FDA Grants Exemption from Some DSCSA Requirements: Evaluating Your Next Steps

Responding to mounting concerns around supply chain disruption stemming from Drug Supply Chain Security Act (DSCSA) implementation challenges, the FDA has issued new exemptions that give eligible trade partners additional time to finalize their DSCSA systems and processes.

The announcement of these exemptions could have a significant impact on the industry's DSCSA preparations. This article explores what prompted the FDA to issue these exemptions, what the exemptions entail, and how you can take advantage of the additional time to ensure your readiness.

Diagnosing the difficulty of DSCSA data exchange

While many in the life sciences and healthcare supply chain have made tremendous progress toward DSCSA compliance, some aspects of the law continue to pose a challenge. The digital exchange of EPCIS data is one of these aspects, with some stakeholders in the supply chain struggling to align their processes and systems to achieve full implementation.

That's why, with the end of the stabilization period for the DSCSA quickly approaching on Nov. 27, 2024, many involved in the supply chain have grown increasingly concerned about the state of the industry's readiness. Given the

interconnectedness of the pharmaceutical supply chain, even just a few compliance gaps can quickly cascade into widespread supply chain disruption that may jeopardize the availability of medications to patients.

In response to these concerns, the FDA has issued a new set of exemptions to the Enhanced Drug Distribution Security (EDDS) requirements of the DSCSA that provide eligible trade partners with additional time to finalize their DSCSA systems and processes. These exemptions are intended to prevent disruption to the pharmaceutical supply chain that could delay crucial medicines from reaching patients, and should not be viewed as justification to delay compliance efforts.

Extent of exemptions, eligibility, and new timelines

The newly issued exemptions specifically cover the enforcement of the EDDS requirements of DSCSA. The EDDS requirements mandate the electronic exchange of EPCIS data as well as the use and exchange of serialization data. Additionally, the EDDS requirements mandate the use of product identifiers as part of suspect product investigations.

The FDA granted the exemption to all eligible trade partners, including manufacturers, repackagers, wholesalers, and dispensers. Eligible trade partners are defined as those who have established or attempted to establish connections with all immediate trade partners, which reinforces the notion that the exemptions are not a justification to further delay compliance projects. Eligible trade partners must provide documented evidence of attempting to establish connectivity with all immediate trade partners.

The new exemptions also introduce a staggered enforcement timeline, which has been a persistent demand from the industry. A phased approach ensures downstream stakeholders will have additional time to stabilize their DSCSA processes and systems after their upstream trading partners have finalized theirs. The new enforcement dates are:

- **Manufacturers and repackagers:** May 27, 2025
- **Wholesale distributors:** Aug. 27, 2025
- **Dispensers with 26+ full-time employees licensed as pharmacists:** Nov. 27, 2025
- **Small dispensers with fewer than 26 full-time employees licensed as pharmacists:** Nov. 27, 2026

It's important to recognize that these exemptions do not mean DSCSA has been delayed. The final set of DSCSA requirements went into effect on Nov. 27, 2023, with the FDA defining a 12-month stabilization period until Nov. 27, 2024. This announcement provides an exemption to eligible trade partners meeting a defined criteria.

Assessing your next steps to ensure DSCSA readiness

While the new exemptions offer the industry additional time, the industry should not mistake the new timelines as a justification to ease up on their DSCSA implementation projects.

Many companies involved in the pharmaceutical supply chain still aren't receiving full sets of serialized product data in their shipments, and their processes and systems also have not been stress-tested for exchanging EPCIS transactions at scale. The processes and solutions for communicating, troubleshooting, and resolving DSCSA compliance exceptions also need to be established—managing DSCSA compliance exceptions is just as important as the data exchange itself.

Moreover, the introduction of the new phased timelines may add an extra level of complexity to implementation efforts. Suppose a trade partner is receiving shipments, such as a wholesaler or dispenser. How do they determine if data was not provided due to the supplier not being ready, or if the supplier is ready but has not "turned on" data exchange, or if there was an error causing a data exchange failure? Navigating each of these scenarios across the industry will be challenging.

However, one item is clear: The industry must use this additional time to continue to work in earnest to ensure that the requirements of the DSCSA can be met and operationalized. The potential of supply chain disruptions and patient impact is too significant.

Ensure your DSCSA readiness with TraceLink

The additional time also offers the life sciences and healthcare supply chain the opportunity to reassess how their current DSCSA compliance solution provider is meeting their requirements. If you've experienced implementation delays, unresponsive customer service, data errors, or solution downtime, you now have an additional six months (or more) to reconsider who you are trusting to ensure your compliance.

No matter the status of your current DSCSA project, TraceLink has solutions that can help with everything from EPCIS data exchange to product verification and exception management. TraceLink's DSCSA compliance solution has been proven to handle the DSCSA data exchange requirements at scale. In the past 90 days, TraceLink customers have exchanged over six million DSCSA EPCIS transactions across our network in a live production environment, underscoring the progress being made by our customers. Customers can also capitalize on our other solutions to drive more value from their business investment, streamlining and automating everything from compliance exception management to recall processes.

If you're not a TraceLink customer already, there is still time to make the switch—especially with the new timelines. Our unique Business-to-Network Integrate-Once™ approach eliminates the need for configuring dozens (or even hundreds) of individual trade partner integrations, linking you to any of the 291,000+ organizations on our network through a single integration to our platform. This dramatically reduces the time, cost, and risk of achieving DSCSA compliance.

Companies thinking about making the switch can fill out the form or email us at

DSCSA [at] tracelink.com (DSCSA[at]tracelink[dot]com) for a complimentary DSCSA assessment. Our experts will identify any gaps and help you lay out a path to DSCSA compliance by the end of the exemption period.

Got questions? Join our live Q&A to ask our DSCSA experts

If you still have questions about the recently announced exemptions, we invite you to join us on Wednesday, Oct. 18 at 11 a.m. ET for a live Q&A. Our DSCSA experts Dan Walles and Shrijan Rajkarnikar will answer your questions live.

Register Today

BlogUS Drug Supply Chain Security ActGlobal Track & TraceRegulatory/ComplianceUnited States
Contact TraceLink for a free DSCSA readiness assessment!
Fill out the form to schedule your meeting.

Related Content

TraceLink Propels Organizations Toward DSCSA Compliance Ahead of the November 2024 Deadline

With the Drug Supply Chain Security Act (DSCSA) stabilization period ending on November 27, 2024, the TraceLink customer and trading partner community of healthcare and life sciences companies continues to demonstrate market leadership in demonstrating compliance readiness.

View More

DSCSA 2023: How to Handle the Influx of DSCSA Compliance Exceptions

With less than seven months to go, organizations across the end-to-end pharmaceutical supply chain—including manufacturers, wholesale distributors, third-party logistics providers, and dispensers—need to act with urgency and prepare now.

View More

U.S. Drug Supply Chain Security Act (DSCSA)

TraceLink DSCSA Compliance solutions provide life sciences and healthcare companies with a complete set of capabilities for achieving and maintaining compliance with U.S Drug Supply Chain Security Act (DSCSA) regulations going into effect in November 2023.

View More