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# PREPARING FOR THE NOVEMBER 2023 DRUG SUPPLY CHAIN AND SECURITY ACT REQUIREMENTS

**Objective:** Provide direction to pharmacists on preparing to meet the compliance standards of the Drug Supply Chain and Security Act (DSCSA), which is scheduled to take full effect by Nov. 27, 2023.

## **DSCSA Overview:**

The DSCSA, Title II of the Drug Quality and Security Act (DQSA) enacted by the United States Congress on Nov. 27, 2013, sets forth requirements for trading partners (i.e., manufacturers, wholesale distributors, repackagers, dispensers, and third-party logistics providers) regarding the tracing of prescription pharmaceutical products during distribution throughout the United States.<sup>1</sup> These interoperable, electronic tracing systems will allow the Food and Drug Administration (FDA) to protect U.S. consumers by readily identifying compromised prescription pharmaceutical products, including those that may be counterfeit, stolen, contaminated, dangerous, or harmful, and removing them from the pharmaceutical supply chain. In addition, the DSCSA will require wholesale distributors and third-party logistics providers to obtain national licensure and report licensure status to the FDA annually.<sup>2</sup>

## **What are the Responsibilities of Pharmacists (“Dispensers”) Under DSCSA?**

The DSCSA defines a dispenser as “a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor and does not include a person who dispenses only products to be used in animals in accordance with section 512(a)(5).”<sup>3</sup>

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## Current Responsibility Overview:

The key responsibilities of pharmacists in 2022 under DSCSA are:<sup>4,5</sup> As of the end of 2022, pharmacists must ensure most products are traceable at the lot-level and the following key responsibilities are met:

1. Engage in business only with licensed, registered trading partners:
  - a. Manufacturers and repackagers are required to have a current registration
  - b. Wholesale distributors and third-party logistics providers are required to be licensed
2. Properly manage product tracing documentation:
  - a. Only accept prescription pharmaceutical products if they arrive with the transaction history (TH),\* transaction information (TI), and transaction statements (TS)
  - b. All product tracing information must be kept in a secure format for six years
  - c. When selling prescription pharmaceutical products to a trading partner, include most product tracing information with the transaction

\*As of Nov. 23, 2023, the TH requirement expires and has “no force or effect.”<sup>6</sup>

3. Implement a system and process to properly manage suspect and illegitimate prescription pharmaceutical products
  - a. Quarantine any suspect prescription pharmaceutical product(s)
  - b. Collaborate with the manufacturer of suspect or illegitimate prescription pharmaceutical product(s) to ensure patients do not receive the illegitimate product(s)
  - c. Report findings of illegitimate prescription pharmaceutical product(s) to the FDA and involved trading partners

## New Responsibilities for 2023:

By 2023, pharmacists should ensure that their organization has policies and procedures in place that allow for unit-level traceability under DSCSA, including:<sup>3,5</sup>

1. Ensuring that all required TI and TS are exchanged between trading partners via a secure, interoperable, electronic system
2. Checking for inclusion of a package identifier (PI) to identify the prescription pharmaceutical product at the package level
3. Verifying the product identifier on a package or sealed case by the trading partners via a secure, interoperable, electronic system is available
4. Ensuring that trading partners can provide TI and TS via a secure, interoperable, electronic system when requested by authorized agents
5. Ensuring that secure, interoperable, electronic systems allow for the prompt production of TI for each transaction going back to the manufacturer
6. Addressing saleable returns by ensuring that secure, interoperable, electronic systems are in place and the TI and TS are returned with the product