

DSCSA Requirements

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Steps to Interoperability

- Compliance with Phase 1 is a precursor to interoperability
- Only accept product with serialized data
- Have a system in place to identify, investigate, and verify Suspect Products (Also, report Illegitimate products)
- Integrate scanning with PMS/WMS for product verification
- Systems in place for interoperability exchange and tracking

“Dispensers are the last line of defense in the publics’ exposure to illegitimate and counterfeit drugs.”

Source: FDA Webinar June 2021

The Cost of Delay

- Unable to sell Grandfathered product*
- Gaps in current systems leading to missed deadlines
- Postponing compliance can leave your Pharmacy/Pharmacist license exposed
- Implementation wait times may leave dispensers vulnerable
- Federal & State Inspections could result in substantial fines

*The FDA defines grandfathered product as a package or homogenous case of product that was introduced to the supply chain prior to Nov. 27, 2018. This product may not be affixed with a product identifier.