Director's Forum

Review of the 2015 Drug Supply Chain Security Act

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The integrity of the pharmaceutical supply chain is threatened by medication counterfeiting, importation of unapproved and substandard drugs, and grey markets – all of which have the potential to distribute drug products with the potential for serious harm. On November 27, 2013, President Obama signed into law Title II of the Drug Quality and Security Act, now known as the Drug Supply Chain Security Act (DSCSA). Over the next 10 years, the DSCSA will require the pharmaceutical supply chain to implement medication tracking and tracing; serialization, verification, and detection of suspicious products; and strict guidelines for wholesaler licensing and reporting. This article reviews the important aspects of the DSCSA and outlines the role of health-system pharmacy leaders in ensuring compliance to the DSCSA. By verifying that medication supplies are free from adulteration and tampering, the DSCSA serves as a foundational law to ensure quality in providing patient-centered pharmacy services.

INTRODUCTION

The pharmaceutical supply chain delivers medications from their source to hospitals, dispensing pharmacies, and other providers (physician offices, clinics, surgery centers). This complex system starts with raw materials processed by manufacturers to engineer complex pharmaceuticals. The supply chain includes primary and secondary wholesale distributors, repackagers, and dispensers such as hospitals and community pharmacies, all leading to the consumer.

Although the US drug supply chain remains relatively safe, increasing complexity has led to a myriad of threats including counterfeiting; importation of substandard, spurious, falsely labeled, falsified, and counterfeit (SSFFC) drugs; and grey markets. These threats resulted in unsafe and ineffective medicines entering the US pharmaceutical supply chain.¹ There are numerous examples of supply chain integrity failures resulting in patient safety risks, harm, and even death.² The Alliance for Safe Online Pharmacies reports that out of 35,000 to 50,000 online pharmacies, 96% do not comply with applicable laws and standards put in place to protect patients.² Patients

have been harmed by unsafe and counterfeit medications purchased from illegitimate online pharmacies. On June 3, 2011, an emergency room doctor, from Texas, suffered a stroke from ingesting counterfeit diet pills from an online pharmacy. The counterfeit diet medication was produced using the controlled substance sibutramine, rather than the approved ingredient orlistat, and was shipped to the United States for redistribution.³ In 2008, the US Food and Drug Administration (FDA) attributed adulterated ingredients within a batch of heparin as a potential cause of fatal allergic reactions in 81 patients.⁴

The other major threat to the pharmaceutical supply chain is the existence of grey markets. A grey market arises when companies operate outside the legitimate drug distribution channel. Medications on shortage are purchased from illegitimate secondary grey market wholesalers and sold at dramatically inflated prices. The World Health Organization (WHO) estimated that the counterfeit and grey markets were worth \$75 billion dollars in 2010.⁵ Patient safety concerns within grey markets include counterfeit medications, suspect storage, and inappropriate

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handling. The authenticity and integrity of the medication distribution system is not guaranteed in this environment, which can lead to ineffective and even harmful treatment for patients' conditions and diseases.

This paper reviews the important aspects of the Drug Supply Chain Security Act (DSCSA) and outlines the role of health-system pharmacy leaders in ensuring compliance to the DSCSA, including the legislation that leads to the DSCSA, the specific requirements of the DSCSA, and the strategies for ensuring compliance. By verifying that medication supplies are free from adulteration and tampering, the DSCSA serves as a foundational law to ensure quality in providing patient-centered pharmacy services.

DRUG QUALITY AND SECURITY ACT

The FDA developed the Drug Quality and Security Act of 2013 in response to the 2012 fungal meningitis outbreak resulting from unsanitary medication compounding conditions at New England Compounding Center and to global concerns regarding the integrity of the pharmaceutical supply chain. The Drug Quality and Security Act legislates 2 independently titled sections: Title I and Title II. Title I is the Compounding Quality Act that implements a voluntary compliance program for compounding pharmacies, enabling them to register as outsourcing facilities. This provides them with oversight by the FDA with similar standards as traditional pharmaceutical manufacturers, such as cGMP requirements, while also providing exemptions from certain FDA approval and drug labeling requirements. Title II is the DSCSA, which describes important critical steps in building an electronic, interoperable system to identify and trace prescription medications.

The American Society of Health-System Pharmacists (ASHP) 2016 Pharmacy Forecast predicts that the majority of health systems will need added resources, such as personnel and software, to help comply with the new DSCSA requirements.⁶ The goal of this article is to introduce the major components of Title II of the Drug Quality and Security Act. In particular, this article aims to assist health-system pharmacy leaders in identifying necessary measures and additional resources needed to maintain compliance with the 10-year incremental requirements of this mandatory pharmaceutical track-and-trace law.

DRUG SUPPLY CHAIN SECURITY ACT

Title II of the Drug Quality and Security Act, the DSCSA, was signed into law by President Barack

Obama on November 27, 2013, with a phased implementation over 10 years eventually leading to a fully interoperable, electronic system for the tracking and tracing of products throughout the supply chain. **Table 1** lists important dates for fully implementing the statutory requirement of the DSCSA. To achieve this feat, the DSCSA addresses several major issues including product tracking and tracing; serialization, verification, detection and response to a suspect product; and wholesaler licensing and reporting.

Product Tracking and Tracing

Effective March 1, 2016, manufacturers, repackagers, wholesalers, and dispensers must provide transaction information, transaction history, and a transaction statement to each subsequent owner of the drug product. This triad of data sources is colloquially referred to as *T3 information*. The transaction history is essentially a statement of all upstream transactions. The transaction information contains specific information about the drug product, whereas the transaction statement verifies that the product was received and distributed with authorized trading partners. A full list of necessary items for T3 information can be found in **Table 2**. To force trading partners to only enter into transactions with valid T3 information, the DSCSA prohibits repackagers, wholesalers, and dispensers from accepting products without full T3 information. The overall intent of passing this information between authorized trading partners is to ensure the product received from the upstream trading partner is what was intended. Additionally, trading partners are prohibited from entering into transactions with trading partners that are not authorized. To become an authorized trading partner under the law, a trading partner must comply with specified regulations. This means that manufacturers and repackagers must have a valid registration with the FDA. Wholesale distributors and third-party logistics (3PL) providers must have a valid license under state law and comply with licensure reporting requirements, and dispensers must have a valid license under state law. The DSCSA requires that a trading partner keep records of the T3 information for 6 years after receipt of the information. To prevent undue burden for trading partners, the FDA has allowed exemptions for the trading of certain products without T3 information. Pertinent exemptions include intracompany distribution, distribution among hospitals or health care entities under common control, and products transferred pursuant to a patient-specific prescription. **Table 3**

Table 1. Important Drug Supply Chain Security Act dates for pharmacy dispensers

Statutory requirement	Implementation date
DSCSA signed into law	November 27, 2013
Authorized trading partners	January 1, 2015
Investigation and notification of suspect product	January 1, 2015
Receipt of T3 information for all transactions	March 1, 2016
All T3 information must be distributed electronically	November 27, 2017
Product serialization	November 27, 2020
Investigation of suspect product at lot number and individual package level verification	November 27, 2020
Unit-level traceability	November 27, 2023

Note: T3 = transaction information, transaction history, and a transaction statement.

Table 2. Information contained within T3 documentation

Transaction history
• Transaction information for each prior transaction going back to the manufacturer of the product
Transaction information
• Proprietary or established name or names of the product   • Strength and dosage form of the product   • National Drug Code   • Container size   • Number of containers   • Lot number   • Date of transaction   • Date of the shipment (if more than 24 hours after transaction date)   • Business name and address of the person from whom ownership is being transferred   • Business name and address of the person to whom ownership is being transferred
Transaction statement
Statement that the entity transferring ownership in a transaction:
• Is authorized as required under the DSCSA   • Received the product from a person who is authorized as required under the DSCSA   • Received transaction information and a transaction statement from the prior owner of the product as required   • Did not knowingly ship a suspect or illegitimate product   • Had systems and processes in place to comply with verification requirements   • Did not knowingly provide false transaction information   • Did not knowingly alter the transaction history

Note: DSCSA = Drug Supply Chain Security Act; T3 = transaction information, transaction history, and a transaction statement.

lists all exemptions listed under the DSCSA and the FDA guidance documents issued after the law was passed. To implement a fully interoperable, electronic system, all trading partners must send this information electronically; however, this is not a requirement until November 27, 2017.

Product Serialization

The overarching goal of product serialization is to have a unique product identifier associated with each individual product. In the current system, many drug products are barcoded with a linear barcode that stores limited information. Typically linear

Table 3. Exemptions to the Drug Supply Chain Security Act

- Intracompany distribution
- Distribution of a product among hospitals or health care entities that are under common control
- Distribution of a product for a public health emergency declaration^a
- Product sample distribution
- Distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use
- Sale, purchase, and trade by a charitable organization
- Products transferred to or from any facility that is licensed by the Nuclear Regulatory Commission
- Products transferred pursuant to a patient-specific prescription
- Intravenous products that are intended for the replenishment of fluids and electrolytes or calories^b
- Product intended for irrigation^c
- Blood and blood components
- Dialysis solutions
- Medical gases
- Medical convenience kits

^aExcept that a drug shortage not caused by a public health emergency is not considered an emergency medical reason.

^bExamples include sodium chloride, potassium, dextrose, and amino acids.

^cExample includes sterile water for irrigation.

barcodes are embedded with the product National Drug Code (NDC) alone, because they do not have the capability to store more information. Beginning in November 2017, manufacturers must start affixing 2-dimensional (2D) barcodes to their products. This 2D barcode must house the product identifier and is required to include the NDC, lot number, expiration date of the drug, and a unique serial number. Following manufacturers in 2018, repackagers will need to affix a 2D product identifier to each product and both the manufacturer and the repackager must keep record of each product identifier for 6 years. Once manufacturers and repackagers have implemented serialization, wholesalers (2019) followed by dispensers (2020) must only engage in transactions with drug products that have unique product identifiers.

Suspect Products

A significant portion of the DSCSA is dedicated to requirements regarding how trading partners should interact with products if they are suspected of being falsified, adulterated, or counterfeit (SSFFC). Starting January 1, 2015, all authorized trading partners must have processes in place to deal with a product if it is believed to be SSFFC or the Secretary of State asks for verification of a possible suspect product. Mitigation strategies include:

- the ability to quarantine a product until it is cleared or deemed illegitimate,
- the ability to notify immediate trading partners, and
- the ability to coordinate an investigation that can determine if the product is illegitimate and validate T3 information.

Once product serialization is in full effect (2020), a trading partner must verify the lot number of any suspect product when conducting an investigation and verify suspect product at the package level using the unique identifier of at least 3 packages or 10% of suspect product (whichever is greater). As with much of the legislation, records of any investigation must be kept for 6 years. Once a product is determined to be illegitimate, the trading partner who discovered the product has a duty to ensure this product is not further distributed through the supply chain. The product must be removed from the supply chain and then immediate trading partners, along with the FDA, must be notified within 24 hours of determination. The FDA issued a guidance document to assist trading partners, especially dispensers, in the identification of suspect and illegitimate products.⁷ The guidance document discusses what characteristics of a product might lead to the suspicion of illegitimacy including the source of the product; the supply,

demand, history, and value of the product; and the appearance of the product.

Wholesaler and Third-Party Logistic Providers

To address the concerns with the grey market, the DSCSA includes a legal framework that outlines higher standards and requirements for wholesalers and 3PL providers. The goal of this portion of the DSCSA is to develop national standards for licensing of these specific trading partners. A draft guidance from the FDA included new requirements with which wholesalers and 3PL must comply once the draft is finalized. The guidance sets standards for how and when a wholesaler/3PL must report specific information to the FDA. Information must include the company name, state license number, any significant disciplinary action by any State or Federal agency, and a unique facility identifier. Dispensers should be knowledgeable of when this portion of the law goes into full effect because a wholesaler or 3PL cannot be deemed an authorized trading partner until they comply with the reporting regulations. The FDA has created a searchable database of wholesalers and 3PL who have begun reporting this information.

STRATEGIES FOR COMPLIANCE TO DSCSA

All health-system pharmacy departments should establish an infrastructure to support T3 information. A successful supply chain data framework requires 2 things: First, it must support receipt and storage of T3 data per DSCSA requirements. Second, the framework should have scalability to meet future needs of the organization. Each pharmacy enterprise has its own unique needs, therefore several factors must be considered when implementing a comprehensive supply chain solution.

Under the DSCSA, all wholesalers must facilitate compliance by providing T3 information to authorized trading partners. The Act allows a drug wholesaler to maintain T3 information on the dispenser's behalf. However, the burden of responsibility remains with the dispenser to ensure that information is properly stored, accessible, and accurate.¹ A stepwise approach is recommended when evaluating any solution that manages T3 data. The following steps for evaluating information management systems are necessary for T3 data capture.⁸ First, identify key stakeholders in procurement, informatics, and drug distribution. Second, identify all sources from which T3 data will be received. Third, review current processes for potential improvement and prioritize the business need for

a 3PL provider. Most institutions will quantify this need based on the number of drug products received external to their primary wholesaler. Evaluation of track and trace processes within the institution should involve the primary wholesaler system. Familiarity with accessing and utilizing transaction data through the wholesaler will provide context when comparing 3PL solutions. The fourth step is to evaluate potential solutions and service providers, ideally limiting the selection to 3 or 4. During this process, validate service provider references when possible. Reach out to colleagues to learn of their experience with a 3PL vendor. Compare with colleagues that have opted to implement a homegrown solution for managing T3 data. Once a solution has been selected, an implementation plan must then be developed and executed.

System Considerations

General considerations for any system include data storage limits, a user-friendly interface, accessibility throughout the health system, and support requirements. Vendors using cloud storage and a web-based user interface should be evaluated for performance where possible. Institutional considerations for supporting a web-based solution would include reliable internet access, downtime contingency plans, and retrieval of exported data in an accessible file format.

The challenge is to choose the most cost-effective and streamlined approach to support the pharmacy enterprise supply chain. The simplest way to meet compliance consists of importing T3 information into an internal repository accessible on a shared drive. Dedicated resources would be required to build and implement a system according to DSCSA requirements. For a small institution with limited drug product received from non-wholesaler trading partners, this may be an adequate solution. Line item transaction data could be maintained and retrieved from a database easily within 2 business days. Transition to a more robust, third-party vendor at a later date would either require merging legacy T3 information into the new system or maintaining 2 systems for a period of time. A homegrown approach could enable compliance quickly with low cost; however, DSCSA requirements for drug product traceability may not be well served in this model. For example, a simplified database would be suboptimal for a large academic medical center that receives product from multiple trading partners. Current product line diversity and long-term growth strategy should be evaluated when comparing systems to maintain T3 information.

Third-Party Vendors

There are many 3PL vendors available on the market to enable DSCSA compliance, including but not limited to Axway, ConsortiEx, TraceLink, and TrackTraceRx. A third-party solution will likely be required by most large health systems. Advantages over an in-house solution include accessibility across the health system, build and implementation support, and ongoing support for maintaining DSCSA compliance. Selecting a vendor will have granular considerations similar to those mentioned previously: ease of use, data extraction capability, availability of pre-established interfaces with authorized trading partners, and customer service support. Each solution should be evaluated for dynamic capability as the supply chain evolves. Future considerations include the ability to accommodate T3 data expansion after serialization and platform flexibility for DSCSA provisions yet to be implemented. Selecting the most comprehensive 3PL solution will also depend on specific services offered by the pharmacy enterprise. Future plans for 340b contract pharmacy establishment, consignment agreements, investigational drugs, and specialty pharmacy drugs administered by a provider may present unique track and trace challenges. As an executor of DSCSA compliance, third-party vendors will be required to respond to these and other drug supply chain nuances that may present in the future.

Wholesalers and T3 Information

A comparison of 3 major drug wholesalers in the United States shows strategic variability in the way T3 information may be delivered to authorized trading partners in the future. AmerisourceBergen Corporation (ABC) entered into a partnership with technology company SAP to develop a new solution, Advanced Track and Trace for Pharmaceuticals (ATTP). This solution includes the redesign of 2 existing SAP solutions known as Auto-ID Infrastructure and Object Event Repository (AII/OER), historically used by pharmaceutical companies to support product traceability.⁹ The ABC and SAP collaboration also included 9 global pharmaceutical companies, contributing to the bottom line of global serialization across the industry. Notably, track and trace vendor TraceLink announced an SAP Migration Kit designed to handle AII/OER migrations shortly after the SAP ATTP solution was launched.¹⁰ McKesson Specialty

Heath has partnered with TraceLink to support T3 information for specialty pharmacy customers. Current customers of TraceLink are provided T3 information from McKesson Specialty Health through their existing registration.¹¹ Cardinal Health provides access to T3 information through an online customer portal, currently without involvement of a third-party logistics vendor, enabling DSCSA compliance.¹²

External Impacts

Global environmental factors must also be considered. Other countries are moving in parallel to the United States regarding supply chain regulation. However, the lack of a unified global standard may result in a challenging transition. The European Union Falsified Medicines Directive (FMD) outlined serialization requirements that will be implemented by 2018. The FMD requires product serialization by a manufacturer-issued number that adheres to GS1 standards.^{13,14} Current Indian law requires manufacturers to serialize primary, secondary, and tertiary drug packaging with GS1-compliant barcodes.¹⁵ In contrast, China expanded serialization to all drug products in late 2015 and is expected to move forward with government-issued Electronic Drug Monitoring Codes (EDMC).¹⁶

Professional pharmacy organizations have invested time in developing supporting documents to help advise pharmacy leaders. ASHP has developed a policy recommendation set forth by the Council on Pharmacy Management regarding drug product supply chain integrity. The purpose of the policy is to encourage the FDA and state authorities to ensure product integrity by developing and implementing regulations to increase distributor accountability for products and to advocate for the establishment of meaningful penalties for companies that violate current good manufacturing practices.¹⁷ Resources on the DSCSA have been developed by ASHP,¹⁸ American Pharmacists Association,¹⁹ and FDA²⁰ to support pharmacy leaders.

Future Considerations

Making a successful transition to DSCSA compliance is a complex process. Internal factors will impact the type of 3PL solution needed, such as number of authorized trading partners, product line diversity, and available resources in procurement and informatics. External movement surrounding

global serialization will have an impact on 3PL solutions. Professional pharmacy organizations continue to peripherally support compliance by ensuring that dispenser regulations receive clarity and guidance when necessary. FDA guidance has been limited. In the absence of FDA guidance, it is prudent for pharmacy leaders to develop robust policies and procedures to support the DSCSA at their individual institution. For example, drop shipments require T3 information to be transferred directly from the manufacturer to the dispenser. The manufacturer requirement to transmit T3 data electronically does not come into effect until 2017, therefore transaction data may come in paper or electronic form. Each institution will need a policy and procedure in place to maintain dual forms of T3 data, paper and electronic, until the manufacturer's requirement is implemented. Maintaining compliance and agility to keep up with each DSCSA implementation phase will be essential for pharmacy leaders. As stated previously, compliance with supply chain regulation will ultimately be the responsibility of the dispenser and, ultimately, the pharmacy leader.

CONCLUSION

Familiarizing yourself with the requirements set forth in the DSCSA is the first step on the road to compliance. A health-system pharmacy leader should understand and communicate the additional resources they will need, including both personnel and technology, to keep their pharmacy department up to date with the incremental requirements. Published guidance documents, literature, third-party vendors, and pharmacy colleagues are all useful resources of valuable information and advice.

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