PDSA
Pharmaceutical Distribution Security Alliance

August 28, 2024

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

Re: PDSA Comments Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements Under the Federal Food, Drug, and Cosmetic Act
Docket FDA-2023-N-4806

Dear Sir/Madam,

On behalf of the Pharmaceutical Distribution Security Alliance (PDSA), I am pleased to submit these comments to your request for information.

PDSA is a multi-stakeholder coalition established in 2011 with a membership that spans the entire spectrum of the U.S. pharmaceutical distribution system, including manufacturers, repackagers, wholesale distributors, third-party logistics providers, and pharmacies. More than 25 companies are formal members of PDSA, while many other external stakeholders provide additional policy and technical support through industry trade associations. Our primary goal is to ensure patients have uninterrupted access to safe, authentic, FDA-approved medicine. PDSA members and industry have been building the foundations and building blocks for a 2023 enhanced system for years. The legislation was crafted to encourage sectors to build off the work of each sequential milestone and collaborate as an industry.

PDSA appreciates the Agency's continued dedication to the successfully implementing the Drug Supply Chain Security Act (DSCSA), and we hope these comments support our continued collaborative implementation of interoperable systems and processes pursuant to the DSCSA. During implementation PDSA members have identified three areas that merit additional discussions and comments.

First, we recognize and appreciate why FDA established the Enforcement Discretion for Small Business Dispensers published June 12, 2024, ***PDSA does not disagree with the exemption.*** The FDA exemptions do not exempt small dispensers from their existing compliance obligations under DSCSA.[1] However, exemptions from certain requirements of section 582 of the FD&C

[1] For example, small dispensers must still: 1. Know their prescription drug suppliers (sources). They must be a trading partner that is authorized as defined in Section 581 of the FD&C Act. 2. Know where current product tracing information (data) is being stored and how to access it. 3. Know how to identify suspect products and have processes in place to quarantine, investigate, and communicate as required. 4. Develop, update, and adhere to robust prescription drug purchasing policies and procedures (P&Ps) that accurately reflect their business location's processes.

Act to small dispensers does not change the practical requirements for the trading partners (TPs) who sell products to those small dispensers.

Second, some waivers, exemptions, and exceptions (WEEs) are an integral tool for trading partners who do not expect to be compliant on November 27, 2024. Frequent and diverse WEEs will add tremendous complexity to the stabilization and many trading partners remain confused about the communication of transitioning products following the notification of the conclusion of a previously granted WEE.

Lastly, PDSA thanks FDA for establishing the CDER NextGen Portal (NextGen), including a Drug Supply Chain Security Act (DSCSA) portal to improve communication between FDA and trading partners. The portal to support critical communications, including information related to investigations of suspect or illegitimate products or during a recall. PDSA has the following recommendations for consideration to improve processes and interaction between FDA and trading partners.

I. Small Dispenser Discretion For Some Trading Partners

We fully recognize and appreciate why FDA established the small-business dispenser exemption for certain requirements of section 582 of the FD&C Act and where applicable their trading partners, until November 27, 2026; Again, PDSA does not disagree with the exemption. This provides small dispensers with additional time to stabilize their operations to fully implement the enhanced drug distribution security requirements of the Drug Supply Chain Security Act. It is critical that FDA understand the ongoing operational realities of implementing the exemption.

In practice, the exemption established by FDA will not extend beyond small dispensers. Although FDA's announcement of the exemption refers to the trading partners of small dispensers, the exemption will have little direct impact on the compliance obligations and implementation of those non-small-dispenser trading partners.

First, there are DSCSA obligations beyond those referenced in the exemption that will still require trading partners to capture and maintain serialized data. For example, wholesalers and manufacturers must verify product identifiers of saleable returns and confirm that the package being returned was sold by that wholesaler or manufacturer.[2] Compliance with that obligation effectively requires those upstream trading partners to capture and maintain serialized data regardless of the exemption status of their small dispenser trading partners.

Second, maintenance of both lot-level and serialized compliance systems for DSCSA while not ideal is the expected short-term outcome. It is far more efficient for upstream suppliers of small dispensers to capture, maintain, and make available serialized data to small-dispenser and non-small-dispenser customers. Therefore, PDSA anticipates that most upstream trading partners will provide unit-level data for all downstream trading partners regardless of the size of their customer. As FDA understands, small dispensers, following the enforcement discretion, are not

[2] Verification is defined in 581(28), and additional requirements are established for trading partners in paragraphs (b)(4), (c)(4), (d)(4), and (e)(4) of section 582 of the FD&C Act.

required to capture, maintain or use the unit-level standardized numerical identifier (SNI) until Nov 27, 2026.

II. Additional WEEs Will Add Complexity and Uncertainty To The Supply Chain

PDSA generally appreciates FDA's decision to drive unprepared trading partners to the WEE process. This approach continues to move the industry toward stabilization while affording those that are unprepared to individually identify themselves and make the case to the Agency for a WEE. It is important for FDA to appreciate the complexity that numerous WEEs will introduce to the supply chain, particularly for WEEs focused on readiness for November 27, 2024, due to the short timeframe for FDA to process and industry to implement and communicate WEEs which could be communicated by both upstream and downstream partners depending on where a trading partner sits in the supply chain. We strongly urge the Agency to standardize the scope and structure of WEEs it grants. FDA has signaled that each WEE applicant should define the scope of its desired WEE, but this could lead to a multitude of WEE scopes, including WEEs issued for:

- Specific lot numbers;
- Specific National Drug Codes (NDCs);
- Specific date ranges;
- Specific types of transactions;
- All products and transactions for designated organizations; and
- And other scopes.

Trading partners have implemented complex systems and processes to meet their DSCSA obligations, and those systems cannot simply be turned on and off for a variety of different contexts across hundreds of trading partners. Based on readiness survey data presented during the June 17th FDA and Partnership for DSCSA Governance (PDG) joint public meeting, PDSA anticipates a large volume of WEEs before November 2024. Managing such a diverse and voluminous array of WEEs will be incredibly complex and inefficient, again, leading to the diversion of limited resources away from valuable data stabilization efforts. We urge the Agency to standardize the scope of WEEs it grants to the maximum extent possible in order to improve efficiency and limit disruption to the industry's continued progress towards stabilization.

III. Communication of WEE Grants and Conclusions Are Critical for All Trading Partners

The Waivers, Exceptions, and Exemptions from the Requirements of Section 582 (WEE Final Guidance) outline important processes for applicants to follow. It is critical that trading partners promptly communicate an FDA-granted, WEE to their direct trading partners, including small dispensers who meet the definition established by FDA for exemption. The WEE Final Guidance outlines expectations for trading partners when a WEE is concluded and how, or if, trading partners are expected to validate each WEE.

PDSA recommends TP utilize the following process and guidelines:

- The WEE requestor/applicant must be the party who communicates to their direct TP, including guidance to pass that information down the chain to subsequent TP.
- Notification should occur prior to the first product shipment once a WEE is granted, or once a WEE is concluded.
- Notification should also occur once a WEE has been concluded or expired.
- DSCSA stakeholders are currently discussing how to establish an effective communication system.

PDSA believes that when a WEE is granted, it is granted for all products and all TP in the supply chain who own the products that fall under the application, and includes an effective period negotiated with FDA. New products/transactions introduced into the supply chain for a first sale will not be grandfathered following the conclusion of the WEE. PDSA suggests FDA explicitly declare WEEs in place through expiry to allow product to pass through the supply chain more efficiently to relieve any confusion.

While the WEE process is laid out in guidance as a method to achieve compliance for entities not prepared, downstream TP are expected to establish complex processes to track these products. TP are expected to communicate with their direct trading partners once a WEE is granted by FDA. Public dissemination of such information could provide a dangerous security gap, but direct communication is critical to allow TP to deliver products to patients. If data does not accompany product, or a WEE is not communicated, safe product will be flagged as suspicious and undergo quarantine instead of being dispensed to patients. Additionally, TP must rely on each other to honestly communicate status. Currently no methods exist that support the validation or authenticity of a WEE claim. TP have no process for validation, nor the time to validate other TP claims for WEEs.

FDA does not provide clear communication timelines for WEE applicants, and previous examples were subject to varying timelines. Specific, and consistent, timelines will also allow FDA to maximize resources, and where appropriate, prioritize applications. Trading partners who submit WEEs must prepare prior to submission for an application to be either granted or denied which takes both time and resources. Similarly, once a determination is made by FDA trading partners will need to implement their plans. Prompt communication between FDA and applicants is critical to ensure maximum patient access is achieved.

Finally, only FDA has full visibility of all applicants. The WEE Final Guidance highlights FDA's role in initiating WEEs to "address an issue that affects a broad segment(s) of industry and/or multiple trading partners, impacts many drug distribution activities, or involves numerous products." Especially when patient access may be compromised, PDSA requests FDA initiate WEEs where appropriate for products, or multiple trading partners. FDA's role is critical to determine what trends exist and how to proactively address compliance concerns. Following FDA's August 1, 2024, deadline, PDSA also requests FDA publicly disclose details of the number of WEEs requested to date, and any initial trends apparent in the data (i.e., Are some sectors, or segments of sectors, requesting WEEs at a higher rate than others? Is FDA granting multiple WEEs for specific products or product types?). We are not requesting public disclosure of who applied for, or received, WEEs to avoid security concerns. Additional clarity will help

reduce uncertainty for trading partners to prepare and resource appropriately, benefiting patient access.

IV. NextGen DSCSA Tools Require Additional FDA Troubleshooting and Support

Following the announcement of NextGen's DSCSA tools PDSA would like to thank FDA but also provide some feedback and areas for improvement.

PDSA understands the DSCSA portion of the portal is new fairly, requiring trading partners, users, and FDA to establish and fine-tune processes and supporting documentation. However, over the course of the last several months, PDSA members have experienced errors, and difficulties, and collected comments about the operation of NextGen. Below are several areas PDSA suggests FDA incorporate into current and future frequently asked question (FAQ) documents, and other technical supporting documents to address the following:

1. If a company is not registered in NextGen how will FDA reach out to ensure appropriate DSCSA questions are routed to the appropriate staff? Many companies have multiple registrations, how will FDA know the appropriate contact for DSCSA instead of other NextGen tiles (i.e., drug shortages)?
2. If a DUNS number is required, which one should be used? Some companies have several numbers.
3. Will state regulators also use the portal or are they expected to have separate systems and processes?
4. PDSA requests further guidance in the form of webinars, videos, or written documents to support continued trading partner learning. Additionally, PDSA members request a walkthrough of a simulated trace/verification request with a trading partner.
5. What if the NextGen Portal is not operational due to technical issues (similar to recent widespread outages of banks and airlines from the CrowdStrike error), a natural disaster, etc.?
6. Will the portal improve search features in the future? Some search functions currently available are not functioning properly such as search for NDCs, company identification numbers, and availability for download of PDFs indicating the end of investigation where the portal shows these available for download, but the PDFs are not there.
7. Submissions to the portal should be allowed in multiple file formats to accommodate various formats currently used by trading partners. Industry stakeholders are currently working on standard Excel, XML, and PDF formats that industry could use to submit information to the NextGen portal in the future.

Conclusion

PDSA thanks FDA for the implementation of DSCSA. We look forward to continued collaboration with the Agency and the opportunity to support you. To the extent it is useful to the Agency, we offer our experience and expertise as a resource and welcome the opportunity for further discussion of our recommendations. Thank you for this opportunity to comment.

Sincerely,

The Pharmaceutical Distribution Security Alliance (PDSA)[3]:

Manufacturers:
Association for Accessible Medicines (AAM)
Pharmaceutical Research and Manufacturers of America (PhRMA)
AbbVie
AstraZeneca
Bayer
Bristol-Myers Squibb
Fresenius Kabi
Genentech
GlaxoSmithKline
Johnson & Johnson
Novartis
Novo Nordisk
Pfizer
Upsher-Smith Laboratories
Viatris (formerly Mylan)

Wholesale Distributors:
Healthcare Distribution Alliance (HDA)
Cencora
CardinalHealth

Third-Party Logistics Providers:
International Warehouse Logistics Association (IWLA)
Inmar

Dispensers:
American Pharmacists Association (APhA)
CVSHealth

[3] Members are listed according to their primary supply chain sector, but many operate business units across multiple sectors.