HEALTHCARE SUPPLY CHAIN ASSOCIATION
Innovators In Evidence-Based Sourcing

November 9, 2022

Submitted electronically via https://www.regulations.gov/

Dockets Management Staff (HFA-305)
Food and Drug Administration,
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852.

Connie T. Jung, R.Ph., PhD
Senior Advisor for Policy Office of Drug Security, Integrity, and Recalls, Office of Compliance Center for Drug Evaluation and Research Food and Drug Administration
Room 2242, White Oak Office Building 51
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: **DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs Guidance for Industry (Docket No. FDA-2014-D-1981)**

Dear Dr. Jung:

On behalf of the Healthcare Supply Chain Association (HSCA), which represents the nation's leading healthcare group purchasing organizations (GPOs), we appreciate the opportunity to comment on the U.S. Food and Drug Administration's (FDA's) revised draft guidance, "DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs Guidance for Industry."

Healthcare GPOs are the sourcing and purchasing partners to virtually all of America's 7,000+ hospitals, as well as the vast majority of the 68,000+ long-term care facilities, surgery centers, clinics, and other healthcare providers. GPOs do not purchase or take ownership of products; rather, they negotiate competitive prices and support a safe and reliable supply of products. GPOs lower costs for patients, providers, payers, Medicare and Medicaid, and taxpayers. One report estimated that GPOs reduce supply-related purchasing costs by 13.1 percent annually and will reduce healthcare spending by up to $456.6 billion between 2017 and 2026. GPOs are particularly critical to smaller and rural hospitals that often lack the purchasing power to procure the essential supplies. The value and services that GPOs provide allow healthcare providers and physicians to focus on their core mission: providing first-class patient care.

Wholesalers and distributors sell drugs and other medical products to GPO members at the GPO-negotiated price. GPOs are frequent supply data partners with wholesalers and distributors, providing appropriate supply inquiries on behalf of their provider members. These inquiries are critical to the function and resilience of the healthcare supply chain and require timely electronic exchanges of information. HSCA applauds the FDA's decade-long effort to improve coordination between healthcare

stakeholders, enhance traceability in the pharmaceutical supply chain, and achieve interoperable electronic health records through the implementation of the Drug Supply Chain Security Act (DSCSA).

The Drug Supply Chain Security Act (Title II of Public Law 113-54) was signed into law in November 2013. HSCA offered comments in April 2014 on the initial standards for the interoperable exchange of product tracing information developed by the FDA. The Drug Supply Chain Security Act (DSCSA) outlines requirements for enhanced drug distribution security, which include the steps to achieve interoperable, electronic tracing of products at the package level. These requirements for enhanced drug distribution security go into effect on November 27, 2023.

The revised draft guidance, released in July 2022, updates the policy articulated in the November 2014 draft guidance to reflect the enhanced drug distribution security requirements that will go into effect in November 2023, including that paper-based methods of product tracing will no longer be permitted and verification of product at the package level will be required, unless a waiver, exception, or exemption applies. This revised draft guidance is intended to facilitate the creation of a uniform methodology for product tracing while ensuring the protection of confidential commercial information and trade secrets. Previously, stakeholders were required to ensure that products were traceable at the lot level, rather than the package level.

Beginning on November 27, 2023, wholesale distributors, dispensers, and repackagers must use electronic-based methods to meet the enhanced drug distribution security requirements. Healthcare GPOs frequently interact with the manufacturers, distributors, dispensers, and repackagers this guidance applies to, and HSCA recognizes that adhering to these conditions requires a significant amount of time and resources from these stakeholders.

Many of the aforementioned stakeholders have already made significant investments into complying with DSCSA standards, according to a 2017 survey by KPMG. However, many compliance efforts stalled during the pandemic as stakeholders turned their attention to disruptions of critical supplies and medications. **HSCA anticipates that some stakeholders will not be able to adhere to the DSCSA interoperability standards by November 27, 2023 and recommends that the FDA outline the processes through which stakeholders will be able to apply for applicable waivers, exceptions, or exemptions.**

Additionally, **HSCA recommends that the FDA consider how to best notify other supply chain stakeholders, including GPOs, of penalties, fines, or suspensions imposed by the agency for noncompliance with DSCSA interoperable electronic standards. It is critically important that the inability to meet the requirements by the stated timeframe does not result in to supply chain disruptions or worsen existing drug shortages, and that all supply chain stakeholders are made aware of potential disruptions so they can ensure consistent access to drugs for providers and their patients.**

HSCA believes that the full implementation of interoperable electronic standards under the DSCSA will create a more resilient pharmaceutical supply chain and improve patient safety by requiring that drugs be traced through every stage of the manufacturing and distribution process.

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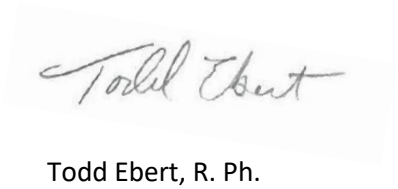
We appreciate the opportunity to provide you with our perspective and we look forward to continuing to serve as a resource to our federal partners to maintain a healthy supply chain and protect access to essential drugs and products. Please do not hesitate to contact me directly if HSCA can be a resource on this issue moving forward. I can be reached at (202) 629-5833 and tebert@supplychainassociation.org.

Sincerely,



Todd Ebert, R. Ph.
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