC submits termination in OPAIS, OPA sends the AO and PC an email with their termination date.

#### 5.5.2.3 Party Responsible for Terminating OPAIS Registration

The AO and PC for the CE are responsible for handling OPAIS registration terminations and changes or transitions for each of their contract pharmacies.

#### 5.5.2.4 Timeframe for CE to Terminate a Contract Pharmacy from OPAIS Registration

A CE must terminate their contract pharmacy’s registration in OPAIS by the last day of the registration period for the quarter prior to the one in which their contract with the pharmacy ends. The following table describes the timeframe for handling termination in OPAIS:

Period in which contract between CE & CP ends	Last Day CP’s Registration in OPAIS can be Terminated	Termination Date (date when CP registration ends)
January 1-March 31	October 15 (previous year)	January 1
April 1-June 30	January 15	April 1
July 1-September 30	April 15	July 1
October 1-December 31	July 15	October 1

## 6.0 Associated Policies

Policy Number	Policy Title
2023.004	<u>340B Patient Eligibility</u>
2023.005	<u>Covered Entity Eligibility and Central Distribution Model Participation</u>
2023.007	<u>Prevention of Duplicate Discounts</u>

## 7.0 Revision History

Date	Action	Section
6/6/2023	Policy Issued	All