APhA
American Pharmacists Association

September 6, 2022

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

RE: Docket No. FDA-2017-D-1956: Identifying Trading Partners Under the Drug Supply Chain Security Act; Revised Draft Guidance for Industry

Submitted via www.regulations.gov to FDA-2017-D-1956

Dear Food and Drug Administration staff:

The American Pharmacists Association (APhA) is pleased to submit comments on the revised draft guidance entitled "Identifying Trading Partners Under the Drug Supply Chain Security Act." APhA is the only organization advancing the entire pharmacy profession. Our expert staff and strong volunteer leadership, including many experienced pharmacists, allow us to deliver vital leadership to help pharmacists, pharmaceutical scientists, student pharmacists, and pharmacy technicians find success and satisfaction in their work while advocating for changes that benefit them, their patients, and their communities.

APhA strongly supports the purpose and goals of the Drug Supply Chain Security Act (DSCSA) to enhance the safety and security of the pharmaceutical distribution supply chain. APhA appreciates FDA's efforts in developing guidance, standards, and other information to assist pharmacists and pharmacies in complying with DSCSA's requirements.

Definition of Dispenser

The guidance states that section 581(3) of the Food Drug & Cosmetic Act (FD&C Act) states that dispenser:

> "(A) means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor; and (B) does not include a person who dispenses only products to be used in animals in accordance with section 512(a)(5)."

APhA supports this definition, as it is codified in law.

Dispensing "Minimal Quantities" for Office Use

Section 503(e)(4)(E) of the FD&C Act excludes "the distribution of minimal quantities of drug by a licensed retail pharmacy to a licensed practitioner for office use" from the definition of wholesale distribution. The revised draft guidance states that FDA considers "minimal quantities" to mean that the total annual dollar volume of prescription drugs sold to licensed practitioners does not exceed 5 percent of the dollar volume of that retail pharmacy's annual prescription drug sales.

There is a longer discussion of this "5% rule" in FDA's proposed rule that was published on February 24, 2022, entitled "National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers." APhA submitted comments to the docket for this proposed rule and defers discussion of this issue to those comments since it is a codification of what is described in this revised draft guidance.

Documenting "Specific Patient Need" Transactions

The revised draft guidance recognizes that, per section 582(d)(1)(ii), 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." As defined in 581(19), 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 but 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. The revised draft guidance states that:

> "[a]lthough 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."

In joint comments submitted to FDA by APhA and the National Community Pharmacists Association (NCPA) to this docket on the original draft guidance on October 23, 2017, APhA

and NCPA expressed concern that FDA's documentation recommendation may confuse dispensers because it is not clear what the FDA expects the sending and receiving pharmacies to document (if not the tracing information) to facilitate appropriate actions in the event of an investigation, recall, or illegitimate product notification. APhA and NCPA suggested that FDA clarify that providing tracing information is not required and provide examples of information that dispensers may consider documenting. APhA appreciates that FDA specifically reiterated that product tracing information is not required, however, FDA did not provide any information regarding what they expect for documentation. APhA requests that the final guidance provide greater clarity and include examples of what documentation would be needed.

Conclusion

APhA appreciates FDA's ongoing efforts in developing guidance, standards, and other information to assist pharmacists and pharmacies in complying with DSCSA's requirements. We look forward to continuing to support FDA's efforts and working to improve the safety and security of the drug supply chain. If you have any questions or require additional information, please contact Heather Boyd, Director, Health Policy at hboyd@aphanet.org.

Sincerely,

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Interim Executive Vice President and CEO