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-2014-D-1981-0019: Drug Supply Chain Security Act Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs; Draft Guidance for Industry

Submitted via www.regulations.gov to FDA-2014-D-1981-0019

Dear Food and Drug Administration staff:

The American Pharmacists Association (APhA) is pleased to submit comments on the revised draft guidance entitled "Drug Supply Chain Security Act Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs." 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 also appreciates FDA's efforts in developing guidance, standards, and other information to assist pharmacists and pharmacies in complying with DSCSA's requirements.

- **Role in the Implementation Roadmap.** APhA supports the overall intent of the guidance in establishing standards for the exchange of transaction information and transaction statements in a secure, interoperable manner at the package level. That said, thoughtful and deliberate implementation across the supply chain is necessary

to ensure there are no disruptions in drug distribution and availability on and after November 27, 2023. This guidance is an important piece of the implementation roadmap, but it is just a piece. It only identifies what standard should be used. It does not identify other essential elements related to day-to-day transactions or within systems or processes. As the draft guidance notes "FDA also published other guidances addressing the enhanced drug distribution security requirements, including the attributes necessary for enhanced product tracing and verification, which should be read in conjunction with this guidance." An important piece of the roadmap for implementation is the guidance required under section 582(h)(3), which FDA published in draft in June 2021 as Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act. Trading partners cannot adequately prepare systems and processes for the enhanced requirements until the full roadmap is finalized, and even then, stakeholders will need time to prepare, train personnel, and implement systems and processes associated with the guidance. APhA urges FDA to finalize these guidances soon to provide sufficient time for implementation and compliance by November 27, 2023.

- **Small Business Dispenser Impact Assessment.** APhA respectfully reminds FDA that pursuant to sections 582(g)(2) and (3), a small business dispenser assessment shall be conducted no later than 18 months after the guidance in subsection (h) is finalized, which includes this guidance. According to section 582(g)(3)(A), the assessment shall be completed no later than 8 ½ years after the date of enactment of DSCSA, which was November 23, 2013. Furthermore, according to sections 582(g)(2)(D)(ii) and (iii), FDA shall give 30 calendar days of public comment on the assessment and shall hold a public meeting no later than 180 calendar days after receiving the final assessment from the contractor conducting the assessment. Congress added these timeframes to ensure that the assessment adequately assess the impact of the "final guidance required under subsection (h)," which includes all the guidances at section 582(h) (2), (3), and (4), in order to determine the cost and burdens of practical implementation based on the final guidance provided by FDA.

Because FDA has not finalized the guidance at subsection (h) and has not conducted the small business dispenser assessment within 8 ½ years of enactment, the small business dispenser assessment will not be able to be conducted and completed with enough time for the required public comment period and public meeting. In addition, there will not be adequate time for affected dispensers to implement of any of the alternative methods for compliance that have yet to be identified pursuant to section 582(g)(2)(B). APhA requests that FDA consider how the small business dispenser assessment delay will impact compliance for affected dispensers and whether and what enforcement discretion will be provided.

- **EPCIS Standard**. APhA 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. Significant work has been done across the supply chain in finessing and testing this standard for use to meet the DSCSA requirements.

- **Web-Based Portals**. The revised draft guidance notes that "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."

  APhA appreciates FDA's recognition that flexibility is needed across the supply chain in applying the standard. In FDA's 2014 draft guidance entitled "DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information," which is the previous version of this revised draft guidance, FDA specifically included different ways to comply by applying the standard recommended at the time. For example, FDA stated that "[w]eb-based platforms (such as Web portals) are 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. In the revised draft guidance, there is no mention of web-based portals.

Most independent and small chain dispensers have agreements with their wholesale distributor trading partners to maintain their transaction documentation in web-based platforms that the dispenser can access. For business and financial reasons, most of these dispensers plan to continue using web-based portals to access their transaction information and transaction statements to comply with the requirements that go into effect on November 27, 2023. APhA requests that the final version of this guidance specifically recognize and endorse the use of web-based platforms and portals for capture, access, and maintaining transaction information and transaction statements.

- **Recommended or Required Standard?** Throughout this revised draft guidance, FDA uses the term "recommends" when referring to the standards for interoperable data exchange. A key aspect of DSCSA is interoperability and uniformity so all trading partners can accurately, efficiently, and consistently exchange information. This enables all trading partners to have systems and processes to securely exchange, capture, and maintain the electronic transaction documentation. By leaving the door open for other standards, there is no consistency, and this can delay or disrupt drug distribution and availability. APhA recognizes that this guidance contains FDA's current thinking and is not binding, however, the intent of DSCSA is for the supply chain to follow uniform standards. Failure to have uniform standards could also be more costly for supply chain stakeholders if different systems are used and will need to be modified to support exchange of transaction documents using different standards. APhA urges FDA to take steps to ensure that the supply chain uniformly adopts the EPCIS standard.

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,

Ilisa BG Bernstein, PharmD, JD, FAPhA
Interim Executive Vice President and CEO