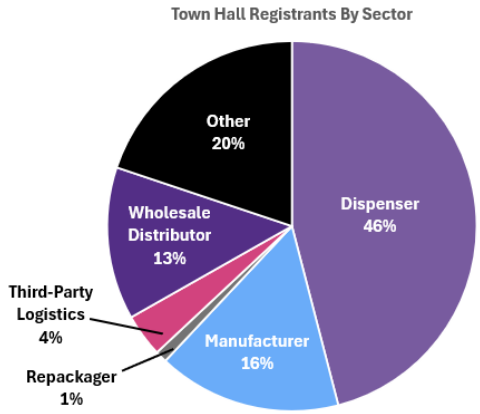
Partnership for DSCSA Governance

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

SUMMARY

PDG's role in the town hall summarized in this report was primarily facilitation of the exchange of information among industry stakeholders and FDA. This report summarizes the comments and recommendations of *participants* in the town hall. PDG TAKES NO POSITION ON THE COMMENTS OR RECOMMENDATIONS MADE BY THOSE PARTICIPANTS AND SUMMARIZED IN THIS REPORT.



The final of three virtual town halls in 2025, hosted by the Food and Drug Administration (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 about 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] Throughout 2025, PDG and FDA hosted three virtual, public town halls, each scheduled two months prior to the expiration of the DSCSA phased exemption periods for eligible trading partners. Each town hall was preceded by a meeting with FDA and PDG membership. The first town hall took place in March 2025 and the second in June 2025. Summaries and other materials are available here.

The most recent large dispenser town hall provided stakeholders with an opportunity to share information to support all trading partners in achieving **enhanced product tracing and verification**

[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 employees 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.

collaboratively. **More than 1,900 individuals registered for the event**, representing the broad diversity of the supply chain and related entities.

During the town hall, participants repeatedly emphasized the **value of the FDA-implemented phased exemption periods**, including progress made throughout the supply chain since the expiration of the exemption period for wholesale distributors on August 27, 2025. Dispensers reported **significant and rapid increases in the volume of data being received** from upstream trading partners, which is a naturally anticipated result of the phased exemption periods. With the increase in data, dispensers and their trading partners are **actively working to improve their exceptions handling knowledge and capabilities**, as well as working across the supply chain to address other challenges as they arise. Although tremendous progress has been made, large dispensers emphasized that **continued progress is needed** over the remaining exemption period to avoid disruptions to public health and highlighted the **critical importance of continued collaboration** among trading partners to maintain and accelerate that progress.

Meeting participants continue to emphasize the value of the phased exemption periods, which have allowed time for dispensers with more than 25 full-time licensed pharmacists and pharmacy technicians to enhance their interoperable systems and processes.

As has been evidenced through all three FDA-PDG town halls, FDA's phased exemption periods for DSCSA implementation have been an **effective and valuable strategy for supporting trading partners, including large dispensers, in meeting interoperability and traceability requirements.** The phased exemptions have provided time for large dispensers to **establish data connections** with upstream trading partners and solution providers, **strengthen their compliance infrastructure**, and begin to **address challenges** in preparation for full implementation.

Several participants reported that the **percentage of errors is steadily decreasing** as trading partners, and particularly large dispensers, are establishing their connections and moving into full DSCSA implementation. Many large dispensers reported that they have established **robust internal systems and processes, dedicated teams, and thorough training and compliance plans** in order to meet DSCSA requirements.

While recognizing that much progress has been made in DSCSA interoperability, meeting participants underscored the need for continued collaboration across all stakeholders to resolve persistent transaction errors and data discrepancies. **It is only through continued and proactive communication that stakeholders can effectuate the goals of the DSCSA – primarily, to protect the country's public health through enhanced pharmaceutical supply chain security.** It was recommended that additional feedback could help to accelerate alignment across the supply chain by facilitating error identification, ensuring open communication, and helping to efficiently address errors.

Dispensers reported significant and rapid increases in the volume of data they are receiving from upstream trading partners, which reflects the nature of the phased exemption approach and the importance of supply chain collaboration that persists beyond the exemption periods.

Dispensers of all sizes reported **a notable increase in the volume of serialized transaction data** they are receiving from upstream trading partners, reflecting the progress made under the phased exemption

periods. PDG's recent survey results confirmed this increase in data transmission, with highlights noted below. A full survey report is available here.

- PDG received responses from 30 pharmacies in June 2025, with an increase to 73 responses in September 2025.
- In June 2025, only 39 percent of pharmacies reported routinely receiving complete serialized data from at least 80 percent of their *suppliers* when purchasing product.
    - Three months later, 70 percent of pharmacies reported receiving complete serialized data from at least 80 percent of their *suppliers* when purchasing product, with 41 percent of these respondents receiving complete serialized data from at least 95 percent of their suppliers.
- Similarly, in June 2025, only 35 percent of pharmacies reported routinely receiving complete serialized data for at least 80 percent of *product* purchased.
    - Three months later, 72 percent of pharmacies reported receiving complete serialized data for at least 80 percent of *product* purchased, with 33 percent of these respondents receiving complete serialized data for at least 95 percent of product purchased.

While this increase in data exchange illustrates the progress towards developing and implementing DSCSA systems and processes, it also underscores the amount of work that remains and the significant complexity associated with managing and reconciling high volumes of product data across multiple systems and stakeholders. Participants recognized that reaching full sophistication of DSCSA data exchange is a substantial challenge, requiring technical alignment and consistent communication among trading partners.

Participants also noted the **efficient progress that has been made in DSCSA implementation in the past year**. As recently as last year, conversations among stakeholders were primarily focused on the logistics of establishing data connections and getting systems online. Now, the dialogue has evolved toward problem-solving and enhancing communication between trading partners. Additionally, stakeholders conveyed the DSCSA framework is an opportunity to improve supply chain visibility and coordination more broadly. This shift reflects meaningful progress across all stakeholders and brings the industry closer to full enhanced pharmaceutical supply chain security.

Dispensers are working with upstream trading partners to improve their exceptions handling knowledge and capabilities and to efficiently resolve issues as they arise.

Meeting participants shared that exceptions handling remains an ongoing challenge as trading partners move toward full DSCSA implementation. **As the volume of exchanged data increases, the incidence of exceptions naturally increases; this is an indicator that DSCSA implementation is progressing**. Town hall stakeholders also emphasized that exceptions handling is not a single compliance task, but rather a capability that must be strengthened over time through continuous learning, training, collaboration, and investments in system readiness.

Participants highlighted specific operational challenges they face when working to resolve exceptions. For example, **distributors encouraged dispensers to provide additional detail to distributors when reporting data discrepancies**, such as the specific package serial numbers received without the

corresponding DSCSA data. While this serial number information is more difficult and time consuming for the dispenser to collect and provide, it dramatically improves the speed of resolving the discrepancy. Additionally, manufacturers reported that, while the large majority of exceptions are resolved quickly and efficiently, there is a **small subset (i.e., less than one percent) that can take more than 24 hours to correct.** This is often due to delays in verification, reliance on email communication, and/or time zone differences. **These logistical challenges reinforce the need for collaboration and clear communication when handling exceptions.**

Finally, **meeting participants agreed that collective knowledge and "muscle memory" of exceptions handling are integral in developing a resilient pharmaceutical supply chain under DSCSA.** Effectively managing exceptions often requires dedicated teams and significant time commitment, particularly as transaction volumes increase. Large dispensers confirmed that they are continuing to work with upstream trading partners and solution providers to ensure the effective and timely management of exceptions. Some dispensers encouraged FDA to remain open to company-specific exemptions or similar flexibility when needed, acknowledging the continued finetuning of DSCSA systems and processes in the months to come.

Stakeholders identified remaining risks, and dispensers stressed the importance of continuous improvement among suppliers to improve the quality of the data provided in advance of the November 27, 2025, deadline.

As DSCSA implementation moves closer to full compliance, town hall attendees identified several remaining risks that could impact the security of the pharmaceutical supply chain. These risks are not necessarily signs of unpreparedness. Rather, they reflect the **significant complexity of implementing final system connections and operational coordination** both internally and among trading partners.

Connectivity with Upstream Trading Partners: While distributors have provided dispensers with access to online portals to obtain serialized data and documentation, the increasing number of portals across multiple trading partners can create operational confusion and inefficiencies for dispensers. Distributors reported that they are still establishing their Electronic Product Code Information Services (EPCIS) connections with some dispensers, meaning some dispensers are currently unable to consistently receive or reconcile all required data without relying on a portal. Despite needed improvements, connections have significantly increased since the end of 2024, with one solution provider reporting a 192 percent increase in the number of system connections. Dispensers emphasized that they need to receive close to 100 percent of EPCIS data from their trading partners to ensure continued product access, and that threshold has not yet been reached. As EPCIS connections continue to stabilize, trading partners should review FDA's September 2023 guidance, *DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs*, which acknowledges that a variety of technological approaches, including web portals, that utilize EPCIS and enable secure access to and exchange of serialized product tracing data may support compliance with the enhanced drug distribution security requirements.

Data Availability and Quality: As described in prior sections, data exchange has improved significantly in recent months; however, remaining gaps are substantial enough to potentially disrupt patient access if progress does not continue. The key challenges in data availability and quality are detailed below:

- **Technical Inconsistencies in Data Standards:** Downstream trading partners, including wholesale distributors and dispensers, reported challenges with EPCIS data, such as misrouted files, discrepancies between physical product and data, or deviations from the GS1 implementation guidelines. Some dispensers reported delays affecting up to tens of thousands of prescriptions due to missing or incomplete EPCIS data.
- **Barcode Encoding and Readability:** Participants noted the continued challenge of barcoding errors. This includes the incorrect encoding of barcodes or incorrect application of barcoding standards, logistical issues that make barcodes unreadable, and errors in the configuration of scanners that prevent proper readability. These challenges create logistical breakdowns that frequently prevent the continued distribution of the product.
- **Variability in EPCIS Data Elements:** Dispensers raised concerns about inconsistent adherence to GS1 standards and variability in the specific data elements included within EPCIS files. Differences in how various service providers and solution vendors interpret the GS1 standards have led to reports of fragmented data and reduced interoperability.
- **Complexity Involved in Managing Data:** Large dispensers emphasized the complexity that they face as they manage multiple suppliers, variable system integrations, and an increasing number of data discrepancies that require dedicated staff to resolve. These discrepancies can be time-consuming to resolve, and they risk diverting resources from patient care. Town hall participants recognized the need for better automation and consistent supplier performance.

Risk of Product Quarantine Beginning November 27, 2025: As the 2025 DSCSA exemptions expire and full compliance becomes mandatory for manufacturers, wholesaler distributors, and large dispensers, stakeholders emphasized their growing concern that continued data quality issues – and even minor data issues – could result in increased instances of product quarantine due to dispensers being unable to verify product legitimacy. Delays in verification can lead to delays in dispensing, reduced inventory, and in some cases, patients being turned away at the pharmacy counter. Several attendees urged FDA to consider reasonable flexibilities to ensure patient access remains consistent, especially in cases involving time-sensitive or life-sustaining medications. These challenges underscore the need for rapid, efficient responses between trading partners to efficiently and effectively resolve data errors and other discrepancies. Trading partners should also review the *Steps for Resolving Aggregation Errors and Other Discrepancies* (see Section V.D.2.) outlined in FDA's January 2024 guidance, *Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act*, which outlines the recommended steps to document and resolve exceptions to ensure continued product distribution when an exception has been identified.

Drop Shipments: Some participants expressed that drop shipments present an ongoing complexity under the DSCSA, given divergence between the flow of serialized product data and the physical movement of product. Though product is sold through a wholesale distributor, it is shipped directly from a manufacturer to a dispenser. Dispensers highlighted common data flow problems with drop shipments, including missing EPCIS files or the use of the distributor's purchase order number instead of the dispenser's purchase order number. Dispensers also noted that drop shipments typically involve higher-cost, specialty medications used in settings such as inpatient care, home infusion, and oncology. Data issues with drop shipments can cause scheduling and treatment delays for patients. This raises the

need for increased clarity and communication between trading partners when effectuating drop-ship arrangements.

340B Drug Pricing Program: Trading partners highlighted 340B transactions as another area presenting unique challenges, particularly regarding distinguishing and managing 340B inventory within DSCSA-compliant systems. Trading partners also noted that managing serialized data for 340B-designated products can be difficult, especially when 340B products flow through different distribution pathways. Further, operational nuances of 340B transactions increase the risk of data inconsistencies. Therefore, 340B transactions require strong coordination across the supply chain in order to align DSCSA requirements with 340B obligations.

While each of these potential risks *could* negatively impact product access, supply chain security, and public health, **large dispensers and their trading partners are actively working to minimize actual impacts** in advance of the November 27, 2025, expiration date and are optimistic in their ability to collaborate with trading partners in that way.

Participants encouraged FDA, industry groups, solution providers, and other trading partners to continue their efforts to educate the dispenser community in understanding DSCSA requirements and ensuring accuracy, efficiency, and compliance.

Town hall participants encouraged all stakeholders to continue working together to educate dispensers and reinforce the importance of DSCSA compliance. While dispenser associations are actively working to increase engagement and readiness, the reach of each entity can only go so far. They requested the development of simplified and up-to-date educational resources tailored specifically for community pharmacies.

Additionally, during the town hall, **wholesale distributors reaffirmed their commitment to supporting downstream partners** by expanding their customer-facing portals and offering robust training materials. However, they also noted that they cannot provide support for connectivity issues between dispensers and third-party solution providers. As trading partners enter the last phase of implementation, it is important that the dispenser community fully understands their DSCSA obligations, and trading partners are working together to ensure that knowledge base.

Overall, entities throughout the supply chain continue to collaborate to resolve remaining DSCSA implementation issues to ensure alignment across organizations.

As the pharmaceutical supply chain advances toward full DSCSA implementation, **collaboration among trading partners to resolve outstanding challenges** and ensure compliance across all sectors remains strong. While significant progress has been made in data connectivity and data exchange, **certain data quality issues and other complex scenarios still pose barriers to implementation**, highlighting the need for continued collaboration.

Ultimately, the final town hall of 2025 highlighted the **substantial progress that has been made in DSCSA implementation over the last year and the way in which the phased exemption approach has facilitated that progress.** Trading partners are continuing to work together as large dispensers face the upcoming expiration of their exemption period on November 27, 2025. The town hall also delineated

areas of improvement and remaining potential risks to the supply chain. **Trading partners remain committed to working together to address remaining challenges and achieve full DSCSA compliance.**

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.