



Track and trace

Clock is ticking on DSCSA enforcement

by Lisa Schwartz,
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The prescription drug supply chain has been developing the tools to be more secure than it was 10 years ago when Congress passed the Drug Supply Chain Security Act (DSCSA) in 2013. We got here by adding serial numbers to the bottle or packaging of most prescription drugs, tracking all the changes in ownership of that serial number, referencing the Food and Drug Administration (FDA) database of registered manufacturers and licensed wholesalers to authorize those trading partners, and as of November 2023, pharmacies were supposed to have the capability to electronically verify and trace a package serial number. So, why am I skeptical that a pharmacy will have this ability when this article is printed in April 2024?

NCPA, other associations, and supply chain stakeholders wrote many comments on proposed guidance documents from the FDA and FDA's requests for information in the past decade. Stakeholders and FDA alike wanted to ensure that implementation of the law is effective but not overly burdensome on pharmacies and other members of the supply chain. NCPA has also been push-

ing the FDA to complete the Congress-mandated small dispenser feasibility study, which was due well before Nov. 27, 2023. But after all this, and still lacking a conclusion on whether interoperable traceability is feasible for small dispensers, the FDA chose to exercise discretion on enforcing the traceability requirement for one year, until Nov. 27, 2024. Pharmacists should note that FDA is adamant that **THE REQUIREMENT IS NOT DELAYED**. Supply chain stakeholders are expected to be making swift progress on traceability, testing electronic data and exchange. The FDA is calling this process "stabilization." Is your pharmacy actively working on this stabilization? Here are some tips for you and pharmacy staff.

VERIFY 4-PART PRODUCT IDENTIFIERS

Go grab a prescription drug stock bottle from your shelf. Somewhere on the label is a 4-part product identifier specific to the bottle: NDC, serial number, lot number, and expiration date. Do you know how to verify that the 4-part product identifier corresponds to one that was issued by the manufacturer? You should have a service lined up for that. The National Association of Boards of Pharmacy's Pulse is one such standalone service expected to be available at no cost to pharmacies. Do you know how to trace the product identifier to confirm it was recorded as being sold to you by your supplier? You were supposed to be able to accomplish either of these tasks by scanning the 2D data matrix on the label last November. If any of your suppliers are sending you

electronic product code information services (EPCIS) data for your shipments, you might be able to do the latter. If something doesn't work as expected, or not at all, contact your sales representative and ask how they can help you trace a product identifier using the EPCIS data you may be receiving. In the future, you'll need this process to resolve order discrepancies along with suspect product investigations. This is the goal of the stabilization period expected to end in November 2024.

VERIFY AUTHORIZED TRADING PARTNERS

Also, verify that you buy prescription drugs from authorized trading partners. Dealing exclusively with authorized trading partners is required by law and it helps ensure that the prescription drugs you intend to dispense have never left the secure supply chain. Every company from whom you buy prescription drugs should have a wholesale prescription drug distributor (or similarly named) license. In most states, the board of pharmacy issues this license, so use the licensee lookup tool on the board's website. And for any drugs you buy direct from a manufacturer, you can verify on FDA's website (www.fda.gov) that they are registered. If you are evaluating a DSCSA technology solution, ask them whether their service includes trading partner verification and the detailed steps they take to perform this important compliance task on your behalf.

UNDERSTAND "SPECIFIC PATIENT NEED" REQUIREMENTS

Be sure you understand the limited circumstances where you might

acquire (by purchase or borrow/barter) inventory from another pharmacy and not have the requirement to receive tracing data. First, verify that the pharmacy that has the drug has a permit in the state where it is located. Next, make sure that you only acquire the quantity that is needed to dispense a prescription for a specific patient. The law refers to this as meeting a “specific patient need.” There should be a written procedure for your staff to follow to determine a specific patient need exists and for documenting the circumstances. If the buyer pharmacy has no specific patient need, the seller is subject to all of the wholesale distributor requirements of DSCSA. Similarly, if the buyer pharmacy desires to replenish with the quantity borrowed (or something of equal value), there must be a specific patient need documented.

SECURELY MAINTAIN DOCUMENTS

Document retention is a familiar concept for all pharmacy owners. Complying with DSCSA means you will store product tracing information you receive from suppliers for six years, along with any documentation pertaining to a suspect or illegitimate product investigation. You have the option to store older tracing information received on paper either on paper or electronic format. Going forward, pharmacies should be receiving electronic tracing data, which is more easily searchable. Some wholesalers offer as a value-added service, the option to provide electronic access to EP-CIS data they generate.

Pharmacies that purchase from multiple suppliers or are contemplating switching primary wholesalers may see value in using a DSCSA technology solution to have a central place for all their EP-CIS data that is supplier agnostic. These solutions

providers often have other features, such as trading partner due diligence, product identifier verification routing to the manufacturer, and support during a suspect product investigation.

TRAIN STAFF

An effective way to check up on your compliance is to have training sessions on identifying and investigating a suspect product with staff who handle prescription drug inventory. Talk through the definitions FDA has published in its “Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act,” available at bit.ly/425N27d. The NCPA DSCSA checklist available at bit.ly/3TpdHdJ has a helpful list of signs that a product is potentially illegitimate and should be investigated. Once it’s clear that staff understand the signs to watch for when checking on the order, ensure that everyone knows how to check that the 4-part product identifier on a suspect product actually came from the wholesaler’s warehouse and the manufacturer before that.

NEXT STEPS

When you are confident that staff can determine whether a given product ID came from the wholesaler or not, ask what happens next. If you have a bottle or other package without corresponding tracing data, you can run a verification request on the product ID to make sure it matches something the manufacturer assigned while also contacting the wholesaler’s customer support to find out if they have tracing data. You’ve all seen discrepancies in an order, but it’s never been to the level of the wrong single bottle of an NDC being picked. It is now. Something that ends up being an order discrepancy doesn’t typically need to have an investigation report. But if you have a product ID with no match at

the warehouse, you need to start documenting a suspect product investigation. Discuss how this suspect product investigation would be reported and where/how it would be retained for six years. If a product ID verification fails or if the wholesaler has no tracing data for a suspect product it seems likely it is illegitimate, the pharmacy would have to file a report with the FDA on FDA Form 3911. Pharmacies that believe they have illegitimate product should work with the FDA and their trading partners and, when applicable, their DSCSA compliance solution, to continue the investigation.

Every supply chain stakeholder needs to be committed to keeping illegitimate product out of the supply chain. Stakeholders do this by knowing their trading partners and only buying from and selling to authorized trading partners by watching for signs of suspect product, responding to tracing requests, and participating in investigations. Enforcement action has put a spotlight on counterfeit product entering the supply chain with falsified tracing data, typically for a deal on a drug in shortage or high price drug. DSCSA is a federal law, but state regulators also have a role in enforcement. It is of utmost importance that pharmacy owners know every dose of every prescription drug that they dispense is safe and effective for their patients. ■

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Useful online DSCSA resources

- nabp.pharmacy/pulse/dispensers
- ncpa.org/dscsa-checklist
- dscsa.pharmacy
- ncpa.org/dscsa-360



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