Your DSCSA Questions, Answered: Exploring 3 Pressing Topics Ahead of the Nov. 27 Deadline



In less than 75 days, the DSCSA stabilization period will end. At that point, all members of the life sciences and healthcare supply chain serving the U.S. market are expected to be compliant with the serialized traceability requirements established by the DSCSA. This article looks at three critical questions that have emerged as the industry begins its final preparations for the Nov. 27 deadline:

- What is the current state of industry readiness for EPCIS data exchange?
- Will Waivers, Exceptions, and Exemptions (WEE) help my company?
- What is the optimal way to manage DSCSA compliance exceptions?

How ready is the industry for EPCIS data exchange?

While progress is being made toward DSCSA compliance, there is still a lot of work to do ahead of the looming Nov. 27 deadline. A **recent survey conducted by the PDG** sheds light on the industry's sentiment and discrepancies between the three major segments of the life sciences and healthcare supply chain: manufacturers, wholesale distributors, and pharmacies.

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Survey respondents are confident in their own DSCSA preparations. Manufacturers, wholesale distributors, and dispensers rate themselves 4.15, 3.42, and 3.29 out of 5 respectively in terms of their confidence that their DSCSA systems and processes will be stabilized come Nov. 27.

Despite many respondents feeling confident in their readiness, the PDG survey also unveiled that few were actually sending and receiving serialized data for most of their product. Only 1 in 10 wholesale distributors said they were receiving a complete set of serialized data for 80+% of the product they purchased. Dispensers fared a bit better, with 3 in 10 receiving complete serialized data for 80% of purchased product.

Why is the industry confident in its readiness when many aren’t receiving serialized data for a large portion of their products? The problem lies with the definition of readiness. Readiness was defined as linking with a partner and sending a test file, when in reality, readiness should refer to exchanging DSCSA EPCIS transactions at scale across all use cases.

As the volume of transactions increases and wholesalers and dispensers start to ingest those transactions into actual workflows and processes, they will uncover new issues. Are these issues insurmountable? No. But working through them takes time and participation from multiple companies, solution providers, and their partners. What is currently occurring is what was expected to happen during the stabilization period.

TraceLink's DSCSA compliance solution has been proven to handle the DSCSA data exchange requirements at scale. To date, TraceLink customers have exchanged over **4.4 million DSCSA EPCIS transactions across our network** in a live production environment. These transactions have occurred between manufacturers, distributors, health systems, retail pharmacies, and independent pharmacies. That number is growing by the day and we continue to work diligently with our customers to achieve compliance.

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Will Waivers, Exceptions, and Exemptions (WEE) help?

With so much to do and little time before the end of the stabilization period, the FDA has defined a Waiver, Exception, and Exemption (WEE) application process. Through this process, a company can apply for a waiver, exception, or exemption from the DSCSA. This is an important process as shipping or receiving product without the required DSCSA compliance information puts a company in breach of the federal law. While the FDA recommended these waiver requests be submitted by August 1, the agency will still accept requests sent at any time.

If you are delaying your DSCSA go-live in hopes of getting a waiver, you should consider that submitting an application does not give you a free pass. The FDA requires detailed information about the request and is not obligated to approve your request. Completing a waiver request requires organizations to produce a detailed statement justifying the request, supporting documentation that goes over the organization's DSCSA plan, and special circumstances regarding their product. Creating a request may also require close coordination with your authorized trading partners and your DSCSA solution provider. Another thing to consider is the potential impact on your trading partners, who may need to adjust their strategy with short notice depending on the outcome of your request.

TraceLink is working closely with our customers and their partners to support the WEE process, ensuring customers can exchange Waiver, Exception, and Exemption status via the EDI 832 Price Catalog transaction and manage the process on the receiving side. There is still much to figure out, but as your DSCSA partner, TraceLink continues to lead and participate in these discussions to ensure you have the guidance you need.

What is the optimal way to manage DSCSA exceptions?

DSCSA compliance exceptions have the **potential to delay product delivery and receiving**. Every exception must be resolved before the trading partner can send the product downstream or sell it to patients, and every delay impacts both

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the company's profits and the availability of the affected medications to patients.

Once the life sciences and healthcare supply chain begins exchanging serialized product data (and assessing the quality and accuracy of this data) in earnest, the number of compliance exceptions will likely surge. If EU FMD is indicative, there will be an especially high level of discrepancies shortly after the conclusion of the stabilization period—in the months after the launch of the EU FMD, there was an alert rate of nearly 7%.

The higher rate of exceptions will be magnified by the fact that handling compliance exceptions is a time-consuming process with no defined system in place for DSCSA. There will be technical issues as the industry adjusts to exchanging serialized product data, and this will be further exacerbated by routine process complications around exception investigation, root cause analysis, and coordination with trading partners.

Some DSCSA solutions try to simplify compliance exception management, but these solutions are hardly a panacea. Many solutions on the market today are limited in scope and don't cover the full compliance exception resolution process—for example, they may only support the resolution of incorrectly formatted EPCIS files and are limited to email alerting.

TraceLink Process Orchestration for Empowered Teams (POET) digitalizes and automates the time-consuming exception resolution process, all in a single centralized platform. With a shared and collaborative workspace dedicated to managing exceptions and digital workflows that automate and accelerate the exception resolution process, life sciences and healthcare companies can resolve exceptions in a fraction of the time while maintaining a documented audit trail to demonstrate process adherence.

If you'd like to learn more about effectively managing DSCSA compliance exceptions, contact your TraceLink Account Executive or email us at **DSCSA [at]**

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tracelink.com. You can also reach out with any questions about the WEE process or concerns about your DSCSA readiness.

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Fill out the form to schedule your meeting.

Thank you for contacting us; we'll be in touch shortly.

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