Partnership for DSCSA Governance

FDA-PDG Town Hall: Progress Toward End of Dispenser Exemption in November 2025

APPENDIX

The final of three virtual town halls in 2025, hosted by FDA and the Partnership for DSCSA Governance (PDG), occurred on September 23 and 24, 2025. This town hall was designed to provide a forum for trading partners across the supply chain and other interested parties to share information on continued implementation of the Drug Supply Chain Security Act (DSCSA) and areas of remaining concern, with a **focus on the November 27, 2025, exemption expiration for dispensers with more than 25 full-time employees licensed as pharmacists or qualified as pharmacy technicians (referred to as "large dispensers" in this report).**[1]

The town hall provided stakeholders with an opportunity to share information to support all trading partners in achieving **enhanced product tracing and verification collaboratively**. This appendix is intended to address frequently asked questions and shared points of uncertainty during the town hall.

1. What is the definition and scope of "health care practitioner," excepted from certain requirements under FDCA Sec. 582(d)(5)?

Stakeholders should review FDA's Draft Guidance, "Identifying Trading Partners Under the Drug Supply Chain Security Act." For additional information on industry's perspective as to this topic, stakeholders can reference Question 2 in the Pharmaceutical Distribution Security Alliance's (PDSA) Q&A document from February 2025.

2. Do pharmacies need to specifically apply for the small dispenser exemption?

No, as FDA stated in its October 2024 informational posting regarding the small dispenser exemption, "small dispensers and their trading partners who utilize these exemptions do not need to submit anything to FDA or inform the agency." Small dispensers should notify their trading partners of their exemption status to ensure smooth transactions.

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[1] In October 2024, FDA published its DSCSA Exemptions from Section 582(g)(1) and Other Requirements of the FD&C Act for Certain Trading Partners, which exempts eligible authorized trading partners from certain DSCSA requirements. These phased exemption periods provide trading partners with additional time as they work towards full DSCSA implementation while maintaining patient access to medicines. The exemption periods follow the FDA-issued stabilization period, which ended on November 27, 2024. The exemption periods expire on different dates based on sector, as follows:

- **Eligible Manufacturers and Repackagers** – May 27, 2025.
- **Eligible Wholesale Distributors** – August 27, 2025.
- **Eligible Dispensers with 26 or more full-time employees** – November 27, 2025.

Collectively, these exemptions are referred to as "the phased exemption periods" in this document.
In addition to the phased exemption periods, **dispensers with 25 or fewer full-time licensed pharmacists or qualified as pharmacy technicians** are also exempt until November 27, 2026. These small dispensers were not the primary focus of this town hall.

3. Which NDCs are/are not "products" subject to DSCSA?

The manufacturer of each product is responsible for determining whether that product is in scope.

4. Can GTIN reference tables be added to the NDC database?

No, as Global Trade Item Numbers (GTINs) are managed by the standards body, GS1. GTIN reference tables are outside of FDA's purview. Interested stakeholders should consider working with GS1 and other industry groups to develop a GTIN-to-NDC reference table.

5. How can organizations confirm that ATPs have approved WEEs and how can dispensers verify an "authorized" status of a trading partner (i.e., licensure)?

For an industry perspective on this topic, stakeholders can reference PDSA's February 2025 Q&A.

6. Is product distributed through a manufacturer's patient assistance program subject to the DSCSA?

For an industry perspective on this topic, stakeholders can reference Q22 in PDSA's October 22 Q&A.

7. What are the applicable DSCSA requirements for human drugs used for animals in veterinary settings?

For an industry perspective on this topic, stakeholders can reference Q3 in PDSA's February 2025 Q&A.

8. Does FDA have any guidance for trading partners as to how to quickly reconcile discrepancies in product tracing information when there is no indication a product is a suspect product in order to allow product to be dispensed as soon as possible?

Yes, in FDA's final guidance entitled Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act, FDA stated that, in a scenario where there is a data discrepancy that is clerical, a trading partner may resolve the discrepancy by (1) confirming with the selling trading partner that the error is clerical; (2) coordinating and reaching an agreement with the selling trading partner on how to correct the clerical error or discrepancy; and (3) ensuring that accurate product tracing information is available for subsequent transactions.

When this process is followed, it should reduce the frequency of future clerical or data errors, and it prevents a product from being placed in quarantine. If the error or discrepancy cannot be resolved and the product is determined to be a suspect or illegitimate product, trading partners must refrain from further distributing or dispensing the product and follow steps for verification of product.

9. Is access to product tracing documentation through a wholesale distributor provided portal sufficient to meet dispenser compliance obligations with respect to receiving and maintaining product tracing documentation?

Yes. In final guidance entitled DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs, FDA recommended that trading partners use the Electronic Product Code Information Services (EPCIS) standard to facilitate interoperable and secure data exchange. FDA further noted that dispensers may meet these requirements through the use of a

third-party solution provider service, developing a customized system and supporting infrastructure, or accessing a web portal offered by their wholesale distributor or manufacturer that uses EPCIS and enables secure access and exchange of serialized product tracing data.

Access to a wholesale distributor provided portal may serve as the simplest manner of compliance with DSCSA requirements for receipt and maintenance of product tracing documentation, particularly for dispensers that primarily purchase from one wholesale distributor. Access to wholesale distributor portals may additionally serve as a stopgap allowing for DSCSA compliance in instances where there may be challenges with receipt of data through a different system of receipt or product tracing documentation.

About PDG

PDG is an independent, balanced, sector-neutral, nonprofit industry governance body that supports the secure, electronic, interoperable tracing, and verification of prescription drugs in the U.S. supply chain, as required by the Drug Supply Chain Security Act (DSCSA). Through our public-private partnership with FDA, we collaborate to develop, advance, and sustain an effective and efficient model for interoperability.

PDG membership includes leading authorized manufacturers, repackagers, wholesalers, third-party logistics providers, and dispensers (hospitals and retail and independent pharmacies), as well as leading industry trade associations and technical experts. Together, these members are working to establish a comprehensive vision for industry's implementation of secure, electronic systems and processes for drug traceability in the United States.

For additional information, visit www.DSCSAgovernance.org.