

What is the Drug Supply Chain Security Act: Are You Ready for the Next Big Milestone?

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INTRODUCTION

President Obama signed the [Drug Supply Chain Security Act \(DSCSA\)](#) into law on November 27, 2013. Prior to that, companies in the U.S. drug supply chain had to comply with state-level pedigree requirements. The DSCSA replaces that complex legal patchwork with unified federal traceability requirements for prescription drugs across the country.

The DSCSA impacts a wide range of businesses in the drug supply chain, including drug manufacturers, primary and secondary/independent wholesale drug distributors, drug repackagers, and pharmacies and other dispensers. It aims to standardize and streamline the exchange of information about the path a drug has taken through the supply chain.

This national, electronic solution will benefit consumers, healthcare providers and pharmacists, as well as drug supply chain partners by:

- ▶ Supporting detection of suspected unapproved, illegal, contaminated or potentially harmful drugs—thus helping to thwart the counterfeit drug trade
- ▶ Enabling verification of the legitimacy of a drug product identifier down to the level of individual saleable units
- ▶ Facilitating more efficient recall of drugs and accelerating the coordinated notification of patients,

healthcare professional, hospitals and pharmacies about the discovery of counterfeit or harmful drugs in the supply chain

At the same time, the DSCSA creates a web of compliance interdependencies around tracing and verification of drug product transactions between suppliers and their trading partners.

IMMEDIATE DSCSA COMPLIANCE CONCERNS

To minimize risks and costs associated with DSCSA compliance, many businesses will need to put new IT resources in place, perform due diligence on logistics partners and other third parties, and document and address any gaps in their overall compliance strategy.

Of particular current relevance, the DSCSA mandates that manufacturers mark each product or saleable unit with a product identifier, serial number, lot number and expiration date by November 27, 2017.

Supply chain partners must all be prepared to electronically share and process that serialization data. Brand owners must confirm that their supply chain partners are DSCSA-compliant or risk regulatory penalties. Wholesalers, repackagers and dispensers should all be ready to handle serialization data.

This fast-approaching deadline is just one of many over the DSCSA's [ten-year implementation timeline](#). As such, ongoing technology investments and changes to supply chain processes and workflows are a certainty across prescription drug supply chains.

IMPACTS ON THE DRUG SUPPLY CHAIN

The new regulations are driving firms to adopt expanded serial codes on drug product packaging, first at the lot level and now at the unit level; and to develop a system to exchange information on the movements of those packages with partners end-to-end across the supply chain. Ultimately there is likely to be similar standardization at the international level as well.

How much will these changes cost? Product serialization and other labeling changes could have cost impacts ranging from [\\$150,000](#) to as much as [\\$500,000 per packaging line](#).

These capital and operating expenses will require significant planning and implementation efforts, and may likewise have contractual and other commercial implications for supply chain partners.





For example, the new legislation mandates stronger and more consistent national distributor licensing standards, which may impact relationships with distributors. Similarly, pharmaceutical companies and their contract manufacturers will need to factor DSCSA compliance into their contracts to clearly specify responsibilities around packaging, labeling, shipping and order fulfillment.

IMPLICATIONS FOR ELECTRONIC DATA INTERCHANGE (EDI)

In conjunction with the DSCSA, manufacturers and their supply chain partners will need to store and transmit codes and transaction histories involving drugs and their movements. Moreover, as of November 2017, pharmaceutical transaction data can no longer be transmitted on paper—it must be available electronically; that is, via EDI.

EDI is already integral to drug ordering processes and will become even more so as companies comply with the November 2017 deadline and ongoing DSCSA mandates. The key

EDI transaction for exchanging DSCSA information will be the 856 Advance Ship Notice (ASN), which is already a commonly used format for documenting the transfer of drug products from sellers to buyers.

While the DSCSA does not include EDI specifics, the Healthcare Distribution and Management Association (HDMA) has provided simple, logical guidance to the wholesale drug distribution industry regarding [use of the ASN to fulfill initial DSCSA requirements](#). This guidance has already been widely adopted across the supply chain in anticipation of the November 2017 deadline.

What data will be transmitted via ASNs? The required transaction information, to be included anytime ownership of a drug product is transferred, comprises:

- Name of product
- Strength and dosage of product
- NDC number of product
- Container size
- Number of containers
- Lot number of product
- Date of the transaction

- Date of the shipment, if more than 24 hours after the date of the transaction
- 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

IMPLICATIONS FOR SUPPLY CHAIN AND WAREHOUSE MANAGEMENT

For many supply chain partners, the DSCSA will require technology investments beyond EDI. One example is a need to manage serialized versus non-serialized inventory via separate processes. Only products that the FDA classifies as prescription drugs are covered by the DSCSA.

Not just drug manufacturers, but also third-party logistics providers (3PLs) and other supply chain partners will need to prepare to manage storage, receipt and fulfillment of serialized inventory alongside non-serialized products.

A related concern is the choice of product codes used within inventory management and/or warehouse

management systems (WMS). As the DSCSA specifies that packages of drug products be marked using GS1 Global Trade Item Number (GTIN) or National Drug Code (NDC) product identifiers (along with a serial number, lot number and expiration date), companies that are using incompatible codes will need to make adjustments.

Forward-looking businesses impacted by the DSCSA are taking a holistic approach to compliance-related investments that considers future as well as current requirements in the context of their end-to-end supply chain processes. This is the path to maximizing and accelerating ROI and competitive leverage while reducing rework.

HOW DSCSA COMPLIANCE CAN BENEFIT YOUR BUSINESS

Compliance with the DSCSA has benefits beyond avoiding fines and sanctions. Successful companies can anticipate "compliance ROI" stemming from business process improvement. Among the potential benefits of successful DSCSA compliance are:

- ▶ Increased accuracy of inventory accounting and disposition
- ▶ Increased supply chain velocity/reduced lead times
- ▶ Improved tracking of new product sales and reorders
- ▶ Improved effectiveness and efficiency of product returns processing and recall management
- ▶ Less gray market leakage
- ▶ Brand protection and reduced financial exposure and liability due to expired and damaged goods

For example, serialization and communication via EDI will enable manufacturers to track how much product is flowing through pharmacies versus mail-order or direct-to-customer channels, driving improved control of channel inventory and ultimately revenue growth.

Additional potential benefits include increased consumer satisfaction through assured/improved product integrity, as well as cost savings through an improved ability to collaborate with the widest choice of supply chain partners.

A HOLISTIC APPROACH TO COMPLIANCE

The November 2017 deadline is just the next of many leading up to the eventual DSCSA mandate of complete, unit-level traceability with aggregation and inference. For most participants in the drug supply chain, this progression of compliance requirements will sooner or later require significant technology investments, new business processes and changes in supply chain relationships.

Because DSCSA requirements impact a company's supply chain on an ongoing basis, vendor and technology choices should be made not only with an eye on "compliance now," but also on minimizing cost and effort associated with future changes.

For example, while many prescription drug manufacturers are well on their way to meeting serialization requirements within packaging lines, the technical challenges of warehouse-level serialization are only now coming into focus. Many distributors, repackagers and dispensers likewise have yet to

comprehensively achieve serialization readiness in areas from labeling to storage to data collection.

Without a holistic view of DSCSA milestones and associated business requirements, the result could be greater IT complexity, more integration challenges and manual effort, and higher overall compliance cost and risk.

FOR MORE INFORMATION

Offering the broadest set of supply chain solutions available from any vendor, TrueCommerce helps businesses of all sizes manage the flow of inventory and information across manufacturing, warehousing, distribution and delivery for maximum performance and value. TrueCommerce enables its customers to go beyond DSCSA compliance to provide integration and operational improvements across supply chain systems and processes.

For businesses looking to achieve timely compliance with the November 2017 directive, the TrueCommerce EDI solution offers drug manufacturers, wholesale drug distributors, drug repackagers and pharmacies and other dispensers [a complete, easy-to-use EDI solution](#) from one trusted source. TrueCommerce provides everything you need to send and receive DSCSA-compliant EDI transactions, including network connectivity, partner-specific data mappings, and unlimited, best-in-class service and support at no additional charge.

[Contact TrueCommerce today](#) for more information about how we can help your organization align with current and future DSCSA requirements.

ABOUT TRUECOMMERCE

TrueCommerce is the most complete way to integrate your business across the supply chain, integrating everything from EDI to inventory management, to fulfillment, to digital storefronts and marketplaces, to your business system and to whatever comes next. That's why thousands of companies across various industries rely on us.

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THE TRUECOMMERCE TEAM IS HERE TO HELP!

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