

DSCSA Enforcement Guidance Update

Advasur analysis of the Enhanced Drug Distribution Security Requirements of the Federal Food, Drug, and Cosmetic Act-- Compliance Policies.

ROCKVILLE, MD, UNITED STATES,
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-- On Friday August 25, 2023, the FDA announced that they will delay full enforcement of the EDDS requirements of the DSCSA until 11/27/2024.

The Advasur logo, consisting of the word "ADVASUR" in blue, followed by a green checkmark inside a circle. Below the logo is the tagline "Be Sure With Advasur!" in a blue serif font.

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The act in and of itself has not been delayed; the FDA is allowing suppliers additional time to complete the conversion from current state transmission of ASN via EDI 856 to EPCIS file formats in what they term a "Stabilization Period".

"There's significant confusion in the dispenser market surrounding the guidance provided by FDA on 8/25/2023, because of third-party organizations sharing their perspective on elements of the release. Advasur recommends that all dispensers review the guidance document itself to determine the requirements that they must sustain and initiate to comply with DSCSA today, upon November 27, 2023, and beyond." said Ted Sullivan, Advasur Chief Commercialization Officer.

The impact of this announcement to your pharmacy practice:

- The first five requirements of the DSCSA are still in place, being enforced, and the subject of inspection and audit by State Boards, FDA, DEA, OIG, and PBMs.
- Only the enforcement of requirements associated with the support of the interoperable database model (EDDS) is affected by the 12 month "Stabilization Period" to run through November 27, 2024.
- The opportunity to implement a solution today to build an accessible data repository in advance of EDDS requirement enforcement will advantage dispensers in future audits with multiyear lookback provisions.

Quoting from the [FDA Guidance](#) document:

"FDA generally expects trading partners to have the systems and processes in place to meet

these [EDDS] requirements as of November 27, 2023, we [FDA} recognize that some technical and operational issues, including issues involving trading partners and other affected stakeholders, may not be fully resolved by that time.”

“This Guidance is not intended to provide, and should not be viewed as providing, a justification for delaying efforts by trading partners to implement the enhanced drug distribution security requirements under section 582(g)(1) [EDDS] of the FD&C Act. FDA strongly urges trading partners to continue their efforts to implement necessary measures to satisfy these enhanced drug distribution security requirements.”

Pertinent comments from the HDA Traceability Seminar 2023:

Wednesday, August 30, 2023: Dr. Leigh Verbois and Dr. Connie Jung, from the FDA CDER Office of Drug Security, Integrity, and Response presented the “Implementing DSCSA and Expectations for 2023 and Beyond” presentation.

Key takeaways from their presentation were:

1. The FDA wants Dispensers and their trading partners to understand they “should not take their foot off the pedal” to continue to remain compliant for the current requirements and work to be compliant on the EDDS requirements.
2. The FDA assumes that most dispensers have already onboarded their Suppliers for electronic advance shipping notices and if not, they need to catch up!
3. The FDA announced this extra twelve-month period has been entitled the “Stabilization Period”. The stabilization period should allow the trading partners, including dispensers, to address EPCIS transmission and data issues and to ensure exception handling procedures are established and synchronized between dispensers and their wholesaler and direct selling manufacturer suppliers.

“Now more than ever, Advasur stands ready to serve dispenser pharmacies in compliance with DSCSA as we have since our founding in 2015.” said Randy Hoggle BPharm, DrPH, Advasur Managing Director.

Referenced Industry Terms:

EDDS - Enhanced Drug Distribution Security – an interoperable system facilitating the electronic tracing of products at the package level.

DSCSA – the Drug Supply Chain Security Act

ASN – the Advanced Shipping Notice is a standard data set that is transmitted to the acquiring

dispensing pharmacy by the supplier at the time of shipment and prior to physical delivery of product.

EDI 856 – is a standard ansix.12 file format utilized for the transmission of specific electronic data that facilitates adherence to the first five dispenser requirements of the DSCSA on dispensing pharmacies.

EPCIS - Electronic Product Code Identification System is an open standard which allows businesses to capture and share supply chain information about the movement and status of goods, within their enterprise and with their business partners.

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