

The Drug Supply Chain Security Act (DSCSA)

The Drug Supply Chain Security Act (DSCSA) (the Act), Title II of the Drug Quality and Security Act signed into law in late 2013¹, creates a system to identify and trace certain prescription drugs distributed within the United States, thus improving detection and removal of potentially dangerous products from the pharmaceutical distribution supply chain. The Act outlines a ten (10) year plan to build an electronic, interoperable system to identify and trace prescription drugs through distribution. Among key provisions to be implemented over the 10 year period are requirements for “trading partners” (manufacturers, repackagers, wholesale distributors, dispensers and third-party logistics providers):

- Product identification:** Manufacturers and repackagers to put a unique product identifier on certain prescription drug packages, for example, using a bar code that can be easily read electronically.
- Product tracing:** Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) in the drug supply chain to provide information about a drug and who handled it each time it is sold in the U.S. market.
- Product verification:** Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to establish systems and processes to be able to verify the product identifier on certain prescription drug packages.
- Detection and response:** Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to quarantine and promptly investigate a drug that has been identified as suspect, meaning that it may be counterfeit, unapproved, or potentially dangerous.
- Notification:** Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to establish systems and processes to notify FDA/stakeholders if an illegitimate drug is found.
- Wholesaler licensing:** Wholesale drug distributors to report their licensing status and contact information to FDA. This information will then be made available in a public database.
- Third-party logistics provider licensing:** Third-party logistic providers, those who provide storage and logistical operations related to drug distribution, to obtain a state or federal license.

Application of the Act to Physicians

A “dispenser” is defined in the Act as “a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor...” [emphasis added].

Although this definition includes physicians who dispense and administer prescription drugs, there is confusion in the industry regarding the Act and its application to physicians. This appears to be the result of a little referenced exception for health care practitioners to most of the trading partner requirements. This exception states:

“Notwithstanding any other provision of law, the requirements under paragraphs (1) and (4) shall not apply to licensed health care practitioners authorized to prescribe or administer medication under State law or other licensed individuals under the supervision or direction of such practitioners who dispense or administer product in the usual course of professional practice.” [21 USC 360333-1(d)(5)]

Of the requirements for dispensers, those relating to product tracing and verification do not apply to physicians and other licensed health care practitioners. The requirements that do apply to physicians and other licensed health care practitioners are use of product identifiers and confirming authorization of trading partners. Use of product identifiers for dispensers is projected for 2020. The requirement to transact with “authorized trading partners” was implemented on January 1, 2015. So currently, only this requirement applies to physicians who administer prescription medications in the usual course of their medical practice. To the extent, however, that physician practices have in-office dispensing pharmacies, they may be responsible for complying with all of the provisions applicable to dispensers. The requirements may only apply to the pharmacy within the office and not the practice side of the business.

Confirming Authorized trading Partners

Compliance with the requirement to transact only with “authorized trading partners” requires education, implementation of a process to verify that each trading partner is authorized, and documentation of such confirmation. According to the FDA, physicians can confirm trading partners are authorized by checking with the trading partner directly or

- For manufacturers and repackagers, check FDA’s drug establishment registration database for registration;
- For wholesale distributors, third-party logistic providers and dispensers, check state authority to confirm licensure. Third-party logistic providers are considered to be licensed under the Act until the effective date of the third-party logistic provider licensing regulations issued by FDA, unless the provider is licensed by a state having a specific third-party logistic provider licensing program.

A list of entities to contact for confirmation that trading partners are licensed or registered with the applicable entity can be found on the FDA website at www.fda.gov/knowyoursource. Documentation that a physician has confirmed authorization of trading partners should be maintained and reconfirmed annually.

FDA Educational Campaign and Enforcement

In September 2014, the FDA launched the “Know Your Source” program to provide physicians with educational information regarding the new requirement. On April 28, 2015, the Center for Drug Evaluation and Research (CDER) Office of Communication, Division of Drug Information (DDI) hosted a webinar titled: “Know Your Source: Protecting Patients from Unsafe Drugs.” See: www.fda.gov/knowyoursource This webinar and an article on the FDA website both highlight recent enforcement actions against physicians and refer to letters the agency is sending to physicians that it suspects have purchased potentially unsafe drugs from a rogue distributor. (See sample letter <http://www.fda.gov/downloads/drugs/drugsafety/drugintegrityandsupplychainsecurity/ucm446811.pdf> and slides <http://www.fda.gov/downloads/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/UCM444793.pdf>)

In May 2015, a legal article about the new requirements stated: “It is not feasible for dispensers, including physicians, to anticipate and protect against all evolving methods that criminals use to get illegal drugs in the drug supply chain, but having defensible procedures in place is an important first step” in protecting patients as well as preparing to respond to state or federal regulators should they seek information from physician practices. It warned that while there are exemptions for physicians under the Act, the fact that the FDA has posted a list of recent enforcement actions and letters to physicians, identifying the physicians whom it believes “may have obtained counterfeit or unapproved drugs from a rogue distributor,” should serve as a caution to physicians that adulterated, misbranded, counterfeit, substandard, fraudulent, unapproved or diverted drug products create significant risk to the public health and present serious potential for civil and criminal liability. (See Drug Supply Chain – July 1, 2015 Deadline for Dispensers, Michael A. Walsh May 19, 2015 <http://www.strasburger.com/drug-supply-chain-july-1-2015-deadline-for-dispensers/>)

Conclusion

Under the Act, “dispensers” are required to transact only with trading partners that are “authorized trading partners” as of January 1, 2015. This requirement applies to all dispensers. To the extent, however, that physician practices have in-office dispensing pharmacies, they may be responsible for complying with all of the provisions applicable to dispensers. The requirements would potentially only apply to the pharmacy within the office and not the practice side of the business. For such physician practices, product tracing requirements will go into effect on July 1, 2015. This means as of July 1, dispensers will be prohibited from accepting ownership of a product, unless their supplier provides the required information.

Further, all dispensers, including physicians who administer prescription medications in the usual course of their medical practice will need to have bar code solutions in place in coming years, presumably by 2020, to comply with the requirements for use of product identifiers. Once compliance with this requirement is enforced, a dispenser may engage in transactions involving a product only if such product is encoded with a product identifier. The requirements to place those identifiers fall on manufacturers. Further details regarding this upcoming requirement will be provided by ASRS in coming months.

ⁱ 21 USC 360333 (Public Law 113-54)