

## Drug Supply Chain Security Act (DSCSA) Additional Dispenser Requirements begin on November 27, 2020

### DSCSA Background

The Drug Supply Chain Security Act (DSCSA), Title II of the Drug Quality and Security Act (DQSA), which amended the Federal Food, Drug, and Cosmetic Act (FDCA), was enacted on November 27, 2013. DSCSA implementation is staggered over a ten-year period, until November 27, 2023, when enhanced package-level requirements for the interoperable, electronic tracing of products go into effect.

### There are two new requirements for Dispensers that become effective on November 27, 2020.

#### **Dispensers Transact only with Product Identifiers:**

First, effective November 27, 2020, Dispensers should only engage in transactions involving product encoded with a product identifier.

- According to the DSCSA, “a dispenser may only engage in transactions involving product if such product is encoded with a product identifier.”
- The FDA has exempted Dispensers from this requirement for product that was in the pharmaceutical distribution supply chain before November 27, 2018. See FDA, *Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier*, Guidance for Industry (Sep. 2018), <https://www.fda.gov/media/109591/download>.

Due to this exemption (i.e., grandfathering), the requirement that all product purchased by a Dispenser must be encoded with a product identifier is not absolute. While a significant proportion of product in commerce presently bears a product identifier, not all product does or will by November 27, 2020. Grandfathered product will still exist on November 27, 2020. Under the DSCSA and FDA guidance, this product may still be purchased by a Dispenser. However, Dispensers may only purchase this grandfathered product if documentation shows the product was in the pharmaceutical distribution supply chain before November 27, 2018.

In its September 2018 guidance, the FDA clarified the terms of its grandfathering policy:

- Product that is not labeled with a product identifier is grandfathered when documentation exists showing it was packaged by a manufacturer or repackaged by a repackager before November 27, 2018. For example, a product without a product identifier but accompanied by transaction information or transaction history documenting a sale before November 27, 2018, is grandfathered.
- In the absence of transaction information or transaction history documenting a sale before November 27, 2018, a Dispenser may rely on the transaction statement as an indication that the product was in the supply chain before that date. In addition, a Dispenser may contact the manufacturer or repackager of the product for the packaging date.
- Trading Partners may continue to engage in transactions involving grandfathered product until product expiry.

The FDA, through this guidance, has stated the presence of a Transaction Statement for a product without a product identifier indicates the product is grandfathered.

Because all DSCSA product has been required to have a Transaction Statement as a part of the DSCSA Transaction Data (3Ts) since 2015, any product a Dispenser receives after November 27, 2020 without the product identifier can be considered grandfathered when the 3Ts are present unless documentation shows a packaging date after November 27, 2018.

There are a couple of important points to note by their absence above.

- Nothing above requires a Dispenser scan product upon receipt to confirm a product identifier is present.
- The November 27, 2020 DSCSA requirements do not require product identifier data be exchanged. **DSCSA does not require the exchange of product identifier data until November 27, 2023.**

## Dispenser Verification of Suspect Product Identifiers:

The second new requirement for Dispensers effective on November 27, 2020, relates to performing verifications of the product identifier when investigating suspect product.

Since 2015, all DSCSA trading partners, including Dispensers, have been required to have policies and procedures to detect and investigate suspect products. As a part of that suspect product investigation, beginning November 27, 2020, Dispensers are expected to add the verification of product identifiers to the process.

The DSCSA explains that “verification” or “verify” refers to validating that the product identifier on a particular product corresponds with the standardized numerical identifier or lot number and expiration date assigned to that product by the manufacturer or repackager. In other words, to verify the product identifier, the Dispenser should ensure that it is a product identifier actually affixed to that product by the manufacturer or repackager.

Beginning November 27, 2020, when investigating a suspect product, a Dispenser is expected to verify with the manufacturer of the product the information in the product identifier. This would include the GTIN (NDC), the lot number, the serial number, and the expiry of the product that is suspect. As part of the investigation, the Dispenser must verify product identifiers of “at least 3 packages or 10 percent of such suspect product, whichever is greater, or all packages, if there are fewer than 3.” This verification can be done through any number of methods including telephone calls, emails, or file transfers between the Dispenser and the manufacturer or repackager. There are some solution providers who are offering a way to scan the suspect product into their system and send the verification request to the manufacturer. Any of these methods is compliant under the DSCSA. The method the Dispenser uses may be dependent upon how often suspect product is encountered and the volume of product processed by the Dispenser.

Dispensers should note that in this November 27, 2020 verification requirement, there is no requirement to verify the product identifier of every product the Dispenser receives. The DSCSA Dispenser verification requirement only applies when performing a suspect product investigation. In addition, the grandfathering policy applies. Thus, Dispensers are not expected to perform product identifier verification of product in the supply chain before November 27, 2018.

### Additional Information:

DSCSA Law Link: <https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf>

FDA *Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier*, Guidance Link: <https://www.fda.gov/media/109591/download>

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