

Submitted electronically via www.regulations.gov

September 6, 2022

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

Re: Identifying Trading Partners Under the Drug Supply Chain Security Act; Revised Draft Guidance for Industry; Availability [[Docket No. FDA-2017-D-1956](#)]

Dockets Management Staff,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide feedback to FDA's Identifying Trading Partners Under the Drug Supply Chain Security Act; Revised Draft Guidance for Industry; Availability.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.

Definition of Authorized Trading Partner

The FDA guidance mentions that the DSCSA has definitions for "authorized" as defined in section 581(2) of the FD&C Act, and "trading partner" as defined in section 581(23) of the FD&C Act. Namely, "authorized," in the case of dispensers in 581(2)(D) means having a valid license under state law. A "trading partner" in the case of dispensers in 581(23)(A) means: "(A) a manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product." Therefore, the guidance states that "[t]o be considered an authorized trading partner, a dispenser must have a valid license under State law and accept or transfer direct ownership of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser." NCPA supports these definitions.

Specific Patient Need Exemption

NCPA supports the specific patient need exemption. In the draft guidance,

“...dispensers are not required to provide the product tracing information prior to, or at the time of, a transaction if the product is dispensed to a patient or if it is a sale by a dispenser to another dispenser to fulfill a “specific patient need.” The term specific patient need refers to the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. This term does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need. Although a dispenser that sells a product to another dispenser to fulfill a specific patient need is not required to provide product tracing information, other requirements of section 582(d) of the FD&C Act may apply to the transferring and receiving pharmacies. Accordingly, such sales or transfers should be documented by each pharmacy in the normal course of business in a manner that would facilitate appropriate actions by the pharmacy in the event of an investigation of suspect or illegitimate product, recall, or notification of illegitimate product. To reiterate, a dispenser transferring product to another dispenser for a specific patient need is not required to provide product tracing information with the transfer. Transfers of product to another dispenser without a specific patient need may constitute wholesale distribution, and thus, the requirements for wholesale distributors in sections 582 and 583 of the FD&C Act may apply.”

NCPA further supports that the FDA is clarifying in Table 1 that “a dispenser who transfers product to another dispenser for a specific patient need” is not a wholesaler.

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,

A handwritten signature in black ink, appearing to read 'Steve Postal', with a long horizontal stroke extending to the right.

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