2023.016 340B Roles, Responsibilities, Training and Education

Policy Number	2023.016
Effective Date	August 31, 2023
Revision Date	
Subject Matter Expert	340B Program Coordinator
Approval Authority	HIV/STD Section Director
Signed by	*Josh Hutchison*

1.0 Purpose

To assign individual roles and responsibilities for ensuring integrity and compliance with 340B Program requirements and ensure responsible individuals receive training.

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' 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; OPAIS 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.

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" throughout this document refers to the 340B program.

Authorizing Official – The person who has the legal authority to bind an organization to a contract. DSHS and CEs have an AO. For example, the AO for DSHS is the Division of Laboratory and Infectious Disease Services (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 Information System (OPAIS) – The system used to verify entity eligibility. This document references this system as the "OPAIS database."

Primary Contact (PC) – An employee of the CE responsible for updating the OPAIS information and ensuring AO makes changes within the correct deadlines for their program. The PC cannot be the same person as the AO and cannot be an individual who is not directly employed by the organization (e.g., a contractor or outside consultant).

3.0 Responsibilities

The CE complies with all 340B Program requirements and has mechanisms in place to ensure appropriate oversight and integrity of its 340B participation and operations.

As a part of its oversight responsibility, a covered entity is responsible for identifying individuals involved in 340B compliance, including the individuals serving as the covered entity's AO and PC. The covered entity ensures individuals responsible for 340B compliance receive appropriate training to perform their respective roles.

Staff or individuals under contract with the CE involved in 340B compliance understand and fulfill their respective roles and responsibilities.

4.0 Policy

4.1

The following staff are responsible for 340B Program implementation and oversight:

Authorizing Official – The AO is usually the CEO, CFO, COO, or Director of Pharmacy and a person who is authorized to legally bind the covered entity and execute contracts on its behalf. For some 318 grantees, the AO may be the grantee of record or the Clinic Director. The AO is the main point of contact for HRSA and receives notifications regarding recertification and other important updates. The AO attests to the accuracy of the information in the Office of Pharmacy Affairs Information System (OPAIS) and the CE's continued compliance with 340B Program requirements on an annual basis.

Primary Contact (PC) – The Primary Contact is the secondary point of contact for the covered entity. While the PC may also receive information from HRSA, this person has no legal authority to bind the covered entity. The PC can help update records in OPAIS and perform other administrative functions; however, only the AO can submit changes or recertifications to HRSA for approval. The PC should be someone other than the AO.

4.2

The CE provides training and educational materials to ensure staff or contractors involved in 340B implementation and compliance understand and comply with 340B Program requirements.

4.2.1 The CE documents 340B Program training and education in each staff person's employment records.

4.2.2 The CE ensures contracts or agreements with a third-party vendor or contractor address 340B education and compliance requirements.

4.2.3 The CE provides educational updates and training as needed and verifies 340B competency for staff and contractors involved with 340B Program implementation and compliance on a regular basis, quarterly, and as staff changes occur.

4.3

The CE will host 340B stakeholder meetings to seek feedback for the 340B Program. Specifically, the stakeholder meetings will provide an opportunity to review workflow processes and seek feedback on the following:

- Comprised of DSHS stakeholders in the following program areas, but not limited to: IT, Finance, Credentialing, Providers, and Pharmacy.
- Meets quarterly
- Seeks performance feedback on the following functions, which include medication administration and medication wastage documentation, no transfer of medication, review of patient eligibility, facility eligibility, provider lists being up-to-date and current if applicable, and CE staff completing compliance training as individuals in certain positions have changed.

5.0 Revision History

Date	Action	Section
8/31/2023	Policy Issued	All