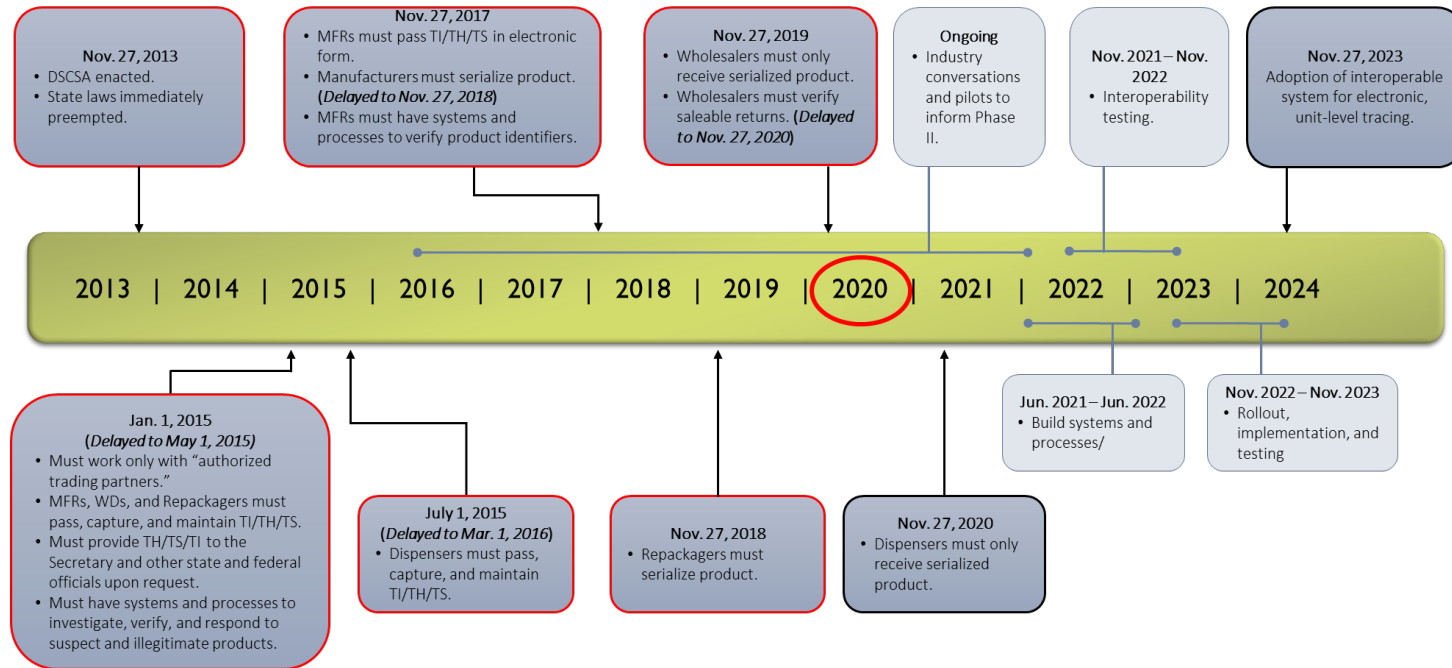


Pharmaceutical Distribution Security Alliance (PDSA) Questions & Answers on Dispenser Requirements under DSCSA

This document is intended to be a resource for dispensing organizations looking to successfully implement the requirements of the Drug Supply Chain Security Act (DSCSA). The image below depicts the requirements for dispensers in the context of DSCSA requirements and implementation across the supply chain. For more information on any of the following topics, please see the Q&A that follows:

- Dispenser requirements under the DSCSA: today; as of November 27, 2020; as of November 27, 2023, and beyond
- Dispenser obligations during a suspect product investigation
- Dispenser requirements for transmitting, storing, and utilizing serialized data
- Restrictions on dispenser borrow and loan activities under the DSCSA
- Restrictions on dispenser distribution activities under the DSCSA



Pharmaceutical Distribution Security Alliance (PDSA)
Questions & Answers on Dispenser Requirements under DSCSA

1. What are the current dispenser obligations under DSCSA?

The DSCSA was signed into law on November 27, 2013. While the obligations of DSCSA phase in over a ten-year period, since 2013, the following obligations have come into effect for dispensers. Therefore, in order to be compliant with the provisions of DSCSA, dispensers must currently have systems and processes in place for:

- Only accepting ownership of a product when the previous owner provides, at the time of the transaction, transaction history (TH), transaction information (TI), and a transaction statement (TS) per Section 582 (d)(1)(A)(i).
- Providing the subsequent owner of a product with TH, TI, and TS at the time of, or prior to, the transaction, per Section 582 (d)(1)(A).
- Capturing and storing TH, TI, and TS information (including lot level information, if provided) for no less than 6 years after the transaction, per Section 582 (d)(1)(A)(iii). Note, this may be contracted out to a third party.
- Respond to requests for information from the Secretary (typically via FDA) or another appropriate Federal or State official within 2 business days, per Section 582 (d)(1)(D).
- Only transact with trading partners who are authorized trading partners, per Section 582 (d)(3).
- Conduct a suspect product investigation, including the capability to quarantine suspect product in the dispenser's possession or control, per Section 582 (d)(4).

2. What are the 2020 dispenser obligations under DSCSA?

The DSCSA established numerous requirements for dispensers (and other trading partners). Several of those requirements took effect in 2015 and continue to apply. Two new requirements of dispensers take effect on November 27, 2020:

First, dispensers may only transact serialized product. This means that all product received must carry a product identifier comprised of the National Drug Code (NDC) (typically embedded in a GTIN) plus a unique alphanumeric serial number; a lot number; and an expiration date. The DSCSA states, in relevant part, "...a dispenser may engage in transactions involving a product only if such product is encoded with a product identifier ..."¹ Dispensers are not required to scan product barcodes upon receipt. However, dispensers may opt to scan some percentage of their received product to ensure that the product carries a product identifier. In the future, scanning will aid dispensers in fulfilling key 2023 obligations under the DSCSA.

Second, under Section 582(d)(4)(A)(ii), when conducting a suspect product investigation dispensers must (1) verify whether the lot number of a suspect product corresponds with the lot number for such product, and (2) verify the product identifier, including the serial number, of at least 3 packages or 10% of such suspect product² (whichever is greater).³ A dispenser is required to conduct an investigation⁴ "upon making a determination that a product in the possession or control of the dispenser is a suspect product, or

¹ Section 582(d)(2)

² 10% of the packages (lowest salable unit) of the suspect product.

³ These two new requirements for suspect product investigations are added to the two existing requirements: (1) dispensers must validate any applicable transaction history and transaction information in the possession of the dispenser; and (2) otherwise investigate to determine whether the product is an illegitimate product. These two requirements are not altered by the 2020 requirements.

⁴ Dispensers are able to contract with third party entities to provide verification information under the DSCSA.

upon receiving a request for verification from the Secretary⁵ that has made a determination that a product within the possession or control of a dispenser is a suspect product.”⁶ This obligation is described in more detail in the FDA draft guidance entitled, “Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act.”⁷ Notably, verification need not be conducted electronically in 2020 (dispensers may choose to use phone, fax, or other means); electronic verification is not required until 2023.

3. What are the reporting obligations for dispensers when a suspect product is identified?

Dispensers are not required to report suspect product, but are required to conduct an investigation of such product. If, through a suspect product investigation, the product is determined to be illegitimate product, dispensers do have affirmative obligations to report the illegitimate product.

Under the DSCSA, when a dispenser, in coordination with the manufacturer, determines that a product in their possession or control is an illegitimate product, the dispenser “must notify the Secretary and all immediate trading partners that the dispenser has reason to believe may have received such illegitimate product of such determination not later than 24 hours after making such determination.”⁸ Practically, this notification is made through use of the Form FDA 3911. More details and instructions for notification of illegitimate product are including in the FDA guidance entitled, “Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification.”

4. Under what conditions can a dispenser expect to receive a request to provide DSCSA-related information to facilitate product tracing (*i.e.*, a tracing request)?

Before 2023, dispensers are not obligated to respond to tracing requests outside of requests made by the Secretary. Dispensers are required to respond, within 2 business days, to a tracing request by the Secretary or other appropriate Federal or State official: (1) in the event of a recall, or (2) for the purpose of investigating a suspect or an illegitimate product.⁹

In 2020, dispenser obligations to respond to tracing requests do not change.

Beginning in 2023, dispensers are additionally obligated to “promptly facilitate the gathering” of transaction information going back to the manufacturer in response to a tracing request. As is currently the policy, a tracing request from the Secretary (or other appropriate Federal or State official), may be made: (1) in the event of a recall, or (2) for the purposes of investigating a suspect product or an illegitimate product. In addition, beginning in 2023, dispensers are obligated to respond to a tracing request from an authorized trading partner: (1) for purposes of investigating a suspect product, or (2) for purposes of assisting the Secretary with an investigation.

Tracing processes are not intended to be used for business practices and tracing is not required or expected to be completed for every unit. Additionally, dispensers are not obligated to respond to requests other than those from the Secretary, or an authorized trading partner, for purposes of a recall, suspect product investigation, or illegitimate product.

5. How will dispensers receive information on grandfathered product?

⁵ Practically, a representative of a federal agency (*e.g.*, FDA) can make this request on behalf of the Secretary.

⁶ Section 582(d)(4)(A)(i)

⁷ Draft guidance is subject to modification by FDA when finalized.

⁸ Section 582(d)(4)(B)(ii)

⁹ Section 582(d)(1)(D)

Grandfathered product is “product that is not labeled with a product identifier and that is in the pharmaceutical distribution supply chain at the time of the effective date of the requirements of [Section 582]” and is therefore exempt from the requirement to carry a product identifier.¹⁰ As of November 27, 2020, all supply chain entities will be required to transact only serialized product. However, this does not mean that all product in the supply chain will be serialized or that all product received by a dispenser will be serialized. This is because grandfathered product will still circulate in the supply chain and is permitted to be transacted without a product identifier.¹¹ The full scope of the grandfathering exemption is described in the FDA final guidance entitled, “Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier.” As indicated in FDA guidance, if the transaction history (TH) and transaction information (TI) does not include a sale before November 27, 2018, and a dispenser does not have any other indicia that a product may be suspect or illegitimate, the transaction statement (TS) provides evidence that the product is compliant with DSCSA and therefore grandfathered. The TS is, in essence, a statement attesting to DSCSA compliance. Therefore, because non-serialized product can only be transacted under the DSCSA if grandfathered, the TS effectively conveys that any non-serialized product is grandfathered product.¹² A dispenser may obtain the packaging date of product lacking a product identifier by requesting such information from the manufacturer or repackager, which currently is via a manual process by contacting the manufacturer or repackager.

For grandfathered product, dispensers are exempt from the obligation to transact only serialized product beginning November 27, 2020. For grandfathered product, dispensers are also exempt from the requirement to, during a suspect product investigation under the conditions noted above, verify the product identifier of a portion of packages beginning November 27, 2020. Dispenser are still required, however, to verify the lot number of a suspect product as described in section 582(d)(4)(A)(ii)(II), validate any applicable TH and TI in their possession as described in section 582(d)(4)(A)(ii)(III), and otherwise investigate the product to determine if it is illegitimate as required by section 582(d)(4)(A)(ii).

6. Does receiving serialized product also require dispensers to receive and/or store serialized data in 2020?

No, serial numbers are not required to be incorporated into transaction information (TI) until November 27, 2023. The transaction information (TI) does not include product identifier/package serial number at this time. While dispensers may need to leverage the serial number, for example, in performing a verification or conducting a product investigation, serialized data does not have to be captured and maintained until 2023.

7. What additional requirements do dispensers have beginning November 27, 2023?

Beginning November 27, 2023, the following requirements come into effect (for product not otherwise subject to grandfathering, or a waiver, exception, or exemption):

- Product identifiers (i.e., serialized data) must be included in the TI that is captured and maintained for each transaction. This means that dispensers must processes and controls to ensure that for each physical product, the data associated with that product is in the possession or control of the dispenser or a third party authorized to act on their behalf. Each individual dispenser has latitude in determining the controls it will deploy in accordance with its own circumstances,

¹⁰ Section 582(a)(5)

¹¹ Product subject to an approved waiver, exception, or exemption may also circulate in the supply chain without a product identifier.

¹² As noted above, legitimate non-serialized product may also be in the supply chain if subject to a waiver, exception, or exemption.

business processes, legal interpretations, and risk tolerance. Often, other trading partners have deployed risk-based controls to ensure the integrity of the DSCSA data they capture and maintain. For example, a dispenser may choose to employ statistical sampling methods to check individual data sets for product purchased from trading partners based on the past accuracy and reliability of data provided by that individual trading partner.

- Information passed will allow product to be traced at the package level, not just lot.
- Transaction history is replaced with an interoperable system for transmitting data in a secure, interoperable, and electronic manner. This means that the requirement for dispensers to receive TH will sunset and dispensers will no longer see TH. In addition, dispensers will no longer see a direct purchase statement.
- Dispensers will be required to implement systems and processes for automated, electronic package-level verification. These requirements for package-level verification are not intended to, nor require, dispenser to scan or confirm the unique data set of each individual package. At an operational level, it is anticipated that systems for electronic verification may require the use of aggregation and inference.
- Dispensers must associate TI and TS for any products being handled as saleable returns.

8. Did DSCSA restrict “borrow and loan” activities?

Yes, the DSCSA does restrict pharmacy “borrow and loan” activities.

DSCSA requires a dispenser transferring ownership of a product to provide TI, TH, and TS (transaction data) to the subsequent owner. This does not apply to dispensers transferring product between entities under common control or for sales from a dispenser to another dispenser to fulfil a specific patient need. Importantly, a change of ownership can occur even if there is no financial exchange. Therefore, DSCSA does restrict “borrow and loan” of product to commonly controlled entities and product transfer for a specific patient need. All other “borrow and loan” activities would require transmission of transaction data.

DSCSA defines “specific patient need” as “the transfer of a product from one pharmacy to another to fill a prescription for an identified patient.”¹³ A specific patient need specifically “does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.” As such, transfers of product to another dispenser without a specific patient need or other exemption or exception may constitute wholesale distribution, including that the dispenser be licensed as a wholesale distributor.¹⁴

The April 2020 DSCSA during PHE guidance specifically waives the requirement for dispenser to dispenser transfers of product needed as a result of COVID-19 regardless of whether there is a specific patient need. FDA defines specific patient need as “the transfer of a product from one pharmacy to another to fill a prescription for an identified patient (section 581(19) of the FD&C Act). This term does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.” This means that under a PHE, “borrow and loan” activities are permitted outside of the two conditions noted above. Once a PHE is lifted, product sales/transfer outside of commonly controlled entities or a specific patient need will require the transmission of transaction data.

9. Did the DSCSA preempt the “5% Rule” applied by many states for licensure purposes?

¹³ Section 581

¹⁴ FDA’s Draft Guidance: “Identifying Trading Partners Under the Drug Supply Chain Security Act,” August 2017. <https://www.fda.gov/media/106961/download>

DSCSA does not include a “5%” Rule,” which was requirement in many state pharmacy/wholesaler laws whereby a dispenser did not need to obtain a wholesale distributor license if they distributed less than 5% of product sales. The DSCSA preempts these “5% Rules. DSCSA requires a wholesale distributor license for any entity engaged in distribution activities, unless exemption or exception applies. As explained below, dispensers would have to obtain a wholesale distributor license, and would therefore be subject to wholesale distribution requirements, unless an individual transaction or the product meets one of the limited instances where a specific DSCSA exclusion would apply.

Section 585(a) of the FD&C Act, added by the DSCSA, preempts all state “requirements for tracing products through the distribution system...which are inconsistent with, more stringent than, or in addition to, any requirements [established by the DSCSA].” In addition, Section 585(b) of the FD&C Act, added by the DSCSA, preempts all state “standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements applicable under [the DSCSA].” The clear and primary intent of the DSCSA was to establish uniformity among states, and as such, states must not exceed or otherwise deviate from the federal standards that will be developed.¹⁵

DSCSA defines wholesale distributor as “a person (other than a manufacturer, a manufacturer’s co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution.”¹⁶ Further, the DSCSA requires that no person may engage in wholesale distribution of a drug without a wholesale distributor license. Section 353 of the FD&C Act defines wholesale distribution as “the distribution of a drug subject to subsection (b) to a person other than a consumer or patient, or receipt of a drug subject to subsection (b) by a person other than the consumer or patient.” This excludes (among others)¹⁷:

- intracompany distribution of any drug between members of an affiliate or within a manufacturer
- the distribution of a drug, or an offer to distribute a drug among hospitals or other health care entities which are under common control
- the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency
- the dispensing of a drug pursuant to a prescription
- the distribution of minimal quantities of drug by a licensed retail pharmacy to a licensed practitioner for office use
- the distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law
- the purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity
- salable drug returns when conducted by a dispenser

The FD&C Act, as amended by the DSCSA, does not exempt dispensers from obtaining a distributor license for distribution activities, regardless of the amount of product that is distributed.

¹⁵ Further discussion of preemption under the DSCSA is available in the PDSA FAQ Document entitled, “PDSA FAQs on Preemptive Effect of the DSCSA,” available at: http://pdsaonline.org/wp-content/uploads/2015/07/PDSA_FAQs_Preemptive-Effect-of-DSCSA_072915.pdf

¹⁶ Section 581

¹⁷ For a full list of exclusions, see: <https://codes.findlaw.com/us/title-21-food-and-drugs/21-usc-sect-353.html>