



Healthcare Distribution Alliance

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GETTING READY FOR EPCIS

September 29, 2020

The Healthcare Distribution Alliance has published a Position Statement, *Enhanced Drug Distribution Security Traceability In 2023 And Beyond*. In that Position Statement, we describe the requirements of the Drug Supply Chain Security Act¹ that become effective on November 27, 2023 and the elements for achieving the interoperable, electronic tracing of pharmaceutical products at the package level. The standards for this interoperable exchange of transaction data must comply with a form and format developed by a widely recognized international standards development organization.²

Currently, EPCIS³ is the only internationally recognized standard that will meet these DSCSA requirements. Though still immature for the pharmaceutical and healthcare industries, EPCIS is expected, when fully implemented, to enable seamless, stable, consistent, compatible, electronic connections between trading partners throughout the pharmaceutical supply chain.

A trading partner's 2023 compliance plan, and its timing for execution of that plan, are individual, independently made, business decisions. However, HDA believes that in order to successfully implement EPCIS by November 27, 2023, trading partners must begin to make significant investments (including both capital and staffing) and have sophisticated and ongoing interactions with trading partners and service providers in the very near term.

Further, addressing the COVID-19 pandemic is placing stresses on, and creating competing priorities for, the pharmaceutical supply chain. An additional complicating factor is that given the many supply chain entities that must meet the DSCSA's 2023 requirements, competition for the services of the limited number of experts and consultants to advise on EPCIS execution will be keen. We anticipate a very high demand for this expertise -- potentially limiting trading partners' ability to obtain the timely help they need just as they face the DSCSA's critical deadline.

Every step of DSCSA implementation has demonstrated that it takes time to establish electronic connections between trading partners in order to provide, receive, and maintain data. To be able to meet the November 27, 2023 deadline, trading partners will need work together, in a timely and diligent way, and will need to do so long before the law's deadline. As has been the case with other, comparable DSCSA data exchanges, it is expected that establishing connections between supplying manufacturers (including repackagers -- collectively "manufacturers") and purchasing wholesale distributors will require significant time, effort, and resources.

¹ The DSCSA is Title II of the Drug Quality and Security Act, Public Law No. 113-54, enacted November 27, 2013 and is an amendment to the Federal Food, Drug and Cosmetic Act (FDC Act). The citations to section 582 referenced in this document refer to sections of the FDC Act as amended by the DSCSA and are codified at 21 U.S.C. §360eee-1 respectively.

² § 582(a)(2)(A); § 582(h)(4)(A)(i).

³ Electronic Product Code Information Services (EPCIS) is a GS1 standard that enables trading partners to share information about the physical movement and status of products as they travel throughout the supply chain.

At the outset, the bulk of this implementation will center on each manufacturer achieving successful EPCIS data exchange with each of its wholesale distributor trading partners. Dispensers, however, may be provided serialized EPCIS event data from their suppliers. We anticipate that those dispensers will likely address EPCIS implementation, individually, in consultation with their wholesale distributor and/or third-party data repository service.

We encourage each pair of manufacturer and wholesale distributor trading partners to work together to establish a joint implementation plan for EPCIS execution that builds in adequate time for putting the necessary infrastructure in place, evaluating data quality, onboarding, testing, and stabilization. The implementation plan should account for and allow sufficient time to develop and meet the following milestones and business requirements with the current goal of wholesale distributors beginning to receive serialized EPCIS event data from manufacturers/suppliers by June 1, 2023 (recognizing that trading partners may need to make modifications and additions to accommodate individual business needs).⁴

- To meet existing DSCSA requirements already in place, manufacturers should have completed their upgrade of manufacturing lines and implemented systems to serialize product, affix product identifiers to products and homogenous cases, and capture product identifier data.
- Trading partners should establish a relationship with a service provider, if needed, and include the service provider in their ongoing discussions.
- Trading partners should develop and implement, as necessary, the internal infrastructure and readiness planning for using EPCIS, including completion of any upgrades necessary in order to capture and store product identifier data, bring contract manufacturing organizations onboard, purchase, install and test software and any equipment, complete employee training, and implement other necessary measures they identify.
- Manufacturers will need to ensure that transaction data, including product identifiers, can be formatted into EPCIS files that conform to GS1 standards and guidelines.
- Trading partners, and their service providers if applicable, will need to set up EPCIS connections with one another. This process will generally involve each manufacturer/supplier establishing an individual point of contact with each of its wholesale distributors; industry-wide this means establishing tens of thousands of individual connections between trading partners. Depending upon how trading partners elect to provide and receive transaction data, there may also be tens of thousands of connections to establish with dispensing customers. Trading partners and service providers need to ensure partners are made aware of all data updates before transmitting and that

⁴ The DSCSA requires item-level traceability by November 27, 2023. This means that a wholesale distributor must be in a position to seamlessly match product identifiers with the serialized EPCIS event data it received from the manufacturer/supplier with the product and data it provides to its downstream customer when it sells the product. A wholesale distributor's product inventory typically turns over within six months. Therefore, in order to provide serialized EPCIS event data to downstream customers by November 27, a wholesale distributor needs to have completed testing EPCIS file sharing with manufacturers/suppliers and to begin receiving EPCIS serialized event data from them by June 1, 2023. This lead time allows the wholesale distributor to sell-down most of the product for which it did not receive serialized EPCIS event data by the statutory deadline. Thus, the lead time will facilitate a smooth and seamless transition with less need to address, such as by requesting "grandfathering," products in the supply chain without serialized EPCIS event data as most of these products will have already been sold.

usable data will be shared between them. This effort likely includes, but is not necessarily limited to, confirming that

- the data intended for transmission are compatible with, and suitable for, the connections, as well as for receipt and handling by their trading partners' systems,
 - applicable GS1 standards and associated guidelines are met,
 - files are formatted correctly,
 - timestamps are sequential, and
 - those connections have been tested.
- Manufacturers are urged to begin sending their EPCIS event data to wholesale distributors by June 1, 2023.⁵
 - Firms are encouraged to make appropriate planning and budgeting decisions. Depending on the firm's budget cycle, consideration could be given to begin budgeting for the above actions during the fall of 2020 for the calendar/fiscal year of 2021.

The goal of the timetable and all of these measures is to assure that, as of November 27, 2023, trading partners have implemented a seamless interoperable system for the tracing of pharmaceuticals in the supply chain.

ILLUSTRATED EPCIS IMPLEMENTATION PLAN

Legend:

- Manufacturer = M
- Service Provider = SP
- Trading Partner = TP
- Wholesale Distributor = WD



The above milestones are for illustrative purposes only. Stakeholders may modify, add, or delete milestones as appropriate for their individual businesses.

⁵ See footnote 4.