Healthcare Distribution Alliance

HEALTH DELIVERED

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Re: Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act; Establishment of a Public Docket; Request for Information and Comments

Dear Dr. Verbois and Dr. Jung,

The Healthcare Distribution Alliance (HDA)[1] thanks the Food and Drug Administration (FDA) for the opportunity to submit comments to the agency's request for information titled "Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act" (RFI).[2] The RFI asks four questions to trading partners on how partners are using the stabilization period to troubleshoot and mature secure, electronic, interoperable systems and processes for enhanced drug distribution security, as required under the Drug Supply Chain and Security Act (DSCSA). The RFI also seeks information on the successes and strategies that trading partners have operationalized since FDA's issuance of its Stabilization Policy.[3]

Industry has roughly ten months left under FDA's Stabilization Policy and we applaud FDA for collecting information from stakeholders during this critical time. Yet time is of the essence, and our members are increasingly concerned that the RFI is not enough engagement from FDA at this crucial moment. In our

[1] HDA represents primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently.
[2] 88 Fed. Reg. 80726 (Nov. 20, 2023).
[3] 88 Fed. Reg. 58498 (August 28, 2023).

comments that supported FDA's Stabilization Policy, we urged FDA to adopt and recommend phased milestones for industry sectors throughout 2024 to allow for adequate time, in a stepwise manner, for stabilization of the complex processes necessary for compliance and tracing at the package level.[4] To date, FDA has not adopted such an approach.

Now, five months after the issuance of the Stabilization Policy, stakeholders need FDA to take an assertive and forward-leaning approach to lead industry into the final phase of DSCSA implementation.

Specifically, HDA asks that FDA:

1. **Use the information collected from the RFI to promptly compose a comprehensive picture of supply chain readiness.**
2. **Acknowledge the reality of readiness in the supply chain and advise industry of FDA's intention to use enforcement approaches following the end of the Stabilization Policy.**
3. **Commit to intensive communication strategies during the remainder of the Stabilization Policy, including the issuance of targeted "Dear Trading Partner" letters.**

We provide more details below.

I. The DSCSA Landscape During the Stabilization Policy

In our comments to the Stabilization Policy, we requested FDA take three actions:

- Swiftly issue accessible communication summarizing what is expected of all trading partners during the stabilization period;
- Renew focus on educational outreach;
- Publicly recognize necessary milestones and clearly describe expectations for trading partners.[5]

Specifically, we asked FDA to publicly endorse a phased approach that builds to full compliance with the DSCSA.[6] As HDA explained, given the interdependency of supplier and customer, where the customer generally cannot send serialized data to its customer if the supplier did not provide it, getting to November 27, 2024, must be done in a stepwise fashion.

Since the issuance of the Stabilization Policy, however, FDA has provided no further direction to industry on these phases. In the absence of additional direction from FDA, our members have described the following continued issues with trading partners, including, but not limited to:

- Some trading partners are continuing to transact sealed cases but cannot or will not provide product identifiers for each package in the sealed case; in some instances, these

[4] HDA Stabilization Comments, *available at* https://www.regulations.gov/comment/FDA-2023-D-1909-0003.
[5] *Id.*
[6] *Id.* HDA stated that FDA should recommend that trading partners meet the following milestones: "1) By April 1, 2024, FDA generally expects that manufacturers and repackagers will be compliant with § 582(g)(1)(A) and (B) requirements for all products they transact with other trading partners. Manufacturers and repackagers would be expected to provide accurate and complete aggregated serialized data[6] by this date; 2) By July 1, 2024, FDA generally expects wholesale distributors will be compliant with § 582(g)(1)(A) and (B) requirements for all products transacted by wholesale distributors to other trading partners; and 3) By September 1, 2024, FDA generally expects dispensers to be compliant with §582(g)(1)(A) and (B)."

suppliers cannot estimate when they will be able to provide package-level data, or if they will ever be able to do so.
- If trading partners are able to provide serialized data for some transactions for some products, the transaction data provided are incomplete or inaccurate.
- Some trading partners are not providing serialized transaction data at or prior to delivery of the product.
- Other trading partners are viewing November 27, 2024, as the only relevant compliance date, and are therefore, delaying the investments and commitments necessary for DSCSA compliance.

Our members continue to address these concerns with trading partners through execution of a variety of individual business-to-business communication strategies. For example, members have described using weekly "score cards" with trading partners for transactions with an Advanced Ship Notice (ASN) or new Electronic Product Code Information Services (EPCIS) data elements, which are meant to strongly encourage migration to the package-level data exchange that enables compliance. Other members describe efforts to use the stabilization period to "turn on" EPCIS data exchange and package-level systems well in advance of November 27, 2024, to be able to scrutinize transaction data, identify errors and gaps, and address the problems and discrepancies with trading partners. In some instances, however, this strategy has been met with pushback from trading partners who argue that compliance with the DSCSA is not required until November 27, 2024. We have learned that some trading partners have warned their wholesale distributor customers of potential legal consequences if they try to "turn on" systems for package-level serialized data before November 27, 2024. Such warnings frustrate the purpose of FDA's Stabilization Policy, which, as FDA has explained, is intended to simply stabilize systems and processes that should have already been in place as of November 27, 2023.

From the perspective of HDA members, progress towards full DSCSA compliance remains too slow.[7] Many trading partners are still not consistently exchanging accurate serialized data for all NDCs for all transactions in accurate and complete EPCIS files. We believe this experience to be consistent with that of other committed stakeholders.

Without a clear picture of the state of the supply chain right now, the end of the Stabilization Policy could mean:
- Wholesale distributors cannot lawfully purchase products unless the manufacturer sends serialized data.
- Wholesale distributors cannot easily provide complete serialized data to customers if they did not receive serialized data from the manufacturer.
- Wholesale distributors cannot concurrently use both the current system of receiving lot-level data (typically in an ASN) and EPCIS for DSCSA compliance.

[7] HDA conducted a survey in October 2023 to capture quarter three (Q3) insights from supply chain partners on sending serialized and aggregated EPCIS data. Each survey was distributed via email, with 85 companies responding: 58 manufacturers (38 brand and 20 generic) and 27 distributors. Given that many HDA members have hundreds of manufacturer-suppliers, this survey is limited in scope and represents only a small subset of the industry who are highly engaged in implementing data exchange requirements under the DSCSA. To that end, the survey paints an inconclusive and incomplete picture on supply chain readiness at this time but does show that of these highly engaged trading partners, there is a modest upward trend of data exchange connections between trading partners. HDA is currently conducting a follow up survey to capture data on EPCIS data exchange in quarter four (Q4) of 2023 and hopes to be able to share the survey results with FDA in the near future.

More succinctly, HDA members have expressed concern that without a clear picture of the state of the supply chain right now, there could be significant supply chain disruptions that could contribute to drug shortages and patient access to needed medications at the end of the Stabilization Policy.

II. HDA urges FDA's leadership to be assertive and forward-leaning during the remainder of the Stabilization Policy.

Stakeholders need FDA to assert its authority and lead industry into the final phase of DSCSA implementation. To that end, HDA asks FDA to do the following:

1. FDA should use the information from the RFI to promptly compose a comprehensive picture of supply chain readiness.

FDA sits in the best position to leverage information collected from the RFI to depict a holistic view of supply chain progress and identify gaps in readiness. Further, FDA should promptly inform stakeholders of what FDA believes is the state of DSCSA compliance well before the expiration of the Stabilization Policy. This transparency would foster collaboration and help ensure stakeholders are aligned towards our shared goal. As FDA understands, some trading partners may be reticent to share successes, failures, and proprietary strategies in a public setting. To that end, we appreciate that FDA has provided an opportunity for trading partners to privately share information with the agency. Utilizing both data sets, we ask FDA to provide needed insights into where the entire industry is right now in terms of readiness.

We urge that FDA do this analysis well in advance of the conclusion of the Stabilization Policy. Completing this analysis by May 1, 2024, would demonstrate the FDA's commitment to timeliness and efficiency. This swift action would help instill confidence in industry stakeholders and expedite progress towards DSCSA readiness.

2. FDA should acknowledge the reality of readiness in the supply chain and advise industry of its intention to use enforcement approaches following the end of the Stabilization Policy.

FDA should issue details about its intended enforcement approaches, post-November 27, 2024, informed by industry-submitted data. Such communication would foster trust and collaboration and might motivate those who continue to delay implementation into compliance. In prioritizing enforcement activities, we urge FDA to consider the nature of the violation and a trading partner's documented good faith efforts to ensure equitable enforcement. This nuanced approach would acknowledge the complexities involved in achieving compliance and incentivize positive behavior through recognition and support.

We also urge FDA to collaborate more openly and frequently with state regulators about trading partners' obligations under the law. Without collaboration with states regulators, FDA risks replicating the pre-DSCSA patchwork of state regulations and interpretations, hindering national supply chain integrity, and undermining the very goals of the statute. HDA members report that some state regulators are already requesting information from businesses on DSCSA compliance practices. Members report that in these instances, they can collaborate with state

regulators on applicable DSCSA requirements. However, to achieve effective oversight, it is imperative that FDA facilitate a unified enforcement message across states.[8]

Finally, while the end of the Stabilization Policy marks a significant milestone for the DSCSA, it is crucial that FDA recognize that the complexity and unprecedented nature of the DSCSA necessitates continuous maintenance efforts far into the future. The DSCSA demands a complete overhaul of the pharmaceutical supply chain infrastructure, requiring seamless interoperability between various stakeholders and intricate data exchange standards. Achieving this level of integration takes time, ongoing refinement, and an understanding that these new systems carry an inherent learning curve. To that end, we specifically urge FDA to acknowledge the realities of moving from lot-level data and the familiar ASN to package-level data in the new EPCIS file format. Interoperable data exchange is a complicated transition for trading partners and FDA should acknowledge that enforcement approaches will remain adaptable and evolve along with these changing processes.

3. FDA should commit to intensive communication strategies during the remainder of the Stabilization Period, including the issuance of targeted "Dear Trading Partner" letters.

As discussed in Section I, HDA members report that throughout the period covered by the Stabilization Policy they have sought to facilitate via business-to-business solutions a phased approach that would enable the interoperable exchange of data. These efforts have resulted in modest success, though the lack of urgency to ramp up connections and data exchange remains a real concern. For the remainder of the Stabilization Period, we urge FDA to bolster our members' continued efforts by communicating with trading partners, in a stepwise approach, to help them understand their obligations under the law. Specifically, we urge FDA to issue "Dear Trading Partner" letters to each sector, outlining requirements and potential enforcement approaches. Letters to manufacturers and repackagers should be sent no later than May 1, 2024, with letters to the wholesale distributor and dispenser sectors following in a staggered pace shortly after. We believe it is significantly more persuasive to trading partners if FDA presents these letters with clear expectations on a post-Stabilization Policy landscape and that these communications originate from the agency rather than trading partners.

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We thank FDA for this opportunity to submit comments to FDA's RFI. If you have any questions, please contact me at kshankle@hda.org.

Sincerely,

/s/ Kala Shankle

Kala Shankle
Vice President, Regulatory Affairs

[8] Though the DSCSA broadly preempts state product tracing requirements which are inconsistent with, more stringent than, or in addition to, any DSCSA requirements, the statute specifically preserves numerous state enforcement authorities, including the authority to regulate trading partners consistent with the DSCSA. *See* § 582(a)(1), (b)(4).