Drug Supply Chain Security Act

Implications for Independent Community Pharmacies

Fact Sheet –February 2016

The Drug Supply Chain Security Act (DSCSA) was signed into law along with comprehensive compounding legislation in late 2013. In a nutshell, this legislation establishes a national system for tracing pharmaceutical products through the supply chain and sets national licensing standards for wholesale distributors and third party logistics providers (3PLs). The following information outlines the "need to know" information for independent community pharmacies regarding the implementation of Phase I of this Act that starts in 2015.

Phase I

Purchase Only from Authorized Trading Partners

- January 1, 2015—Dispensers must only purchase products from authorized (appropriately licensed) trading partners

Information Exchange/Receipt of Information

- July 1, 2015 -- Requires dispensers to pass, capture and maintain certain types of information with respect to each transaction (or change in ownership). The Act addresses three types of "information":

  (1) **transaction information (TI)** that includes name of product, strength and dosage form, NDC, container size, shipment date and name and address of sender and recipient; (2) **transaction history (TH),** a list of all prior transactions; and (3) **transaction statement (TS)** an attestation by the prior business that is transferring ownership that they have complied with the Act.

FDA Enforcement Discretion

- On December 24, 2014, the FDA announced that it would exercise its enforcement discretion and not enforce the product tracing requirements of the DSCSA on manufacturers and wholesalers until May 1, 2015. The FDA's decision did not apply to other requirements in the DSCSA that took effect on January 1, such as trading partners having systems in place to verify suspect and illegitimate products, and that trading partners engage in transactions only with authorized trading partners.
- On June 30, 2015, the FDA announced that it would exercise its enforcement discretion and not enforce the product tracing requirements of the DCSA on dispensers until November 1, 2015 due to concerns about readiness because systems used to exchange, capture and maintain product tracing information would not be operational by the original July 1 effective date. Like the previous enforcement discretion

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for manufacturers and wholesalers, the FDA's compliance policy does not extend to other requirements under the DSCSA such as requiring trading partners to engage in transactions only with authorized trading partners and developing systems to verify suspect and illegitimate products.

- The June 30 enforcement discretion did not extend to the requirements under the law that trading partners (manufacturers, wholesale distributors, and repackagers) provide product tracing information to dispensers. Nor does it extend to transactions in which dispensers must provide the subsequent owner with product tracing information, including transaction history, as required by law. If a dispenser has not received product tracing information prior to or at the time it takes ownership of a product, FDA recommends that the dispenser work with the previous owner to receive this information.
- On October 29, 2015, FDA announced that it would grant dispensers an additional 4 months (until March 1, 2016) to comply with the product tracing requirements of the DCSA.

Exceptions from definition of "transaction"

(1) The dispensing of a medication by a pharmacist to a patient is exempted from the definition of a "transaction" as well as the distribution of a product pursuant to the sale or merger of a pharmacy or pharmacies.

(2) The transfer of a product from one pharmacy to another (regardless of whether the two pharmacies are affiliated in any way) to fill a prescription for an identified patient is also exempted from the definition of "transaction."

Returns

(1) For saleable returns, a dispenser may return product to the trading partner from which the dispenser purchased the product without providing the requisite information

(2) For non-saleable returns, a dispenser may return product to the manufacturer or repackager, to the wholesale distributor from whom the product was purchased, to a returns processor, or to a person acting on their behalf without providing the requisite information.

Role of Wholesaler in Capture/Storage of Required Information

(1) A dispenser may have a third party (including a wholesale distributor) maintain the TI, TH, TS required to be captured and stored by pharmacies. Please be advised that wholesalers are not "required" by law to do this on behalf of pharmacies and there must be an agreement in place. This will require a written "agreement" between a pharmacy owner and applicable wholesaler(s). In some cases, this could mean the addition of a phrase or paragraph to the existing contractual agreement that is already in place. In some cases, wholesalers will establish and maintain a web portal based-system in which dispensers may access the relevant information about his/her

transactions. Also, please be certain that any agreement that you enter into also provides for the necessary storage of the information for the required six years.

(2) If dispensers do not buy from a wholesaler that will agree to "hold" the information for them (probably a secondary wholesaler), they still must receive the TI, TH, TS, for the product from the wholesaler and keep it (or hold it) for six years or make alternate arrangements with another third party

Requests for Information

As requested by the Secretary of Health and Human Services (or other appropriate federal or state official), a trading partner (including dispenser) must provide the relevant data (TI, TH, TS) to the official as part of a recall or investigation of a product that is suspect or illegitimate. Dispensers must reply within two business days

Treatment of "Suspect" or "Illegitimate" Products

- Beginning no later than January 1, 2015, a dispenser shall have a system or process in place to investigate and quarantine products that are "suspect" or illegitimate, and notify FDA and immediate trading partners, if illegitimate product is found. To assist manufacturers, repackagers, wholesale distributors, and dispensers to comply with the new verification requirements, FDA published the draft *Guidance for industry, Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification* in June, 2014.

- According to the statute, "suspect product" is one in which the label, container, or drug product itself does not appear to be consistent with what has been seen in the past or appears to have been tampered with, or the dispenser has received notification from others in the supply chain that there are problems with the product.

- "Suspect" product is defined as a product for which there is reason to believe that:

  (a) Is potentially counterfeit, diverted or stolen;
  (b) Is potentially intentionally adulterated such that the product would result in serious, adverse health consequences or death to humans;
  (c) Is potentially the subject of a fraudulent transaction; or
  (d) Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans

- The law requires that dispensers develop a standard operation procedure outlining what pharmacy personnel should do to identify and investigate a suspect product. The FDA has identified scenarios where dispensers and other trading partners should be particularly diligent, such as purchasing from a new source, receipt of unsolicited sales offer from an unknown source, alterations to product

appearance and missing information, or a product has been counterfeit in the past. Upon determining a product is suspect, or upon receiving verification request from the FDA, dispensers must quarantine the product and conduct an investigation of the product in "coordination with trading partners."

- "Illegitimate" product is considered to be any product for which there is credible evidence showing that the product is:

  (a) Counterfeit, diverted or stole;
  (b) Intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
  (c) Subject of a fraudulent transaction;
  (d) Appears otherwise unfit for distribution such that it would result in serious adverse health consequences or death to humans

- If a product is determined to be illegitimate, the dispenser must notify the Secretary and its trading partners, take steps to disposition the product (set aside/quarantine), and, if requested by an appropriate government official, retain a sample.

Waivers and Exceptions

- The Secretary shall by guidance establish a process by which a manufacturer, repackager, wholesaler or dispenser may request a waiver from any of the requirements if the Secretary determines that compliance would result in an economic hardship

Other Provisions of Note

- Beginning November 27, 2017, manufacturers must affix a "product identifier" to each individual package and homogeneous case of product. A product identifier is a standardized graphic (two-dimensional dot matrix) that carries the product's standardized numerical identifier (SNI), lot number, and expiration date in both human- readable and machine-readable format

Phase II Requirements—In Ten Years

- A second phase of requirements is slated to go into effect in 2023 which would require some additional usage of the product identifier. NCPA was able to secure significant protections for small dispensers (25 or fewer FTEs). See below:

  No later than 18 months after the Secretary issues the final guidance required under subsection (i) of the law, the Secretary shall enter into a contract with a private, independent consulting firm with expertise to conduct a technology and software assessment that looks at the feasibility of dispensers with 25 or fewer full time employees conducting interoperable, electronic tracing of products at the package level. The consulting firm must agree to consult with small dispensers (25 or fewer FTEs)

The assessment shall examine whether the hardware and software is readily accessible, not prohibitively expensive to small dispensers, and whether the necessary hardware and software can be integrated into business practices.

The Secretary shall prescribe alternative methods of compliance/timelines for small businesses to comply, and a waiver process.