Partnership for DSCSA Governance

# LISTENING SESSION REPORT

## PDG-FDA Stakeholder Listening Sessions: *DSCSA Stabilization Progress and Remaining Risks to Patient Access and Public Health*

**PDG's role in the listening sessions summarized in this report was purely facilitation of the exchange of information among industry stakeholders and FDA. This report summarizes the comments and recommendations *of stakeholders who participated* in those listening sessions. PDG TAKES NO POSITION ON THE COMMENTS OR RECOMMENDATIONS MADE BY THOSE STAKEHOLDERS AND SUMMARIZED IN THIS REPORT.**

During September 2024, the Partnership for DSCSA Governance (PDG) facilitated two joint stakeholder listening sessions with the Food and Drug Administration (FDA). A listening session on September 18, 2024, allowed a broad array of dispensers[1] not subject to the Exemption for Small Business Dispensers[2] to share their experiences, progress, and remaining challenges in the stabilization of their DSCSA systems and processes. A listening session on September 23, 2024, facilitated the exchange of similar information among wholesale distributors.[3] The listening sessions were designed to promote increased information sharing and support FDA's and the industry's understanding of progress that has been made throughout the current stabilization period,[4] challenges that remain, and the public health risks those challenges may present.

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[1] The dispenser listening session included representatives of the American Pharmacists Association (APhA), American Society of Consultant Pharmacists (ASCP), American Society of Health-System Pharmacists (ASHP), CVS Health, Federation of American Hospitals (FAH), National Association of Chain Drug Stores (NACDS), National Community Pharmacists Association (NCPA), Publix, and Walmart. The session was also observed by the National Association of Boards of Pharmacy (NABP). Several participants also submitted comments to FDA's Request for Information, Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements Under the Federal Food, Drug, and Cosmetic Act (Docket No. FDA-2023-N-4806).

[2] On June 12, 2024, FDA issued a letter with exemptions from the section 582(g)(1) and associated requirements of the FD&C Act to small dispensers (defined as the company that owns the dispenser has 25 or fewer full-time employees licensed as pharmacists or qualified as pharmacy technicians), and where applicable their trading partners, until November 27, 2026. On July 12, 2024, FDA re-issued the letter with clarifying edits to the June 12, 2024, issuance.

[3] The wholesale distributor listening session included representatives of the Healthcare Distribution Alliance (HDA), Cardinal Health, Cencora, McKesson, and Smith Drug. The session was also observed by dozens of representatives from additional individual wholesale distributors. HDA also submitted comments to FDA's Request for Information, Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements Under the Federal Food, Drug, and Cosmetic Act (Docket No. FDA-2023-N-4806).

[4] In August 2023, FDA published its *Compliance Policy, Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act*, which established a 1-year stabilization period. This stabilization period is intended to afford trading partners the necessary flexibility to maintain patient access to medicines while the industry undertakes necessary actions to mature and stabilize their interoperable systems and processes.

During the listening sessions, stakeholders shared the **tremendous progress** that has been made during the stabilization period and reiterated the **important role the stabilization period played** in supporting that progress. Stakeholders also provided important detail on the **critical gaps and challenges** that remain.

Both dispenser and wholesale distributor stakeholders consistently and repeatedly emphasized that they **have established their respective systems and processes** for enhanced drug distribution security under Section 582(g) and most are actively exchanging some transaction information at the serialized package level. However, stakeholders also uniformly explained that the **data being exchanged for individual transactions has not yet reached the level of consistency and reliability that is necessary to avoid widespread disruption to patient access and public health**.

Stakeholders across both listening sessions **urged FDA to utilize its authority under the DSCSA to establish an exemption that will ensure patient access and maintain public health while technologies and data quality improve**. Stakeholders consistently urged that such exemptions apply to entire sectors and that any exemption for dispensers have a longer duration than for wholesale distributors, recognizing that stabilization of technology and data across the wholesale distributor sector is a critical input to the stabilization of technology and data in the dispenser sector.

### *The stabilization period has afforded industry the valuable opportunity to make tremendous progress in implementation.*

The current stabilization period has provided the industry the ability to make tremendous progress in the implementation of systems and processes for enhanced drug distribution security, including, most importantly, the systems and processes necessary to exchange transaction information at the serialized package level. At the beginning of the stabilization period, stakeholders reported widespread instances of trading partners that had not established their respective systems and processes for data exchange, had not established the necessary data connections with their direct trading partners, and were not prepared to send/receive/capture transaction information at the serialized package level.

While outliers remain, **trading partners across the supply chain[5] have generally been successful in utilizing the stabilization period to establish their respective systems and processes for enhanced drug distribution security**, establishing the necessary data connections with their trading partners, and beginning the exchange of transaction information at the serialized package level. Trading partners have also established the **processes necessary to identify, understand, and resolve data errors and discrepancies**.

### *Data, technology, and communication are improving, but critical challenges remain.*

Trading partner systems and processes continue to mature rapidly, but the trajectory—while generally positive—is inadequate to achieve stabilization by November 27, 2024. For example, a recent HDA

[5] References to trading partner readiness in this report generally exclude those dispensers covered by the Exemption for Small Business Dispensers.

survey indicated that the percent of (inbound/purchase) transactions accompanied by accurate serialized transaction is improving month-to-month, which is promising. The survey also indicated, however, that a quarter (or thousands) of serialized packages per day, per distribution center may not have accurate serialized transaction information today.

Wholesale distributors broadly, and many dispensers, report that most suppliers are providing some transaction information at the serialized package level, but **data is often inconsistent and unreliable**. Data challenges include errors in aggregation data, inaccurate package-level data, and missing data. The processes to work through these types of data errors (*i.e.*, data exceptions) are resource intensive and highly dependent on trading partner relationships and communication. **Exception handling processes are improving but remain immature**, with errors typically taking several days to resolve. Given the DSCSA's strict requirement to not accept product ownership unless accompanied by transaction information, **these errors could disrupt and delay distribution of as much as one-quarter of the product in the supply chain** according to data presented by stakeholders.

### *Myriad waivers, exceptions, and exemptions (WEEs) would further complicate stabilization.*

Stakeholders across both the dispenser and wholesale distributor listening sessions emphasized the difficulty of managing hundreds of diverse individual WEEs, particularly with the limited time that remains before November 27, 2024. For example, a dispenser purchasing from three suppliers could encounter three (or more, if a WEE further upstream 'follows' the product downstream) overlapping WEEs that may or may not apply to an individual transaction. Even where such complexity could be managed through technology systems, system changes of that scale would take several months to implement. **Managing such a diversity of WEEs would be an added layer of complexity that could further complicate efforts to stabilize technology and data quality.**

### *Stakeholders identified significant risks to patient access and public health if the regulatory environment does not support further stabilization activity.*

Dispenser and wholesale distributor stakeholders identified multiple public health risks that should be anticipated if the regulatory environment does not support continued technology and data stabilization. Among the most significant risks highlighted were:

- Trading partners will soon (and in some instances may already) adjust their inventory management and purchasing activity in anticipation that a significant portion of product will be held or returned due to data discrepancies. Such practices would add significant **waste and costs** to the system.
- Limitations on physical capacity to quarantine product will lead to a significant increase in returns. Many suppliers destroy, rather than resell, returns, leading to significant **waste**.
- Supply disruptions would exacerbate existing **product shortages** and could create additional product shortages.
- **Patient access** to product not subject to a WEE could be seriously impeded.

- Supply and access disruption can lead to **abandonment of therapy, patient non-adherence, and disruption of care and treatment**. This would seriously impact patient **health outcomes** and add cost to the healthcare system.
- Patients and providers may be incentivized source product from **less safe and less secure alternative sources**.

### *Stakeholders identified specific actions they would take to stabilize their data and technology if afforded the requested regulatory flexibility.*

To reduce the patient access and public health risks above, stakeholders across both listening sessions urged FDA to establish an exemption that will ensure continued patient access and maintain public health while technologies and data continue to stabilize. Stakeholders affirmed their **commitment to successful implementation** of the DSCSA (including ongoing security requirements such as verification systems and authorized trading partner processes) and identified specific actions they would take to stabilize technologies and data if such an exemption were granted, including:

- **Continuous improvement** of systems and processes to achieve consistent, reliable exchange of transaction information at the serialized package level.
- Continued **refinement and improvement of exception handling processes**, including process improvements, strengthening of relationships, and ensuring timely resource capacity.
- **Increased engagement** with direct trading partners to support continuous improvement of systems and processes, including enhanced discussions of data "scorecards" provided to suppliers.
- Reduction in the volume of **transition inventory**[6] and the complexity in managing such inventory.
- **Scaling up the volume of outbound transaction information** at the serialized package level.
- **Continued education** of downstream trading partners.

### *Regulatory certainty is needed urgently.*

Stakeholders across both listening sessions emphasized the importance of rapid regulatory clarity. Trading partners are actively considering, and in some instances undertaking, compliance and commercial strategies to mitigate the patient and public health risks of the current regulatory environment. **Regulatory certainty is urgently needed to minimize the risks** associated with these impending decisions.

[6] Transition inventory refers to product purchased before November 27, 2024 and accompanied by lot-level transaction information, but sold after the date on which serialized transaction information is mandatory.

## 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.