Drug Supply Chain Security Act (DSCSA)
Pharmacy Checklist 2018[1]

1) **Authorized Trading Partner: are you trading with an authorized trading partner?**
   - **Manufacturers and Re-packagers:**
     - ✓ Must have valid registration with FDA
     - ✓ Check FDA's drug establishment current registration site database (DECRS) to verify[2]
   - **Distributors and 3PLs:**
     - ✓ Must have valid State or Federal license and compliance with reporting requirements
     - ✓ Check FDA's drug establishment current registration site database (DECRS) to verify
   - **Dispensers (Pharmacies):**
     - ✓ Must have valid State license

2) **Suspect or Illegitimate Product: do you have standing operating procedures in place to identify 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
   - **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
     - ✓ You must 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[3]

3) **Product Tracing: do you have processes in place to trace product?**
   - **Receive:** do you only accept prescription drugs with product tracing information, including the transaction Information (TI), transaction History (TH), and transaction Statement (TS)?

[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.

[3] Access to the FDA 3911 Form can be found here: file:///C:/Users/kshankle/OneDrive%20-%20ncpanet/Desktop/FDA-3911_(5.17).pdf.

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- **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.
- **Respond:** 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?
- **Store:** do you store product tracing information you receive in paper or electronic format for at least 6 years?
  - ✓ Note: your wholesaler may hold your tracing information, but it is your responsibility to ensure this relationship complies with the DSCSA requirements

4) 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
- **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?[4]
- **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?

[4] Access to the FDA 3911 Form can be found here: file:///C:/Users/kshankle/OneDrive%20-%20ncpanet/Desktop/FDA-3911_(5.17).pdf.

- ✓ 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?

5) Product Identifiers: are you on the lookout for product identifiers in your pharmacy in 2020?

- ➢ Starting November 2018, manufacturers and re-packagers must place product identifiers on prescription drug packages that are in human and machine-readable format and are on the smallest individual saleable unit
  - ✓ A Product Identifier contains an NDC, serial number, lot number, and expiration date
- ➢ Starting November 2020, dispensers can only buy/sell product that are serialized