CHAPTER 6 340B Pharmacy Supply Chain

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The pharmacy supply chain is complex in the best of times. Without 340B, the pharmacy supply chain requires diligence to keep the right amount of the right drug at the right price available for the right patient at the right time. When the requirements of the 340B program are added, standard supply chain practices must be enhanced to include elements that make supply chain practices compliant with 340B requirements. Because of the financial stakes involved, 340B compliance takes precedence over other processes for drug procurement and inventory management. The day-to-day execution of purchasing, receiving, and distributing medications with 340B in mind are pivotal activities that can either keep the covered entity compliant, or result in Health Resources and Services Administration (HRSA) audit citations and the potential loss of access to the 340B program.

Drug diversion is among the top three HRSA audit violations, ranking behind Office of Pharmacy Affairs (OPA) registration violations and duplicate discount violations. 340B drug diversion includes three types:

1. Purchasing and dispensing group purchasing organization (GPO) drugs for 340B-eligible outpatients; a violation of the GPO prohibition.[1]
2. Purchasing 340B drugs for unregistered areas outside the four walls of the registered covered entity.
3. Using 340B drugs to treat inpatients and nonqualified outpatients or to fill prescriptions for nonqualified Contract Pharmacy patients.

GPO PROHIBITION

Understanding the GPO prohibition statute, and where and how it applies, is a fundamental requirement to develop a compliant 340B pharmacy supply chain. The GPO prohibition was included in the original Veteran's Healthcare Act of 1992. Over the course of the program, HRSA issued several clarifications in the *Federal Register*.[2,3] Although generally well understood, variations in practice along with the growing complexity of the hospitals' application of the 340B program led the HRSA Office of Pharmacy Affairs to issue a 340B Drug Pricing Program Notice, Release No. 2013-1 effective August 2013.[4]

The statute states: Disproportionate share hospitals (DSH), children's hospitals, and free-standing cancer hospitals may not "obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement." These entities must attest to compliance with this provision during their annual recertification. The statute further states: "If a covered entity

subject to this prohibition participates in a GPO, the covered entity will no longer be an eligible covered entity and cannot purchase covered outpatient drugs at the section 340B discount prices." In other words, a covered entity that violates the GPO prohibition could be sanctioned or expelled from the program.

> Covered entities may also be subject to repayment to manufacturers for the time period for which the violation occurred. Covered entities removed from the 340B Program for GPO prohibition violations must demonstrate the ability to comply with the GPO prohibition to be considered eligible to reenter the 340B Program during the next regular enrollment period.[4]

340B grantee clinics and rural hospitals (critical access hospitals, rural referral centers, and sole community hospitals) are not subject to the GPO prohibition. A separate chapter outlines the unique elements that apply to this group. The principles and practices outlined in the remainder of this chapter, absent the specific references to the GPO prohibition, apply to all categories of covered entities.

Hospitals join group purchasing organizations to achieve discounts on drugs used to treat inpatients and outpatients that are not covered by the 340B program. To achieve discounts for both inpatients and 340B-eligible outpatients, hospitals must take precautions to avoid diversion across this boundary.

KEY POINT

Disproportionate share hospitals (DSH), children's hospitals, and free-standing cancer hospitals may not obtain outpatient drugs through a GPO or other GPO arrangement. A hospital's inventory and supply chain policies and practices should be designed to limit the risk of deliberate or inadvertent transfer of GPO-purchased drugs to outpatients.

DEFINING OUTPATIENT STATUS UNDER THE 340B PROGRAM

GPO-purchased drugs must be reserved exclusively for inpatients, and the GPO prohibition specifically states that the covered entity is prohibited from purchasing GPO medications for any of its eligible outpatient clinics. Therefore, it is imperative that the covered entity understand patient status in more detail and develop a practical method to identify exactly when a patient becomes an inpatient or an outpatient. A patient may convert from outpatient to inpatient at various points throughout a patient encounter. An emergency department patient may be admitted; a patient may be in "observation" status as an outpatient; a patient may be an outpatient for infusion therapy or for chemotherapy; and an outpatient having complications may be admitted as an inpatient for continuing treatment. All the internal stakeholders, including the 340B Steering Committee, must understand how to define inpatient versus outpatient status and develop technology and other processes that inform the procurement process.

For covered entities that have a retail pharmacy and/or participate in 340B contract pharmacy, it is important to identify and exclude outpatient encounters that would not directly result in a prescription being generated. For example, a visit for laboratory or radiology services would not typically be considered to generate a 340B-eligible prescription, thus should be separately considered as a type of outpatient status (i.e., these visit types should not feed into 340B software as a 340B qualified outpatient encounter).