



Healthcare Distribution Alliance

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Re: Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act— Compliance Policies Guidance for Industry, 88 Fed. Reg. 58498 (August 28, 2023), Docket No. FDA–2023–D–1909

Dear Dr. Verbois and Dr. Jung:

The Healthcare Distribution Alliance (“HDA”)¹ thanks the Food and Drug Administration (“FDA”) for this opportunity to submit comments regarding the agency’s Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act— Compliance Policies Guidance for Industry (“Stabilization Policy”). We greatly appreciate the agency’s leadership and timely release of this guidance as it provides critical clarity for the pharmaceutical supply chain as it continues to work toward achieving compliance with the Drug Supply Chain Security Act’s (“DSCSA”) requirements for interoperable, secure, electronic tracing of products at the package level.

The Stabilization Policy, in some respects, is aligned with the principles of HDA’s [Proposed Phased Approach To Achieving Interoperable Electronic Exchange Of Product Identifiers In Transaction Information](#) (“Phased Approach”) submitted on June 2, 2023. HDA’s proposed Phased Approach was broadly supported by industry stakeholders to help achieve the prescription drug product traceability and security goals of the DSCSA, while also minimizing the potential for supply disruptions and interruptions to patient care.

In our comments below, we discuss HDA’s support for FDA’s Stabilization Policy and how it addresses certain concerns we raised in HDA’s proposed Phased Approach. We next describe challenges to implementation of §582(g)(1) that the Stabilization Policy does not address, but should, to facilitate the supply chain’s ability to achieve full compliance with the DSCSA. Addressing these

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.

obstacles is beyond the ability of any single trading partner and as such, FDA's continued, timely, and clear leadership is especially critical. To that end, we respectfully ask that FDA:

- Issue further communications summarizing what the Stabilization Policy means and what the agency expects of all trading partners for the Stabilization Policy to apply;
- Renew its focus on educational outreach to stakeholders; and
- Publicly recognize that certain milestones must be achieved across the supply chain in a stepwise manner to achieve §582(g)(1) compliance in an efficient and orderly manner and clearly describe the agency's expectations for trading partners to meet those milestones. Specifically, FDA should recommend that trading partners meet the following milestones:
 - 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 data² by this date.
 - 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.
 - By September 1, 2024, FDA generally expects dispensers to be compliant with §582(g)(1)(A) and (B).³

1. HDA Supports the Stabilization Policy

HDA's proposed Phased Approach grew from numerous issues that had to be addressed, and milestones that had to be achieved, to build the capacity and capability for full, end-to-end, supply chain compliance with § 582(g)(1). The Stabilization Policy is a meaningful step that resolves some of these issues, and HDA is pleased to support it.

Specifically, we appreciate that the Stabilization Policy addresses, to an extent, the challenges of interdependency in the DSCSA, with each supply chain partner's compliance in part dependent upon its supplier's compliance, yet all trading partners having the same compliance effective date. The one-year stabilization period will give time for more serialized data to move between manufacturers and wholesale distributors, which will, in turn, enable more serialized data to move between wholesale distributors and dispensers. We also thank FDA for specifying that the Stabilization Policy's non-enforcement is predicated, in part, upon trading partners continuing all current

² We refer to "serialized data" as the requirement of §582(g)(1)(B) that the transaction information ("TI") required for a transaction shall include the product identifier at the package level for each package included in the transaction. Section 582(g)(1)(A) requires that the TI (including the product identifiers for the packages in the transaction) and transaction statements ("TS") (collectively "transaction data") must be exchanged in a secure, interoperable, and electronic manner.

³ We recognize that some dispensers may believe they need additional time beyond November 27, 2024, and that compliance dates may be impacted by the small business assessment currently underway pursuant to §582(g)(3). See [Drug Supply Chain Security Act \(DSCSA\) Assessment of Small Dispensers](#) and 88 Fed. Reg. 54320 (Aug. 10, 2023).

methods of data exchange until November 27, 2024. Finally, FDA's assurance that products in transitional inventory⁴ introduced by the manufacturer or repackager in a transaction before November 27, 2024, can continue to be transacted with lot-level transaction data is helpful.

2. Remaining Challenges

Though the Stabilization Policy is useful in moving the supply chain to full compliance with §582(g)(1) requirements, certain concerns that are outlined below remain.

a. Reluctant Trading Partners

Following the release of the Stabilization Policy, HDA members report that many of their trading partners have properly understood that FDA "generally expects trading partners to have the systems and processes in place to meet these [§582(g)(1)] requirements as of November 27, 2023." These trading partners are using the Stabilization Policy to be more measured and deliberate as they begin, or ramp up, package-level data exchange; they are working with other trading partners to implement a phased approach at a business-to-business level.

However, there are also trading partners who have interpreted FDA's announcement as a one-year delay. At the HDA Traceability Seminar on August 30, 2023, numerous attendees described to FDA the dozens of requests they were receiving from trading partners intending to stop their §582(g)(1) implementation plans and only restart in mid or late 2024. FDA recognized the problem of these trading partners during the Traceability Seminar.⁵

To motivate these reluctant trading partners, we urge the agency to be very clear that the Stabilization Policy's application is predicated upon trading partners **both** continuing current requirements **and** being generally compliant with §582(g)(1) as close to November 27, 2023, as possible (including demonstrable efforts to achieve full compliance). In Section 3a, we urge FDA to widely communicate these critical conditions.

b. Unaggregated Products

While aggregation is not specifically required in the DSCSA, the statute does contemplate its use and FDA has recognized it is an essential business process for the efficient purchase and resale of products.⁶ Most fundamentally, to generate the required transaction data, no trading partner can sell a larger sealed container that contains individual, serialized products unless the trading partner has captured the product identifiers on the units within the sealed container and aggregated those individual identifiers to the identifier on the larger sealed container. When the DSCSA required manufacturers and repackagers to affix product identifiers to the smallest saleable unit in 2017 and 2018, many also at that time updated labeling and packaging processes to accomplish aggregation.

⁴ We have referred to "transitional inventory" as products first entering commerce in a transaction before November 27, 2023, that are accompanied by compliant current, lot-level transaction data that are resold after November 27, 2023, when serialized data exchange requirements would otherwise apply.

⁵ HDA's Phased Approach proposed that any reluctant trading partners who could not provide serialized data in complete and accurate EPCIS event files had to obtain an exemption from the agency. Unless they are directly accountable to FDA, we continue to be concerned that trading partners who have delayed may continue to avoid the necessary implementation costs and commitments, putting the supply chain – and the compliance of other trading partners – at risk.

⁶ [Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act Guidance for Industry](#).

Others, however, delayed this investment and are now faced with knowing there is serialized product in sealed cases but not knowing which serial numbers are in which cases.

As we discussed in our proposed Phased Approach, HDA understands that there are still manufacturers who are not aggregating the products and still cannot generate serialized data for the products in sealed containers, including cases.⁷ We are concerned that the Stabilization Policy places upon wholesale distributors the burden of policing these non-compliant trading partners. Our members do not know how much unaggregated product remains in their suppliers' inventory nor when they can expect to receive serialized data for all NDCs. We include in Section 3 suggestions for how FDA can help support the rapid transition to serialized data exchange and resolve this uncertainty.

c. Transitional Inventory

As discussed in Section 1 above, we support how the Stabilization Policy addresses transitional inventory.⁸ Allowing such products to continue to be transacted with lot-level data is helpful to supply chain efficiencies, may prevent supply disruptions, and avoids various complex, expensive, and highly technical workarounds.

However, there are practical considerations that regulators should be aware of that result when some products entered commerce in a transaction with serialized data, and identical products, with the same NDC are not supported by serialized data. Realistically, such products – one package or case with serialized data and an identical package or case without – will be in a wholesale distributor's (and dispenser's) inventory at the same time. There will be no way to distinguish these products until a trading partner scans the identifier on a package or case and realizes it does not have serialized data. Moreover, there is no way of determining if the absence of serialized data is because the product first entered into commerce in a transaction before November 27, 2024, or whether it is because of a "clerical error" or other data discrepancy as addressed in the Final Guidance for Industry, [Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act](#).

These transitional products are a natural result of the DSCSA itself, and they will be in the supply chain for some time. The package or case was not transacted with serialized data because there was no requirement that the manufacturer or repackager provide it; therefore, a package cannot be traced at the package level and, if returned, cannot be associated at the package level, with the transaction data for that package. Each trading partner will need to develop business processes for the management of these products as its inventory slowly transitions solely to products supported by serialized data. Education of FDA inspectors and state regulators will also be important so that regulators understand how the bank of serialized products and data associated with them will build over time and that end-to-end tracing at the package level will not be possible until all trading partners are exchanging and maintaining accurate and complete serialized data.

The ability of downstream trading partners to maintain and provide serialized data depends upon having received serialized data from manufacturers and repackagers. Encouraging manufacturers to

⁷ To address this issue, HDA's Phased Approach proposed that such manufacturers would need to obtain exemptions from FDA, making them accountable to the agency; these manufacturers would have to explain when they would be able to generate serialized data when they introduce these products in a transaction in interstate commerce.

⁸ See Stabilization Policy at page 5.

aggregate products and provide serialized data as soon as possible is critical to reducing the amounts of such products in wholesale distributor and dispenser inventories.

3. HDA Asks for Continued FDA Leadership and Specific Actions

HDA described in its comments to the DSCSA Public Meeting in December 2022⁹ and in its proposed Phased Approach that moving from lot-level data and the familiar Advanced Ship Notice (“ASN”) to item-level data in the new Electronic Product Code Information Services (“EPCIS”) event file format and interoperable data exchange is a very complicated transition for trading partners. FDA’s Stabilization Policy recognizes that there will be “some technical and operational issues” and that time may be needed “for systems to stabilize and be fully interoperable for accurate, secure, and timely electronic data exchange.”¹⁰

Given the interdependency of supplier and customer, where the customer generally cannot send serialized data if the supplier did not provide it, getting to November 27, 2024, must be done in a stepwise fashion. In HDA’s proposed Phased Approach, we suggested two years of specified milestones. FDA’s Stabilization Policy has given the supply chain one year. Thus, ***for every trading partner to achieve full §582(g)(1) compliance by November 27, 2024, there is an urgent need for additional FDA leadership and direction.***

To that end, HDA requests that FDA take the following actions:

a. **Swiftly Issue Accessible Communication Summarizing What Is Expected of All Trading Partners During the Stabilization Period**

We appreciate that FDA utilized HDA’s Traceability Seminar to announce its Stabilization Policy to communicate FDA’s expectations to the supply chain. However, it is critical that the agency does more outreach. As has been reported to FDA, some trading partners who may have already been behind heard “one year delay” and immediately stopped efforts to achieve compliance. Reaching these trading partners is imperative.

Stakeholders who are pushing these slow and reluctant adopters believe that a concise and unambiguous statement from the agency is critical. To reach the maximum audience effectively and swiftly, this message should be crisp, easily accessible, and in formats that can be easily shared. Trading partners, advocates, reporters and bloggers, trade associations, service providers, and others in the DSCSA “ecosystem” should be able to easily amplify FDA’s message.

We urge this level of outreach to be done swiftly and be very brief. We suggest a Q&A format in which FDA sets out succinctly the two essential conditions of the Stabilization Policy: (i) Continuation of current requirements; and (ii) Generally having the systems and processes to meet §582(g)(1) as close to November 27, 2023, as possible with demonstrable efforts toward achieving full compliance.

b. **Renew Focus on Educational Outreach**

The ability of the entire supply chain to achieve the enhanced drug distribution security requirements of §582(g)(1) depends upon each trading partner being able to, as applicable, exchange accurate and complete serialized data electronically and interoperably. These new requirements are layered

⁹ HDA’s comment is available [here](#).

¹⁰ Stabilization Policy at page 4.

on top of existing requirements in §582 that continue, such as only doing business with authorized trading partners, only transacting serialized products, and having verification systems and processes in place.

It is HDA's understanding that there continues to be widespread confusion about the DSCSA's requirements. Many trading partners are unaware of current requirements and/or continue to delay implementation of the final, §582(g)(1) requirements. State regulators, similarly, continue to not understand the applicable requirements so that they may knowledgeable inspect against them. Therefore, we ask that, in addition to the above-described communication on the Stabilization Policy, the agency also bolster its DSCSA education and outreach to all stakeholders.

c. Publicly Recognize Necessary Milestones and Clearly Describe Expectations for Trading Partners

HDA's proposed Phased Approach suggested implementing the final requirements of §582(g)(1) in phases to allow adequate time to stabilize the complex processes necessary for compliance and tracing at the package level and ensure a smooth transition to full implementation.

We still believe that the principles of HDA's proposed Phased Approach are valid though we acknowledge that the Stabilization Policy addresses some of the concerns that prompted submission of our proposal. Given the interdependencies of §582(g)(1) and that generally, compliance cannot begin for a customer until its supplier is providing serialized data, we continue to believe that the supply chain will have to reach the DSCSA's final requirements in phases.

HDA's proposed Phased Approach asked FDA to endorse a two-year timeline. Now, with FDA's Stabilization Policy that provides one year, we ask for FDA's support for a similar, albeit far more compressed, phased approach that builds to compliance with final § 582(g)(1) requirements, but in the shorter allotted time.

To that end, we suggest that FDA announce the following expectations for trading partners to continue to have the benefit of the Stabilization Policy's non-enforcement:

- All trading partners are expected to comply with all current §582 requirements¹¹ until November 27, 2024, to maintain current levels of supply chain security.
- FDA generally expects trading partners to have the systems and processes in place to meet §582(g)(1) requirements as of November 27, 2023, and that the one-year period of non-enforcement is to allow systems for interoperable, electronic transaction data exchange to mature and stabilize.
- FDA does not intend to issue a further broad compliance policy applicable to the entire supply chain. If a trading partner cannot meet all applicable §582 requirements by November 27, 2024, it will need to submit a request for an exemption to FDA, with such exemption request being submitted no later than September 1, 2024, if the trading partner expects a timely response.

¹¹ Compliance with certain verification requirements for wholesale distributors and dispensers is currently extended until November 27, 2024 pursuant to [Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product — Compliance Policies](#).

- To assist trading partners in meeting this aggressive timeline with all trading partners fully compliant with all § 582(g)(1) requirements by November 27, 2024, FDA should recommend that trading partners meet the following milestones:
 - 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 by this date.
 - 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.¹²
 - By September 1, 2024, FDA generally expects dispensers to be compliant with §582(g)(1)(A) and (B).
- As set forth in the Stabilization Policy, FDA further expects trading partners to be working on data and file accuracy and stabilization of systems for interoperable, accurate, secure, and timely electronic data exchange. FDA expects trading partners to communicate with one another about transaction data quality and accuracy to improve and stabilize interoperable data exchange.

We believe it is significantly more persuasive to trading partners if FDA presents specific milestones as expectations and recommendations of FDA that trading partners should meet if they wish to enjoy the continued benefit of non-enforcement during the Stabilization Period. Specifically, this underscores the seriousness of FDA's actions and would help to deter trading partners who may intend to rely upon last-minute compliance policy extensions. Importantly, in the absence of FDA leadership, meeting the necessary milestones for §582(g)(1) compliance becomes a strained, contentious, and repetitive business-to-business negotiation. We strongly urge the agency to recommend the above milestones as a means for the supply chain to collectively build to full § 582(g)(1) compliance by November 27, 2024.

* * *

We thank FDA for this opportunity to provide comments on the Stabilization Policy. If you have any questions, please contact me at kshankle@hda.org or 202-964-4439.

Sincerely,

/s/ Kala Shankle

Kala Shankle
Vice President, Regulatory Affairs

¹² As discussed above, the Stabilization Policy provides that product introduced by the manufacturer or repackager in a transaction into commerce before November 27, 2024, may still continue to be transacted, through expiry, under current data exchange requirements and “that FDA does not intend to take action if the transaction information for [such] product ... does not incorporate—at the package level for each package in the transaction—the product identifier.” Stabilization Policy at page 5.