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As Supply Chain Partners Ramp Up For November DSCSA Deadline, US FDA Gives Them Another Year

by Bowman Cox

Potential distribution hitches could spark shortages of legitimate drugs if the system is not fully ready for package-level tracing requirements, US FDA says in delaying enforcement of the program a decade in the making. Poll shows supply chain partners were making significant progress in preparing for the 27 November deadline.

The US Food and Drug Administration has given pharmaceutical distribution trading partners an extra year to comply with package-level Drug Supply Chain Security Act product tracing requirements that take effect 27 November before it starts enforcing them.

The DSCSA was enacted a decade ago to enhance the FDA's ability to protect consumers from drugs that might be counterfeit, stolen, contaminated or otherwise harmful. It set a series of deadlines for lot-level and ultimately this November for package-level tracing of drug products. The latest announcement of FDA enforcement discretion to ease DSCSA compliance was not the first. There was one in December 2014 (Also see "*Track-And-Trace Enforcement Delay Is FDA's Christmas Gift To Industry*" - Pink Sheet, 31 Dec, 2014.), and another in June 2017. (Also see "*FDA Gives Drug Makers One-Year Reprieve From DSCSA Product Identifier Requirement*" - Pink Sheet, 30 Jun, 2017.)

The latest enforcement discretion became effective immediately under final agency guidance issued 25 August for five of the six pending package-level drug distribution security requirements DSCSA added to the Food, Drug & Cosmetic Act at Section 582(g)(1) (*21 USC 360eee-1*).

The five provisions the FDA will not enforce until 27 November 2024 are requirements for trading partners – manufacturers, wholesale distributors, dispensers and repackagers – to

establish systems and processes for:

- Exchanging package-level transaction information and transaction statements;
- Verifying products at the package level using a standardized numerical identifier;
- Promptly providing transaction information and statements when requested by government officials in connection with recalls or investigations of suspect or illegitimate product;
- Promptly facilitating the gathering of historical transaction information all the way back to the manufacturer when requested by government officials or, in ways that protect confidential commercial information and trade secrets, when requested by authorized trading partners; and
- Only accepting saleable returns of products that can be associated with their transaction information and transaction statements.

The guidance says the FDA believes the enforcement discretion on salable returns will enable wholesale distributors to keep associating saleable returns with transaction information and transaction statements as required under a DSCSA provision that took effect 27 November 2019 and sunsets 27 November 2023 while their partners in the distribution chain catch up with their saleable returns processes.

The FDA did not specifically grant enforcement discretion for a sixth requirement, to include package-level product identifiers with every transaction. But this will only become relevant when the agency begins enforcing the requirements to exchange transaction information and verify products at the package level.

Extra Time Given To Avoid Shortage-Inducing Disruptions

The guidance says the FDA believes the delay will give trading partners and other supply chain stakeholders the time they need to develop and refine their systems for package-level tracing. With the agency's endorsement, stakeholders have agreed to implement these systems by using the EPCIS (Electronic Product Code Information Services) standard developed by GS1. (Also see "*US FDA Backs EPCIS, Refines Advice As November 2023 DSCSA Deadline Approaches*" - Pink Sheet, 5 Jul, 2022.)

The guidance alludes to a possibility patient access to legitimate drugs might be impaired if enforcement begins before the interoperable system is fully in place.

As the FDA explained in a *notice* scheduled for publication in the 28 August Federal Register, the

guidance "is intended to provide clarity and flexibility to trading partners to help ensure continued patient access to prescription drugs as the supply chain transitions to the interoperable, electronic product tracing at the package level under the DSCSA."

The FDA noted that the section 582 requirements for trading partners also affect other stakeholders such as solution providers, standards organizations, trade groups and state and federal authorities.

The agency acknowledged concerns raised by stakeholders about the readiness of trading partners to keep up the flow of product distribution once the section 582(g)(1) requirements take effect, given that some trading partners remain behind the curve in understanding what their obligations will be and how they will meet them.

The FDA also recognized apprehension among stakeholders regarding the status of products that will be in distribution when the requirements take effect.

The notice emphasized the importance of giving more time "for systems to stabilize and be fully operational for accurate, secure and timely electronic data exchange."

Cautions Raised Against 'Blanket' Enforcement Discretion

The Healthcare Distribution Alliance applauded the FDA's announcement of enforcement discretion, saying it "puts the health and safety of Americans first," although the guidance did not address its June proposal to phase in compliance over two years.

In calling for a phased approach, the alliance, which represents pharmaceutical distributors, had said, "a slow build, not a single 'on switch'" would work better.

Plus, the group said, "simply extending the compliance date without a rational phase-in just moves the date on which the problems and issues become apparent once again."

Worse, the HDA said, "a blanket grant of enforcement discretion *would be catastrophic* for wholesale distributors" if it allows some manufacturers to start sending serialized package-level EPCIS event files while letting others continue to send lot-level data, typically in advance ship notices, or ASNs (emphasis in the original). Wholesale distributors are not set up to handle EPCIS event files and ASNs simultaneously.

As it turns out, the one-year enforcement discretion period the FDA established coincides with a one-year Phase 1 period the alliance proposed in which manufacturers would continue sending lot-level data while ramping up and stabilizing their provision of package-level data.

Manufacturers would keep sending both package-level and lot-level data over the first six

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months of the second year of the phase-in period the HDA proposed so wholesale distributors could work out the kinks in their package-level systems while forwarding lot-level data to dispensers.

In the final six months under the alliance proposal, manufacturers and wholesale distributors would send package-level data and dispensers would work on stabilizing their processes for receiving that data.

Only after the two-year phase-in period would all trading partners be expected to fully comply.

The FDA has not said whether it agrees with that approach even though its one-year delay would not be inconsistent with it.

Trading Partners Were Progressing In Ramp-Up For November Deadline

As trading partners scrambled to implement package-level transaction DSCSA requirements in advance of the deadline, they had made significant progress on resolution of data discrepancies since February, Riya Cao, CEO of LSPedia, which provides DSCSA training, solutions and products to manufacturers, wholesale distributors, third-party logistics providers and dispensers, told a 17 August HDA webinar.

In February, resolution took about 20 days on average. But DSCSA gives just three days. “So, in February, we were just really scratching our heads.”

By July, the average was down to 76 hours, within reach of the three-day requirement.

Also, she said the backlog of unresolved data files has been coming down from an estimated 4 million hours of work in February to 1 million in July, which shows trading partners are actively working on exceptions.

EPCIS process time for data files increased to 2 seconds from 1, but the files were getting larger as trading partners ramped up for production.

Error rates also have been increasing, which may make sense as trading partners work toward full-scale operation, “because you’re sending a lot of data exchange files.”

However, Cao said, “We are tracking almost about a 10% error rate,” which means shipments will stall when the system goes live unless trading partners can bring it down significantly.

Polled on their organizational readiness to send and receive EPCIS data files with their trading partners, 28% of webinar participants said they were fully ready and 55% said they were partially ready.

“This is really encouraging,” Cao said. “I think that all of you guys here have really dedicated a majority of your career in getting this DSCSA implemented. So, I’m super pleased that a large majority of you guys are almost there [and] a lot of you guys are already there.”

The progress was especially significant in light of the alliance’s June 2022 readiness survey, which showed it would take a sprint finish to avoid triggering drug shortages at a time when the FDA was adamant that it had no plans to exercise enforcement discretion. (Also see "*Meeting 10-Year DSCSA Serialization Mandate Requires Industry Big Push In Final Year*" - Pink Sheet, 20 Oct, 2022.)