

2023.013 340B Authorizing Official Back-up

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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

To ensure an effective transition of authorizing official (AO) responsibilities from the Associate Commissioner of Laboratory and Infectious Disease Services (LIDS) in the event they become unavailable to maintain registration and other administrative duties for the Department of State Health Services (DSHS) covered entities in the [Office of Pharmacy Affairs Information System](#) (OPAIS) for the 340B program, such as during a declared state of emergency or transition of employment.

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 using a DSHS grant number to register 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 CE 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/HIV Medication Program, and Texas AIDS Drug Assistance Program (ADAP). Each CE also has one unique 340B ID for each location registered (e.g., if a CE has more than one location receiving federal funding or in-kind services through DSHS, the CE 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 procedure refers to the 340B Program.

Authorizing Official – The person who has the legal authority to bind an organization to a contract. DSHS and CEs 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 CEs may be a chief executive officer, chief financial officer, chief operations officer, clinic administrator, or program manager.

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. The use of the term “OPAIS database” refers to this system.

Primary Contact (PC) – An employee of the organization or CE 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 CE registered in OPAIS under a DSHS grant ID number must also designate a primary contact for their CE. The primary contact cannot be the same person as the authorizing official and cannot be an individual who the organization does not directly employ (e.g., a contractor or outside consultant).

3.0 Persons Affected

- Deputy Commissioner of the Department of State Health Services
- Associate Commissioner of Laboratory and Infectious Disease Services
- Deputy Associate Commissioner of Laboratory and Infectious Disease Services
- Division Heads

4.0 Responsibilities

Deputy Commissioner of DSHS – Identifies and assigns duties to the division head selected if the Associate Commissioner and Deputy Associate Commissioner are unable to perform the duties of the authorizing official.

5.0 Procedures

5.1

In the event the Associate Commissioner of LIDS is unavailable to perform the duties of the authorizing official for the 340B program, the Deputy Associate Commissioner of LIDS performs the authorizing official duties. If both LIDS division heads are unavailable, the Deputy Commissioner of DSHS identifies a division head who performs the authorizing official duties.

5.2

The Deputy Associate Commissioner, or other identified division head, creates an account on the OPAIS database at 340bopais.hrsa.gov/home.

5.3

Deputy Associate Commissioner or other identified division head performs the next steps four (4) times, once for each registered 340B program [Tuberculosis (TB), Sexually Transmitted Disease (STD), HIV Services Branch/HIV Medication Program, and Texas AIDS Drug Assistance Program (ADAP)].

5.3.1 Perform a “covered entity search” to locate each (4) DSHS CE.

5.3.2 Navigate to the “CE details” page and click the “change” button next to the authorizing official. The details populate with the information used to register the requestor’s information (Deputy Associate Commissioner or other division head).

5.3.3 The Authorizing Official Signature area appears at the bottom of the page. Click the check box, enter information or comments which are useful to the current AO and OPA when reviewing the request, and click the Authorize and Submit button.

5.4

OPA must approve authorizing official change requests. Upon OPA approval of the change request, both the new (temporary) AO and previous AO receive an “approval of online 340B change request” email from OPA.

5.5

Once the Associate Commissioner of LIDS can resume authorizing official duties, PC submits a change request to restore duties by completing steps 5.3.1–5.3.4.

6.0 Revision History

Date	Action	Section
6/5/2023	Policy Issued	All