

Drug Supply Chain Security Act: Checklist for Pharmacies

Authorized Trading Partner Verification (effective January 1, 2015)

Verify trading partners have a valid licensure and/or registration per federal and/or state law.

- Develop and implement protocols to verify applicable state and/or federal licensure and/or registration for all new trading partners.
- Develop and implement protocols for regular audits for verification of trading partners.

Suspect/Illegitimate Product Identification and Notification (effective January 1, 2015)

System or process in place to identify suspect product currently in inventory and as new product is received.

For FDA draft guidance on identification/notification requirements, visit <http://media.pharmacist.com/FDADraftGuidanceDSCSASuspectProduct.pdf>.

System or process in place to inform trading partners with regard to identification of suspect product.

System or process in place to quarantine suspect product from the regular inventory until the product is either cleared to be dispensed or removed from the supply chain.

System or process in place to promptly conduct an investigation, in coordination with other trading partners, to determine whether a suspect product is an illegitimate product.

System or process in place to remove, or assist in removing, illegitimate product from the supply chain.

Process may include disposal and/or retaining a sample of the product if further physical examination or laboratory analysis is requested by FDA or the manufacturer.

System or process in place to notify FDA and all immediate trading partners within 24 hours after making determination that product is illegitimate.

- Educate pharmacy staff regarding FDA Form 3911 to notify FDA of illegitimate product. More information found within [FDA final guidance Identification of Suspect Product and Notification](#).

Transaction Data (effective July 1, 2015) (Note: FDA delayed enforcement of some requirements below until March 1, 2016).

Only accept product if the previous owner provides the "3Ts" (Transaction History, Transaction Information, and a Transaction Statement). (effective March 1, 2016).

Information can be provided in paper or electronic format (e-mail or Web-based).

Provide the subsequent owner with the 3Ts. Does not include sales to patients or sales between pharmacies if those sales are for a specific patient need (effective July 1, 2015).

"Specific patient need" refers to the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. It does not include product transfer in anticipation of a need.

FDA will not take action against a trading partner who transfer product ownership directly to a first responder without providing product tracing information to the first responder.

Trading partners, including pharmacists, capture and maintain the 3Ts for 6 years from date of transaction. (effective March 1, 2016).

Pharmacies may contract out for capture and maintenance function of 3Ts with wholesale distributor(s) or other third-party vendor(s). Make sure to review contractual terms (e.g., are there costs to access 3Ts, charges associated if no longer a customer, etc.).