APhA
American Pharmacists Association

FDA Public Meeting on DSCSA Enhanced Drug Distribution Security
at the Package Level

Remarks by
Ilisa BG Bernstein, PharmD, JD, FAPhA
American Pharmacists Association
November 16, 2021

- Thank you for the opportunity to respond to FDA's request for information regarding DSCSA enhanced drug distribution security requirements. I am Ilisa Bernstein, Senior VP of Pharmacy Practice and Government Affairs at the American Pharmacists Association. APhA is the largest association representing pharmacists in all practice settings. Our members strive to improve medication use, advance patient care, and enhance public health. FDA has been in the spotlight, working hard and under tremendous pressure during the pandemic and we appreciate all that you and your colleagues have been doing.

- For those of you who don't know me, I worked at FDA for over 30 years. While working there I was involved in discussions with Congress during passage of DSCSA and led efforts at FDA implementing DSCSA up until when I retired from FDA two years ago.

- Today, I am highlighting and embellishing on some of the issues raised in the comments that APhA submitted related to the draft guidance on enhanced drug distribution security (EDDS) at the package level as well as answer the questions you posed for this meeting.

- SLIDE 2: First, you asked how implementation of the enhanced requirements are progressing for our organization and the challenges. I'll answer generally regarding dispenser implementation. Quite frankly, although some larger chains and health systems are well under way, most community pharmacies have not started. Hospital and health systems also have made little to moderate progress.

2215 Constitution Ave. NW
Washington, DC 20037
800 237 2742
pharmacist.com

- There are several reasons why implementation is not further along, but I'll highlight 2.

    - First, pharmacies have been on the front line during the pandemic, providing COVID testing, vaccinations, therapies, symptomatic relief, and more, in addition to the patient care services and dispensing that they provide in communities. Additionally, the health care ecosystem is providing financial strains on pharmacies…whether community, hospital and health system, long term care, or other pharmacies. It's a struggle and pharmacies are focusing on keeping the doors open and addressing patients' needs.

    - Second, there are no final established standards or final guidance setting forth the requirements. Until there is some certainty, many dispensers, particularly independent community pharmacies, are reluctant to invest or consider what they will do to meet the requirements. And, many dispensers are relying or will rely on their wholesalers for hand holding for implementation.

- SLIDE 3: Next, you asked if the proposed recommendations in FDA's draft guidance are helpful to achieve compliance, and if not, what would be useful. The next few comments will address this question.

- SLIDE 4: As several prior speakers noted, there is no single system being developed; and the law does not require a "system." As our comments explained in detail, DSCSA requires <u>individual trading partners</u> to have systems and processes to comply with the provisions and DSCSA specifically calls for <u>requirements</u> for enhanced drug distribution security. DSCSA does <u>not require a system</u> for enhanced drug distribution security. Enhanced system is a misnomer. Using it implies that there is another level of integration or specific place to share data that's needed in order to comply. What is being developed is B2B or "business to business" interoperability, not a centralized system or significant use of decentralized databases for interoperability.

    - Yes, you are probably saying that I used the term "enhanced system" regularly when I was at FDA. True. That's what we envisioned and that's what we thought trading partners would develop as the approach to

implement the requirements. However, the supply chain went in another direction and has been focusing on B2B interoperability, relying on EPCIS, with their own individual systems. **FDA needs to pivot too.** The agency needs to focus on the requirements for the framework to ensure electronic interoperability from a B2B perspective -- enabling a dispenser's own system to be able to talk and receive transaction information from any of their trading partners' systems, without having to have several ways of electronically talking with each trading partner.

- SLIDE 5: If you want more uniform compliance across the supply chain, keep it simple and stick with the basic DSCSA requirements. FDA should do their own analysis of current and predicted state of readiness by 11/23 across the supply chain. This will give you a better sense of reality and what to expect when November 2023 comes around. You may find that despite all our efforts across the supply chain, all the requirements or capabilities cannot be implemented in time without disrupting drug distribution and drug availability for patients. Consider a tiered approach to implement and reassess as systems, processes, and experience matures.
    - The draft guidance includes bells and whistles and elements to further enhance supply chain security. We urge you to avoid imposing standards or features that may well enhance drug distribution security but are not required in the law.

- SLIDE 6: The draft guidance describes steps for reconciliation by dispensers that are not practical. The draft calls for automated reconciliation, reconciling each product package with transaction documentation, and automatically uploading information into their system. In most pharmacies, current systems, processes, and resources won't support these steps. And, if a pharmacy chooses to partner with their wholesaler or a third party to store their transaction documentation, the systems aren't set up to routinely reconcile each product package automatically, quickly, or efficiently.
    - Pharmacies do check inbound orders and may read the bar codes…sometimes the linear barcode, sometimes the 2D barcode, but it's connected to their inventory database and not where the transaction documentation is held.
    - We recommend that FDA consider establishing a risk-based approach to reconciliation and verification that is based on whether there is reason to

believe that a product may be suspect or illegitimate, integrating some of the elements in FDA's Guidance on Identifying Suspect Product.

- SLIDE 7: Finally, you asked whether there are areas where FDA could provide more clarity.

- SLIDE 8:

    - The draft guidance says that the interoperable integration of individual systems should allow appropriate access for FDA and other officials to communicate with trading partners' individual systems. It's unclear what this means. I doubt that FDA intends this to mean that they want to reach into trading partners' systems, but that's what it sounds like. Please clarify.

    - DSCSA requires trading partners to provide applicable transaction information, including that which facilitates the gathering of transaction information going back to the manufacturer. What "facilitates the gathering" means and what trading partners need to do was not sufficiently described in the draft guidance. Please clarify this and provide examples.

    - The draft guidance sets forth a 3-day time frame for resolving clerical or data errors. This is not reasonable and could impact patient care. Resolution of the error is oftentimes out of the dispenser's control while they wait for information from the seller. Instead of a pre-determined time limit, FDA should clarify by developing criteria for when it would be appropriate for product subject to data or clerical errors to be dispensed.

    - The draft guidance has unreasonable expectations for handling alerts. Individual systems are not capable of storing and creating red flags for products subject to an alert. That said, there is a large gap and disconnect between FDA and the supply chain regarding alerts of illegitimate product. This is a supply chain blind spot. There has to be a better way to quickly and efficiently widely share alerts across the supply chain and ensure that this information gets in the right hands for appropriate urgent action. Press releases don't work. FDA should explore how alerts can be

communicated in a more systematic and reliable way, without imposing new costs for technologies, hardware, or software on trading partners.

- Finally, as mentioned by other speakers, we recommend that FDA hold a focused DSCSA workshop for dispensers – but it should be when the time is right and the messages are clear and specific. Holding this too early will only provide more confusion. Additionally, the dispenser small business study that is required by DSCSA will be critical. APhA and others in the pharmacy community welcome the opportunity to provide input into the focus and design of this study so it delivers adequate data and information for dispenser implementation and compliance.

- Thank you again for holding this meeting. APhA looks forward to continuing to work with FDA on DSCSA implementation.

2215 Constitution Ave. NW
Washington, DC 20037

800 237 2742
pharmacist.com