Partnership for DSCSA Governance

MEETING REPORT

PDG-FDA Joint Public Meeting: *DSCSA Stabilization Period Midway Checkpoint*

On June 17 and 18, 2024, the Partnership for DSCSA Governance (PDG) and the Food and Drug Administration (FDA), hosted a two-day joint public meeting that served as a checkpoint midway through the DSCSA stabilization period.[1] This hybrid meeting brought together approximately 800 stakeholders from across the drug distribution ecosystem to share information towards supporting all stakeholders in efficiently executing the remaining steps needed to achieve enhanced product tracing.

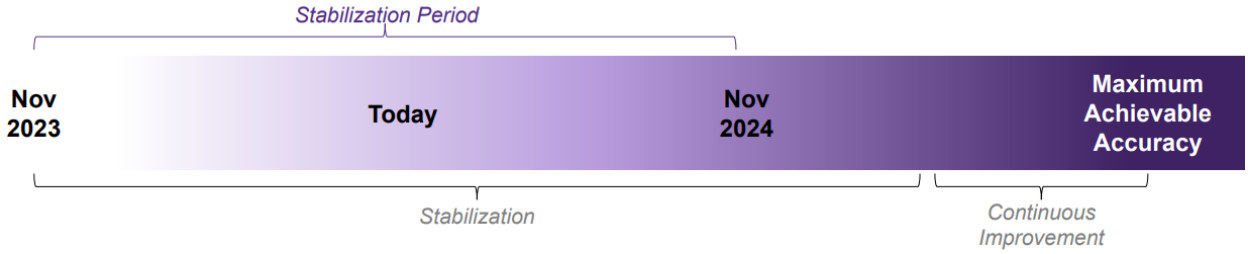
At the public meeting, stakeholders shared the **tremendous progress** that has been made during the stabilization period and shined a light on the **critical gaps and challenges** that remain. Gaps and challenges are most critical among trading partners that have been less engaged or unengaged in industry collaboration to date, and those trading partners span the supply chain. This mix of preparedness creates challenges in data management and data quality, and it is essential that trading partners **establish business processes to manage the expected data imperfections and continuously improve their systems and processes.**

The public meeting highlighted a critical distinction between the Stabilization Period and stabilization activities.

Public meeting participants validated that the stabilization period has afforded stakeholders a defined period to improve DSCSA data exchange and data quality while minimizing disruption to product distribution as systems and processes advance through the early adoption stages. The stabilization period has enabled trading partners to complete the work needed to establish necessary technical connections for serialized data exchange, increase the volume of data being exchanged, improve the quality of data exchanged, and refine processes for managing data exceptions. Those activities have supported continued implementation without interrupting product access.

Although the stabilization period has supported implementation efforts, stabilization activities—the continued maturity of systems and processes to improve the accuracy and reliability of DSCSA data—will continue well beyond November 27, 2024. Even as systems and processes achieve stabilization, continuous improvement will be ongoing as the industry pursues improved data quality to support enhanced security and improved efficiency, as represented graphically below.

[1] In August 2023, FDA published its *Compliance Policy, Enhanced Drug Distribution Security Requirements Under Section 582(q)(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.



Managing expected imperfection is a key to success.

Critical to the framework above is the reality—acknowledged repeatedly throughout the public meeting—that 100 percent accuracy of DSCSA data is not attainable, even in the long-term. Billions of unit-level transactions occur each year, and perfection is simply unrealistic at that level of granularity and volume. The public meeting emphasized two key areas for industry focus based on this reality.

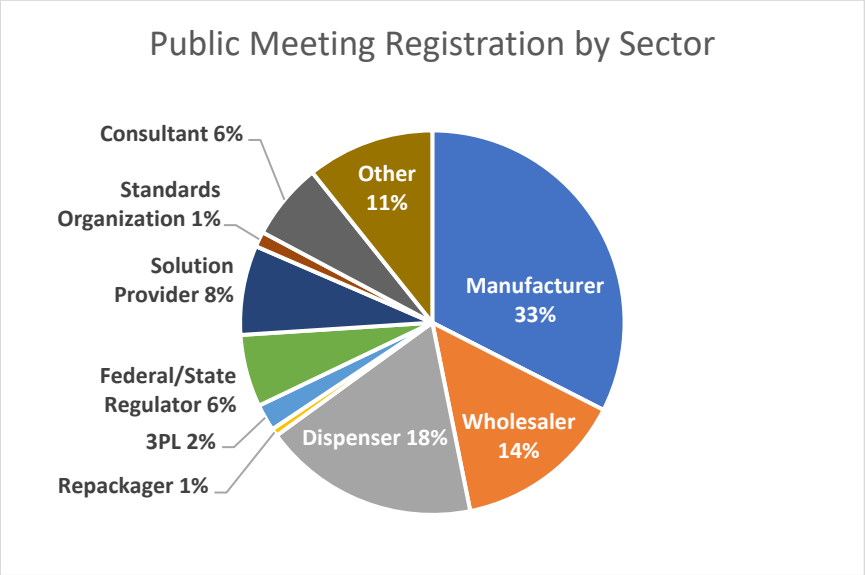
1. **Trading partners should have well-controlled, risk-based processes established for managing the expected errors (*i.e.*, exceptions) in DSCSA data.** By focusing on quality management and continuous improvement, trading partners should be **empowered to make business decisions** that **balance** patient need, patient protection, and data accuracy rather than striving for an unattainable level of data perfection.
2. **Continuous improvement efforts**—*ongoing* processes to analyze data quality, identify the root causes of errors, and make incremental changes to systems and processes to address those root causes—**are needed to attain the maximum achievable level of accuracy.** Perfection is not attainable, and continuous improvement is essential.

Work on exception handling processes grounded in the two principles above is underway throughout many parts of the supply chain, and the trading partners doing so are actively progressing toward successful implementation and compliance. Sustained work on these processes among the well-engaged, and continued education on risk-based continuous improvement processes among the less-engaged, is critical to avoid supply chain disruption and patient access.

The public meeting provided a landscape of industry readiness, but few demographics were discernable.

A broad, diverse cross-section of stakeholders attended the public meeting, as represented by the chart below. Likely enabled by the hybrid meeting format, questions and dialogue throughout the meeting indicated that the public meeting provided an opportunity for engagement by many trading partners that have not historically engaged in cross-industry forums on DSCSA implementation and are early in their implementation journey. Although the meeting did not identify significant *new* gaps, it did highlight and bring a voice to the **known gaps, most prominently among small dispensers** and other smaller companies. **Communication and collaboration** to keep these smaller organizations engaged and support their continued implementation is critical.

Regarding manufacturer transactions—predominantly transactions between manufacturers and wholesale distributors, but also between manufacturers and dispensers or repackagers—public meeting participants suggested that "a corner has been turned" in the stabilization process. **Significant work remains**, particularly regarding data misalignment exceptions, **but progress has been significant and encouraging** in recent months. Manufacturers *generally* reported that:



- **Data connections** are nearing completion, with most reporting near-100 percent rates of customer onboarding. Where connection setup remains a challenge, data can typically be provided via a portal.
- **Volume of data** flowing from manufacturers to their customers has increased significantly in recent months. Among manufacturers active in the public meeting dialogue, many reported that they are provided data for all or nearly all transactions. Wholesale distributors reported significantly lower volumes of data across *all* manufacturers, but nonetheless indicated that there has been a marked improvement.
- **Data quality and accuracy** remains a significant challenge and is a primary focus among manufacturers. While there is significant diversity in data quality, many manufacturers expressed they have seen a positive shift with less of a focus on systemic data quality issues and more one-off data quality issues. Manufacturers emphasized that continued and expanded feedback on data quality from wholesale distributors and dispensers is critical to continued progress.

Far greater challenge and concern exists regarding downstream transactions between wholesale distributors and dispensers. Though progress has been made, wholesaler distributors have been hamstrung by the practical necessity to receive higher volumes of data for product they purchase to ramp up the volume of data they provide for downstream transactions. Public meeting participants *generally* indicated:

- **Data connections** have increased significantly, and many participants indicate they are on track to complete remaining data connections soon. Where connection setup is not complete (or not desired), data can typically be provided via a portal.
- **Volume of data** flowing from wholesaler distributors to their customers is beginning to increase, but as noted above, remains at least partially dependent on improved data from upstream suppliers.

- **Data quality and accuracy** remains a challenge, and trading partners are just beginning to understand the quality of the data being provided for these downstream transactions.

Very few demographic trends were discernable beyond the sector-based trends in readiness noted above. Comments in the meeting clearly indicated that the public meeting was successful in engaging with stakeholders that do not routinely engage in cross-industry DSCSA forums, and *generally*, those comments reflected that newcomers to the conversation were early in their individual implementation. This dichotomy between engaged and well-prepared versus latecomers was generally consistent across all sectors, though the sheer volume of dispensers in the supply chain places increased focus on the number latecomers in the dispenser sector. Stakeholders across the supply chain made repeated calls for continued and increased collaboration, communication, and education to continue to reach latecomers, particularly among dispensers. Focused efforts to engage latecomers and support their establishment of well-controlled, risk-based processes will be critical.

Many stakeholders expressed support of FDA's decision to establish the Exemption for Small Business Dispensers[2] and validated that the exemption is necessary to limit supply chain disruption. A notable number of stakeholders did, however, argue that the exemption did not go far enough and should have applied to a broader swath of dispensers.

In conjunction with the Exemption for Small Business Dispensers, FDA encouraged entities that do not expect to be in full compliance by the November 27, 2024, deadline but do not qualify for the small dispenser enforcement discretion to request a waiver, exception, or exemption (WEE). The complexity of managing those anticipated WEEs was a common theme across all trading partners and transaction types. While it was recognized that the WEE pathway is one FDA can provide to limit supply disruption while stabilization continues, trading partners expressed **significant concerns about the complexity of managing widespread and diverse WEEs**. This new complexity is an added layer of risk that trading partners will need to manage—and dedicate attention to—as stabilization continues.

Ultimately, the public meeting highlighted the diversity of preparedness across the supply chain, ranging from trading partners that have prioritized and led DSCSA implementation for years to trading partners just beginning their implementation. Throughout the public meeting, this diversity highlighted the **critical difference between preparedness and interoperability**. Every company can control their preparedness, and many public meeting participants expressed great confidence in the preparedness of their systems and process. No individual company, however, can control interoperability; interoperability is a collective capability across the supply chain. Many Public Meeting participants emphasized the **difficult position** in which they are left when they have been diligent in preparation of their systems and processes but face risk in interoperability due to the diversity of preparedness across the entire supply chain. **Collaboration and communication are essential** to overcoming those risks and achieving interoperability.

[2] The exemption grants small dispensers—defined as owners that have 25 or fewer full-time employees licensed as pharmacists or qualified pharmacy technicians—two years of enforcement discretion to comply with the electronic transaction and tracing requirements of the DSCSA. FDA notes the stabilization period will end for all other trading partners on November 27, 2024, as scheduled.

The public meeting developed cross-stakeholder understanding of what it means for interoperable systems and processes to be stabilized.

Measuring continued progress toward stabilization, and onto continuous improvement, is dependent on a clear understanding of what stabilization means in practice. While stabilization will inevitably look different across different stakeholder groups, several themes emerged throughout the public meeting. Successful stabilization may be characterized by:

- Consistent and timely **exchange of data for all transactions**.
- Broad trading partner **confidence in DSCSA data**.
- The ability to **quickly and efficiently resolve the data errors** that persist.
- **Consistent and reliable access** to DSCSA data and the **ability to use** it to respond effectively and efficiently to suspect and illegitimate products.
- Broad **understanding and adoption of risk-based standard operating procedures** (SOPs) for resolution of data misalignment exceptions.
- **Consistent application of standards** across systems.
- Seamless **integration of systems between *and within* trading partners** in a manner that limits latency.
- **Minimized risk of quarantine, return, or destruction** of legitimate product due to DSCSA compliance activities.
- **Ease of communication and collaboration** built on strong relationships among trading partners.

Collaboration and communication are essential to stabilization.

The importance of collaboration and communication was emphasized throughout the public meeting, including both direct collaboration between commercial trading partners and through broader industry forums. Collaboration and communication are particularly important as late-comers begin, and seek to expedite, their implementation. Reaching the remaining corners of industry will require creative strategies that communicate DSCSA implementation expectations in ways that are **actionable and simplified**. Success in that regard will require that DSCSA implementation be communicated as a **business priority**, not strictly a compliance requirement. This work has begun through resources such as the pharmacy-oriented resource site https://dscsa.pharmacy and PDG's *Blueprint* resources, but continued efforts to build broader awareness of these resources are needed, and room for improvement remains in simplifying these resources.

PDG and FDA will continue to leverage their public-private partnership to carry these messages forward and support continued collaboration. Through the partnership we will continue to build reciprocal understanding of key issues and challenges between public and private stakeholders, and PDG will continue to support stabilization through tools and education, striving to make stabilization actionable for **all** trading partners.

Stakeholders are also encouraged to continue to provide feedback on stabilization to FDA through 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).

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, re-packagers, 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.