Drug Supply Chain Security Act (DSCSA)
Pharmacy Checklist 2021[1]

1) Authorized Trading Partner: are you trading with an authorized trading partner?

- **Manufacturers and Re-packagers:**
  - ✓ Must have valid registration with FDA.
  - ✓ You may check FDA's drug establishment current registration site database (DECRS).[2]
- **Distributors and 3PLs:**
  - ✓ Must have valid State or Federal license and compliance with reporting requirements
  - ✓ You may check FDA's drug establishment current registration site database (DECRS).
- **Dispensers (Pharmacies):**
  - ✓ Must have valid State license.

2) Product Tracing: do you have processes in place to trace product?

- **Receive:** do you respond to a request for information from a trading partner within 2 business days in the event of a recall or to investigate a suspect or illegitimate product?
- **Provide:** do you generate and provide product tracing information with each transaction if you sell a prescription drug to another trading partner?
  - ✓ Note: You do not need to provide product tracing information when you dispense a prescription drug to a patient, or you sell to a pharmacy for dispensing to a specific patient (known as "specific patient need")
- **Respond:** do you only accept prescription drugs with product tracing information, including the transaction Information (TI), transaction History (TH), and transaction Statement (TS)?
- **Store:** do you store product tracing information you receive in paper or electronic format for at least 6 years?
  - ✓ You must also store information about any suspect or illegitimate product investigations you conduct for 6 years.
  - ✓ Note: your wholesaler may hold your tracing data, but it is your responsibility to ensure this relationship complies with the DSCSA requirements.

[1] This "Pharmacy Checklist" is a general overview of the current requirements for dispensers pursuant to the DSCSA and is largely based on the FDA's Pharmacists Webinar that can be accessed here: https://collaboration.fda.gov/p8uo9k0lkn2/?launcher=false&fcsContent=true&pbMode=normal&proto=true. However, it should be noted that the FDA continues to release industry guidance in this space. Please consult the following webpage to access up-to-date regulatory action on the implementation of the DSCSA: https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm424963.htm

[2] Access to the DCERS site can be found here: https://www.fda.gov/drugs/informationondrugs/ucm135778.htm.

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3) Suspect or Illegitimate Product: do you have standard operating procedures in place to identify as suspect or illegitimate product at your pharmacy?

- **Suspect Product is when you have reason to believe that product potentially is:**
  - ✓ Counterfeit, diverted, stolen, subject of fraudulent transaction, intentionally adulterated, or appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.
  - ✓ FDA examples: Altered product info, missing info on label, looks different than product on shelf, no "Rx only" symbol, bubbling on the label, foreign language, lot numbers or expiration dates do not match the outer/inner container, missing or wrong package inserts, damaged, broken seal, open package, different product name than FDA approved version.
  - ✓ Starting November 27, 2023, pharmacies must verify the product identifier of the suspect product of at least 3 packages or 10 percent of products under suspect investigation.[3,4]
- **Illegitimate Product is when you have credible evidence that shows the product is:**
  - ✓ Counterfeit, diverted, stolen, subject of fraudulent transaction, intentionally adulterated, or appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.
  - ✓ Do you notify the FDA if you have illegitimate product within 24 hours using Form FDA 3911, notify other trading partners within 24 hours, and request notification termination using Form FDA 3911?[5]
- **Other Considerations:**
  - ✓ Do you quarantine and investigate suspect prescription drugs to determine if illegitimate?
  - ✓ During such investigation, do you validate applicable transaction information and transaction history?
  - ✓ If the product is illegitimate, do you work with manufacturer to take steps to prevent it from reaching patients?
  - ✓ Do you store records of investigation of suspect product and the disposition of illegitimate product for at least 6 years?

4) Product Identifiers: are you on the lookout for product identifiers in your pharmacy?

- Starting November 2018, manufacturers and re-packagers were required to place DSCSA-compliant product identifiers on prescription drug product. Starting on November 27, 2019, wholesale distributors are required to only trade with product that contains the DSCSA-

[3] Note that in a 2019 Compliance Policy statement FDA announced that it would delay enforcement of certain requirements until November 27, 2020, recognizing that a delay was necessary to ensure that the pharmaceutical distribution supply chain was not disrupted. As this deadline approached, FDA became aware that many affected entities would not be able to comply with certain requirements and issued the 2020 Compliance Policy to delay enforcement for an additional three years until November 27, 2023.

[5] Access to the FDA 3911 Form can be found here: https://www.fda.gov/media/99191/download

compliant product identifier unless the product is grandfathered product or is subject to a waiver, exception, or exemption under the law.

- Under the law, "[a] product identifier is a standardized graphic that includes the product's standardized numerical identifier (composed of the NDC and a unique alphanumeric serial number), lot number, and expiration date, in both human- and machine-readable formats. The machine-readable format must be on a data carrier that conforms to the standards developed by a widely recognized international standards development organization. The product identifier data is specifically required … to be in a '2-dimensional data matrix barcode' for packages and in a 'linear or 2-dimensional data matrix barcode' for homogenous cases."
- A DSCSA-compliant product identifier contains an NDC, serial number, lot number, and expiration date.
- As of November 27, 2020, dispensers can only buy/sell product that contain the DSCSA-compliant product identifier unless the product is grandfathered product or is subject to a waiver, exception, or exemption under the law.[6]

5) Solutions Out on the Market: are you engaging with a solutions provider or other business partner to help you comply with the law? The following are some questions to ask business partners:

- ✓ Are you working on providing my pharmacy with tech to read a 2D data matrix?
- ✓ Can the software integrate with other pharmacy software?
- ✓ Is there a value-add beyond DSCSA compliance?
- ✓ Does this tech work in conjunction with all my wholesalers and other systems that are holding my tracing information?
- ✓ Will this tech be updated as industry changes?
- ✓ Will this cost me more?
- ✓ What data standards does your technology solution support? Which are not compatible?
- ✓ How will the technology vendor ensure my data is secure? What happens if there is a breach? Is my data backed-up?
- ✓ Does the vendor have access to master data? What support services does the vendor provide to the pharmacy? Can the vendor be reached 24/7? Via phone, email, etc.?
- ✓ How are vendors identifying grandfathered products or exempt/excepted/waived products?

[6] Note that the enforcement delay for specific provisions of Section 582: Section 582(c)(4)(D) verification of saleable return product and Section 582(d)(4)(A)(ii)III) verification of product identifiers when investigating suspect or illegitimate product) do not apply to Section 582 as a whole.