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September 6, 2022

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

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Act Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs; Draft Guidance for Industry; Availability [Docket No. FDA–2014–D–1981]

Dockets Management Staff,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide feedback to FDA's Drug Supply Chain Security Act Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs; Draft Guidance for Industry; Availability. NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a $67 billion healthcare marketplace, employ 215,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.

Seeking Clarity on Permissibility of Certain "Electronic-Based Approaches"
The draft guidance states that "Beginning November 27, 2023, electronic-based approaches are generally required to be used among all trading partners to meet the enhanced drug distribution security requirements outlined in section 582(g) of the FD&C Act."

Independent pharmacy companies do not have the resources to develop applications that meet the interoperability requirements on their own. NCPA anticipates that all independent pharmacies will have to identify a solutions provider and incur the cost of that service directly or indirectly from their dispensing system vendor. This is a significant cost to the pharmacy which they cannot recoup by increasing prescription prices due to 90+% of prescriptions being subject to third-party payer contracts. NCPA reminds FDA that the agency is required "to conduct a technology and software assessment that looks at the feasibility of dispensers with 25 or fewer full-time employees conducting interoperable, electronic tracing of products at the package

level." And that "[s]uch assessment shall be completed not later than 8 1⁄2 years after the date of enactment of the Drug Supply Chain Security Act."[1]

NCPA notes that, while the prior draft guidance expressly permitted the use of web portals, the current draft does not. Portals are a common modality used by dispensers. For example, many wholesale distributors provide the dispenser with the required transaction data by means of a portal. Pursuant to a written agreement,[2] the wholesale distributor may also store the data for the required 6-year time frame and the dispenser is able to access its data via the portal. NCPA would like to ensure that tracing data might be in their wholesalers' portals, and the dispensers may leave that data there until the wholesalers are no longer required to maintain such data.

NCPA asks that FDA be prepared to exercise enforcement discretion if an otherwise authorized trading partner continues to rely on a web portal for maintaining TH/TS/TI received previously and clarify that a pharmacy is not required to convert paper-based or web portal-based records to the EPCIS standard. Likewise, if a distributor is not required to convert paper-based or web portal-based records (generated prior to 11/27/23) to EPCIS, a pharmacy may accept that format and continue to use a web portal for the record retention period.

NCPA asks that FDA provide guidance on the following: if a dispenser makes a saleable return, can the dispenser's trading partner accept the format in which the dispenser has the data?

FDA's Recommendation For Trading Partners to Use the EPCIS Standard

NCPA supports FDA's recommendation 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. Stakeholders have widely adopted EPCIS as the building block for the interoperable exchange of TI and TS. EPCIS is, at this time, the only standard that meets DSCSA legal requirements and can support the interoperable sending and receiving of the product identifier in TI.

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[1] Title II, DQSA, §582(g)(3)(A) states: "(A) In general.--Not later than the date that is 18 months after the Secretary issues the final guidance required under subsection (h), the Secretary shall enter into a contract with a private, independent consulting firm with expertise to conduct a technology and software assessment that looks at the feasibility of dispensers with 25 or fewer full-time employees conducting interoperable, electronic tracing of products at the package level. Such assessment shall be completed not later than 8\1/2\ [sic] years after the date of enactment of the Drug Supply Chain Security Act.

[2] Title II, DQSA, §582(s)(1)(B) states: "Agreements with third parties.--A dispenser may enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party confidentially maintains the transaction information, transaction history, and transaction statements required to be maintained under this subsection on behalf of the dispenser. If a dispenser enters into such an agreement, the dispenser shall maintain a copy of the written agreement and shall not be relieved of the obligations of the dispenser under this subsection."

Conclusion
NCPA thanks FDA for the opportunity to provide feedback, and we stand ready to work with FDA to offer possible solutions and ideas.

Should you have any questions or concerns, please feel free to contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

Steve Postal, JD
Director, Policy & Regulatory Affairs
National Community Pharmacists Association