HDA
Healthcare Distribution Alliance

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Re: Drug Supply Chain Security Act Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs; Draft Guidance for Industry, 87 Fed. Reg. 40258 (July 6, 2022), Docket No. FDA-2014-D-1981

Dear Dr. Jung, Ms. Deshields, and Mr. Ripley:

The Healthcare Distribution Alliance ("HDA") thanks the Food and Drug Administration ("FDA") for this opportunity to submit comments regarding the agency's Revised Draft Guidance, *Drug Supply Chain Security Act Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs*, 87 Fed. Reg. 40258 (July 6, 2022) ("Revised Draft Guidance"). We greatly appreciate the agency's release of this Revised Draft Guidance as it provides critical information to assist the pharmaceutical supply chain to achieve the Drug Supply Chain Security Act's ("DSCSA") requirement of interoperable, electronic tracing of products at the package level beginning November 27, 2023. With its clear declaration of EPCIS ("Electronic Product Code Information Services") as compliant with DSCSA requirements, the Revised Draft Guidance gives the pharmaceutical industry needed confidence in this global standard and enormously advances efforts to meet the DSCSA's 2023 requirements.

1. About HDA

HDA represents primary pharmaceutical distributors – the vital link between the nation's pharmaceutical manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, clinics, and others nationwide. This essential function is provided with little public recognition or visibility, and at great savings to the healthcare system. HDA members serve as the central link in a sophisticated national supply chain. HDA members take this mission very seriously, and we support manufacturers, healthcare providers, and the government in ongoing efforts to ensure the U.S. medicine supply remains secure, efficient, and highly regulated.

2. Discussion of the Revised Draft Guidance

The Revised Draft Guidance updates a Draft Guidance issued in November 2014, available here ("2014 Draft Guidance"). HDA was very supportive of the 2014 Draft Guidance, believing that it set forth achievable means for the provision and receipt of transaction data at that time, while also creating a roadmap to DSCSA-mandated interoperability in 2023. In our comments to the 2014 Draft Guidance, we stated:

> The Draft Guidance's approach is highly appropriate, particularly given the challenges the supply chain faces with the DSCSA's complex data provision requirements, the relatively short time frame for providing the data, and the extremely high volume of prescription drugs involved.
> …
> We also support the Draft Guidance's explicit recognition of the multiple methods for the exchange of transaction data, including, but not limited to:
> - Paper or electronic invoices;
> - Paper packing slips;
> - Electronic Data Interchange (EDI) standards, such as the 856 Advance Ship Notice (ASN);
> - EPCIS (Electronic Product Code Information Services); and
> - Email or Web-based platforms (such as Web portals).

HDA's comment on the 2014 Draft Guidance is available here.

Since the DSCSA's enactment, the supply chain has slowly matured and moved away from paper (which is not interoperable) and the ASN (which cannot support the product identifier in Transaction Information ("TI") as required in 2023 and is not a standard of an international standards setting body). The Revised Draft Guidance settles upon and recommends the use of EPCIS to meet the 2023 requirements:

> WHAT STANDARDS SHOULD TRADING PARTNERS ADOPT FOR THE ENHANCED DRUG DISTRIBUTION SECURITY REQUIREMENTS?
>
> FDA recommends that trading partners use the Electronic Product Code Information Services (EPCIS) standard to provide and maintain the data associated with transaction information and transaction statements. EPCIS is a global GS1 standard that allows trading partners to capture and share information about products as they are transacted through the supply chain. Use of EPCIS can support and enable electronic and interoperable interfaces used by trading partners to help ensure compliance with the DSCSA requirements and is compatible with a range of different technological approaches. FDA believes that EPCIS is an appropriate globally recognized standard, and FDA understands there is considerable agreement among stakeholders that EPCIS is a suitable standard to adopt for the enhanced drug distribution security requirements.
>
> It is essential for trading partners to adopt standards for how the data associated with transaction information and transaction statements are electronically exchanged to achieve enhanced drug distribution security

> interoperability. To help ensure successful, efficient enhanced drug distribution security interoperability, FDA recommends that trading partners make a collaborative effort to follow the same standards for how the data associated with transaction information and transaction statements are electronically exchanged.

Revised Draft Guidance at Lines 137-153.

We thank FDA for this clear, concise recommendation of EPCIS. We agree with and endorse the above and believe the Revised Draft Guidance has eliminated any lingering uncertainty about this global standard and will drive the supply chain toward needed adoption and implementation of EPCIS to meet the DSCSA's requirements set out in § 582(g).

The Revised Draft Guidance also states:

> FDA recognizes there are a variety of technological approaches available to trading partners to comply with enhanced drug distribution security requirements outlined in section 582(g)(1) of the FD&C Act, and FDA does not expect all trading partners to rely upon a single technological approach. However, the Agency recommends that a trading partner use a technological approach utilizing the EPCIS standard.

Revised Draft Guidance at Lines 158-161. We appreciate this recognition that while there may be different approaches used, EPCIS is the standard that FDA recommends trading partners adopt and implement.

We offer, below, limited comments on the Revised Draft Guidance that we would like to see addressed in the final guidance:

- **Addition of portals as acceptable for 2023 compliance.** The 2014 version of the guidance identified, "Email or Web-based platforms (such as Web portals) as acceptable means to transmit or access the product tracing information, as long as the information is captured, maintained, and provided in compliance with section 582." 2014 Draft Guidance at Lines 185-187. The Revised Draft Guidance, however, does not include portals, and we ask that the final guidance be revised to include this data-sharing repository. Many of our members' customers do not have the resources, capability, or need, to set up the business-to-business connections to receive and store an EPCIS event file containing transaction data. The portal is how we, and our customers, both satisfy our § 582 obligations.

  We ask that FDA include in the final guidance language similar to that in the 2014 Draft Guidance that permitted and endorsed portals, such as:

  > Web portals are an acceptable means to transmit or access the product tracing information, as long as the information is captured, maintained, and provided in compliance with section 582.

- **Recognition of GS1 US guideline implementing EPCIS.** Lines 141-143 state, "Use of EPCIS can support and enable electronic and interoperable interfaces used by trading partners to help ensure compliance with the DSCSA requirements and is compatible with a range of different technological approaches." In the final guidance,

we ask that FDA include a footnote with this sentence that references the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability Release 1.2.* While EPCIS is a global standard applicable to all products, industries, and transactions, the GS1 US Implementation Guideline explains how to format the EPCIS file format so that it includes all elements of transaction information ("TI") and the transaction statement ("TS") the DSCSA requires. The footnote could state:

> GS1 US has published the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability Release 1.2.* which explains how to format EPCIS event files to include the transaction information and the transaction statement that are necessary for compliance with § 582 requirements.

- **Correct recitation of § 582(g)(1) requirements.** Lines 114-121 paraphrase the enhanced drug distribution security requirements outlined in section 582(g)(1). Section 582(g)(1) is complex, and its nuanced requirements can be lost when attempts are made to shorten or simplify it. We recommend that the final guidance quote § 582(g)(1)(A) through (F) verbatim and include citations to each important, relevant part of the enhanced drug distribution security requirements the statute imposes for 2023.

- **Protection of confidential commercial information and trade secrets.** Lines 161-167 state (footnotes omitted):

> In addition, any technological approach a trading partner uses should utilize data standards that facilitate a uniform process or methodology for product tracing and ensure the protection of confidential commercial information and trade secrets. We note that trading partners' efforts to protect such information should not be limited to adhering to EPCIS, but should also include using individual system(s) and procedure(s), and business practices that ensure the confidentiality of such information.

We agree, of course, that trading partners should take appropriate measures to protect their transaction data from cyber-related threats and crime. The DSCSA also includes numerous provisions for the protection of confidential commercial information and trade secrets.[1] We are, however, unaware of "data standards that facilitate … the protection of confidential commercial information and trade secrets." We ask that this phrasing be deleted or

[1]The DSCSA is very concerned with the security of transaction data and the circumstances under which a trading partner must disclose it are well-defined. For example: § 582(b)(4)(D), § 582(c)(4)(C), § 582(d)(4)(C), and § 582(e)(4)(D) (manufacturers, wholesale distributors, dispensers and repackagers may each develop its own "secure electronic database" to meet verification requirements); § 582(d)((1)(B); § 582(g)(2)(A) (dispensers may have third parties "confidentially maintai[n]" their transaction data); § 582(c)(1)(A)(v)(II) (wholesale distributors must "maintain the confidentiality of the transaction information…, transaction history, and transaction statement for a product in a manner that prohibits disclosure to any person other than" a government official, the trading partner it received the data from or provided the data to, or if pursuant to an agreement); § 582(g)(1)(E)(ii) (in the circumstances in which a trading partner may request from another trading partner the information necessary to "facilitate gathering" the transaction information for a product, the systems and processes for making and responding to a request must be "in a secure manner that ensures the protection of confidential commercial information and trade secrets.").

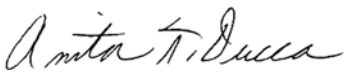
clarified with an explanation of the applicable data standards, or amended to reflect the obligations the DSCSA imposes.

* * *

HDA thanks FDA for this opportunity to comment on the Revised Draft Guidance. We urge FDA to issue the Revised Draft Guidance in final form with the suggested changes as soon as possible.

If you have any questions, please contact me at 703-885-0240 or aducca@hda.org.

Sincerely,



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