



Pharmacy Implementation of the Drug Supply Chain Security Act

The Drug Supply Chain Security Act (DSCSA)* of 2013 created a national system in which companies involved in pharmaceutical distribution work together to safeguard the U.S. pharmaceutical supply and protect consumers from compromised or counterfeit drugs. Pharmacies play a critical role in preventing unsafe products from reaching consumers.

Why pharmacy participation matters

Pharmacies are the last stop in the distribution supply chain before medicines reach patients, so their participation is an essential component of the new DCSCA system. In the past few years, unsafe drugs have been inserted into the U.S. pharmaceutical supply, allowing them to reach pharmacies undetected and be dispensed to patients. Instances of breaches to the supply chain include the following:

- In 2012, the U.S. attorney for the Southern District of New York uncovered a massive criminal drug diversion and relabeling scheme that placed unknown numbers of consumers at risk and cost the state's Medicaid program more than \$500 million.¹ The diverted drugs were purchased on the street, illegally sold back into distribution, and then eventually reached pharmacies. Unsuspecting patients who received the compromised drugs were exposed to medicines that may have been contaminated, mislabeled, or expired.²
- In 2009, thieves in North Carolina stole a truck containing over 120,000 vials of insulin.³ According to an FDA affidavit, the temperature-sensitive medicine was illegally sold back into the supply chain through wholesalers and then retail pharmacies in Texas, Georgia, and Kentucky.⁴ Diabetic patients who received the stolen drugs reported health complications.⁵

DSCSA provides pharmacies with important new tools to identify unsafe medicines and prevent them from reaching consumers.

Rollout of pharmacy responsibilities under the new law

DSCSA requires pharmacies to take the following steps to participate in a national serialization and traceability system. These include the following:

January 2015: Pharmacies will receive a document known as a transaction history with each drug shipment that lists every company that previously owned the drugs. They also will receive a transaction statement attesting to the legitimacy of the drugs. These documents will make it easier for pharmacies to verify that the medicines they purchase come from authorized suppliers.

* Title II, Drug Quality and Security Act (DQSA), 2013.

July 2015: Pharmacies must investigate any prescription drug in their possession that appears suspicious—for example, a product that seems to be physically altered or is missing required information such as the expiration date or a drug identifier (e.g., the unique three-segment National Drug Code number). They must retain records of their investigations of suspect products for six years and must report to FDA any product they determine to be counterfeit, stolen, or otherwise illegitimate. In addition to identifying harmful drugs, these requirements will support FDA investigations of supply chain breaches.

2017: A two-dimensional (2D) bar code with a unique serial number will be placed on the label of each package of drugs. Pharmacies may choose to check these numbers and verify products' authenticity before dispensing them to patients, but they are not required to do so.

2020: Pharmacies must purchase only bar coded, serialized pharmaceutical products, and they must verify the serial numbers of a certain percentage of suspect medicines when conducting investigations into products that appear potentially compromised or unsafe.

2023: Pharmacies and all other companies in the U.S. pharmaceutical distribution system must participate in a fully electronic traceability system that uses the new serial numbers to help detect and remove illegitimate drugs.

The Pew-Booz Allen Hamilton Report

In 2013, The Pew Charitable Trusts' drug safety project and Booz Allen Hamilton conducted a qualitative assessment of stakeholder perspectives on serialization and traceability systems across the U.S. pharmaceutical distribution supply chain. The resulting report, *Implementing a Pharmaceutical Serialization and Traceability System in the United States: Stakeholder Perspectives and Investments*, analyzes industry expectations, system preferences, and anticipated investments that can inform implementation of DQSA.

Provisions for effective pharmacy participation

The new law contains provisions that support effective and meaningful pharmacy participation in a serialization and traceability system.

Affordability: DSCSA establishes a more affordable system for pharmacies than previous estimates have suggested. One report released several years before the law⁸ was enacted assumed that pharmacies would have to accommodate both 2D bar codes and a more expensive technology—radio frequency identification tags—resulting in extremely high cost estimates. However, because the law establishes the 2D bar code as the standard for serial numbers, pharmacies can focus solely on acquiring the equipment needed to read the bar codes rather than other technologies. The Pew-Booz Allen Hamilton report (see text box) provided lower estimates, including a prediction of costs to an independent pharmacy as low as \$2,000 a year.⁹

Clarity: DSCSA makes clear the expectations placed on pharmacies, allowing for more realistic assessments of implementation needs and costs. For example, retail pharmacies have already started to deploy 2D bar code readers as part of routine technology upgrades at their point-of-sale terminals,¹⁰ a change that will be helpful with

subsequent technology adoption by the sector.

Efficiency: Provisions in DSCSA will help ensure that pharmacies can participate effectively and efficiently. The law requires FDA to conduct pilot programs with industry and to use an independent consulting firm to assess how small dispensers can participate in the enhanced drug distribution security system required in 2023.*

According to the Pew-Booz Allen report, several possible cost- and time-saving approaches are worth investigating. These include use of a cloud-based service to store supply chain transaction data (as demonstrated in recent industry pilots),¹¹ and wholesale distributors potentially offering serialization and traceability services, such as management of local and shared data, to pharmacies.¹²

Transparency: Although the specific parameters of the fully electronic system in 2023 are yet to be defined, the law requires FDA to work with the public and industry to define its requirements over the next eight years.

Next steps for pharmacies

Robust implementation of DSCSA will require strong pharmacy participation. Eighty percent of industry respondents in the Pew-Booz Allen Hamilton study believed all sectors must participate in a national serialization and traceability system, and many emphasized the importance of pharmacy participation in particular.¹³ Going forward, pharmacy participation in pilot programs and discussions with FDA is essential to ensuring that the new system is as feasible and effective as possible. This cooperation also will offer the opportunity to make improvements for nonregulatory purposes, such as supply chain visibility, inventory management, recall optimization, and detection of potential drug shortages.

* The assessment will look at costs and other factors affecting feasibility and will be completed by May 27, 2021.

Endnotes

- 1 "Manhattan U.S. Attorney Announces Charges Against 48 Individuals in Massive Medicaid Fraud Scheme Involving the Diversion and Trafficking of Prescription Drugs," United States Attorney's Office, Southern District of New York, press release, July 17, 2012, <http://www.fbi.gov/newyork/press-releases/2012/manhattan-u.s.-attorney-announces-charges-against-48-individuals-in-massive-medicaid-fraud-scheme-involving-the-diversion-and-trafficking-of-prescription-drugs>.
- 2 Ibid.
- 3 "Update to FDA Alert About Stolen Insulin," U.S. Food and Drug Administration, accessed Nov. 12, 2010, <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm180320.htm>.
- 4 Michelle M. Ciolek, special agent, Office of Criminal Investigations, U.S. Food and Drug Administration, affidavit in support of search warrant, United States v. Altec Medical Inc. and RX Healthcare Inc., document number 8:09-cr-00814-WMC, July 21, 2009.
- 5 "Update to FDA Alert about Stolen Insulin," U.S. Food and Drug Administration.
- 6 The Drug Quality and Security Act, U.S. Congress, Nov. 27, 2013, <http://www.gpo.gov/fdsys/pkg/BILLS-113hr3204enr/pdf/BILLS-113hr3204enr.pdf>.
- 7 Accenture, Current Status of Safety of the U.S. Prescription Drug Distribution System (June 2008), <http://www.ncpanet.org/pdf/ccpastudy.pdf>.
- 8 The Pew Charitable Trusts and Booz Allen Hamilton, Implementing a Pharmaceutical Serialization and Traceability System in the United States: Stakeholder Perspectives and Investments (April 29, 2014), <http://www.pewtrusts.org/en/research-and-analysis/analysis/2014/04/29/implementing-pharmaceutical-serialization-and-traceability-perspectives-and-investments>.
- 9 Lorna Pappas, "Peripheral Primer," Retail Info Systems News, Oct. 1, 2007, <http://risnews.edgl.com/retail-news/Peripheral-Primer38606>.
- 10 Dirk Rodgers, "The Significance of the Abbott, McKesson and VA Pilot," RxTrace, Nov. 12, 2012, <http://www.rxtrace.com/2012/11/the-significance-of-the-abbott-mckesson-and-va-pilot.html/>.
- 11 "Technology Services," Cardinal Health website, accessed May 5, 2014, <http://www.cardinalhealth.com/us/en/ChainRetailPharmacies/TechnologyServices>.
- 12 The Pew Charitable Trusts and Booz Allen Hamilton, Implementing a Pharmaceutical Serialization and Traceability System in the United States.

For further information, please visit:
pewtrusts.org/en/projects/drug-safety-project

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