Drug Supply Chain Security Act: Checklist for Dispensers
Future Requirements

Dispenser transactions with identified products only (11/27/2020) For additional information see FDA Final Guidance Identification of Suspect Product and Notification.	
	Only engage in transactions if the product identifier[i] is affixed or imprinted on the unit / case, unless the product is grandfathered, meaning there is documentation the product was packaged by a manufacturer before November 27, 2018[ii]
	Suspect product identification investigations by dispensers shall include: - Verifying: (1) the suspect product's lot number corresponds with the lot number for such a product and (2) the product identifier of at least 3 packages or 10% of such suspect product, whichever is greater, or all packages if fewer than 3, corresponds with the product identifier for such product - Validating any applicable transaction history and transaction information in the possession of the dispenser to determine whether the product is an illegitimate product - Keeping records of the suspect product investigation for 6 years - If the suspect product is not determined to be an illegitimate product, the dispenser must promptly notify FDA and the product may be further distributed or dispensed
	If the dispenser in coordination with the manufacturer conclude that a product in the dispensers' possession or control is illegitimate then the dispenser shall: - Disposition[iii] of the illegitimate product and assist trading partner's disposition - Retain a sample of the product for further physical examination or laboratory analysis - Notify FDA and all immediate trading partners not later than 24 hours after making an illegitimate product determination - Respond to notification from FDA that product is illegitimate and identify all illegitimate product subject to the notification - Terminate the notification if such a determination is made in consultation with FDA - Maintain records of disposition of an illegitimate product for 6 years after the disposition

Unit-level Traceability/ Enhance Drug Distribution Security (11/27/23)	
	Exchange transaction information (includes product identifier at the package level) and transaction statements in a secure, interoperable, electronic manner
	Implement systems or processes for package level product verification which may include the use of aggregation and inference as necessary
	Implement systems or processes for verification of product at the package level, including the standardized numerical identifier[iv], which may include the use of aggregation and inference as necessary
	Implement systems or processes necessary to promptly facilitate gathering the information necessary to produce the transaction information and transaction statement for each transaction going back to the manufacturer if requested by FDA for a suspect or illegitimate product investigation or if requested by an authorized trading partner
	If a dispenser enters into a written agreement with a third party, including an authorized wholesale distributor, to confidentially maintain required information and statements, then the dispenser must maintain a copy of the written agreement

This checklist was developed as a guide only and is not legal advice. Compliance with the checklist does not guarantee compliance with DSCSA. For specific language in the DSCSA with regard to pharmacists' requirements (referred to as "dispensers"), visit FDA's website (www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm). Last updated Oct. 6, 2017.

[i] According to DSCSA, the term “product identifier” means a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.

[ii] On November 27, 2017, FDA published Draft Guidance, “Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier, available at: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586509.pdf.

[iii] According to DSCSA, “disposition”, with respect to a product within the possession or control of an entity, means the removal of such product from the pharmaceutical distribution supply chain, which may include disposal or return of the product for disposal or other appropriate handling and other actions, such as retaining a sample of the product for further additional physical examination or laboratory analysis of the product by a manufacturer or regulatory or law enforcement agency.

[iv] According to DSCSA, “Standardized numerical identifier” means a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.” It is important to note, the “standardized numerical identifier” is different from the “product identifier” because the standardized numerical identifier is a component of the product identifier.