Healthcare Distribution Alliance

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Douglas C. Throckmorton, M.D.
Deputy Center Director Regulatory Programs
Office of the Center Director
Center for Drug Evaluation and Research
Food and Drug Administration
Building 51
10903 New Hampshire Avenue
Silver Spring, MD 20993
Douglas.Throckmorton@fda.hhs.gov

Leigh Verbois, Ph.D.
Director
Office of Drug Security, Integrity, and Recalls
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
Building 51
10903 New Hampshire Avenue
Silver Spring, MD 20993
leigh.verbois@fda.hhs.gov

Connie T. Jung, R.Ph., PhD
Senior Advisor for Policy
Office of Drug Security, Integrity, and Recalls
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
Building 51
10903 New Hampshire Avenue
Silver Spring, MD 20993
connie.jung@fda.hhs.gov

Dear Doctors Throckmorton, Verbois, and Jung:

The Healthcare Distribution Alliance (HDA) thanks the Food and Drug Administration (FDA) for this opportunity to provide you with our proposed *Phased Approach To Achieving Interoperable Electronic Exchange Of Product Identifiers In Transaction Information* (*Phased Approach*). As we have discussed with each of you, this Phased Approach sets out our recommendations for achieving the prescription drug product traceability and security goals of the Drug Supply Chain Security Act (DSCSA) while also minimizing the potential for supply disruptions and interruptions to patient care.

About HDA And The DSCSA

HDA represents primary pharmaceutical distributors – the vital link between the nation's pharmaceutical manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, clinics, and others nationwide. This essential function is provided with little public recognition or visibility, and at great savings to the healthcare system. HDA members serve as the central link in a sophisticated national supply chain. HDA members take this mission very seriously, and we support manufacturers, healthcare providers, and the government in ongoing efforts to ensure the U.S. medicine supply remains secure, efficient, and highly regulated.

HDA and its wholesale distributor members have long supported the DSCSA. We collaborated with FDA and industry stakeholders to achieve passage of the DSCSA in 2013. Since that time, HDA's pharmaceutical wholesale distributor members have invested years of work and millions of dollars to reach the DSCSA's final requirements on November 27, 2023.

The Problem

Congress mandated in the DSCSA that ten years after the law's enactment, by November 27, 2023, prescription drug manufacturers, wholesale distributors, and dispensers must begin interoperably and electronically exchanging data with each other that identifies each prescription drug package purchased and sold. This data exchange will make it possible to trace prescription drugs forward and back in the supply chain at the individual, package level. This very complex capability does not exist today. Rather, today, prescription drugs can only be traced at the lot level, not the individual package level.

The package-level data exchange Congress envisioned is both interdependent and becomes effective for all trading partners at the same time. This means that the ability of wholesale distributors and dispensers to purchase and resell needed medicines from manufacturers is dependent upon a manufacturer's provision of this package-level data. Though this requirement has been known since 2013, given the complexity of developing necessary systems, many, if not most, manufacturers will not be ready by November 27 to send package-level data to their customers. Or, if they are ready, much of the data will not be accurate.

This lack of readiness creates serious risks to pharmaceutical supply. If manufacturers cannot interoperably exchange accurate package-level data, the DSCSA would prohibit wholesale distributors and dispensers from lawfully purchasing the prescription drugs needed for patient care. In other words, this lack of readiness by most manufacturers means their downstream trading partners cannot lawfully purchase the medicines dispensers and other healthcare providers administer and dispense to patients and could result in a significant disruption in patient care.

HDA's Recommended Solution

Given the lack of manufacturer readiness and the DSCSA's single compliance date for all trading partners, HDA recommends that FDA reach the DSCSA's final requirements in phases to build capacity and stabilize these complex processes. As we describe in the attached document, this *Phased Approach* would include an FDA grant of enforcement discretion limited to certain DSCSA requirements and trading partners, with full implementation phased in over a period of 2 years. Trading partners would continue current business practices needed to move medicines to patients safely and securely while also continuing the push toward the package-level tracing and enhanced supply chain security Congress envisioned.

Urgent Action Needed

We are now less than 6 months from final DSCSA implementation. HDA's wholesale distributor members are facing real business consequences right now as they prepare for the November 27 deadline. Our members report they must hire and train hundreds of new employees to implement DSCSA requirements. Many other trading partners are facing similar challenges, decisions, and required investments. We ask that the agency move very swiftly to address these concerns. We feel the recommended *Phased Approach* would be a workable solution that would forestall a potentially significant disruption to the nation's pharmaceutical supply chain.

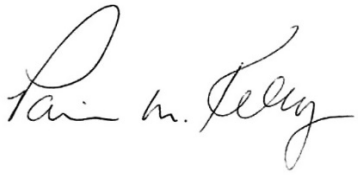
If the agency intends to grant enforcement discretion, it must do so quickly. As we explain, we oppose a blanket delay of the DSCSA 2023 requirements for all trading partners and urge this more nuanced approach. Though it preserves the status quo as trading partners ramp up interoperable data exchange, the *Phased Approach* will take time to understand and implement.

Further Engagement

We welcome the opportunity to meet with you to discuss our proposed *Phased Approach* and how we believe it will mitigate patient impacts while still achieving the important pharmaceutical tracing goals and will of Congress. We are in the process of sharing our *Phased Approach* with other pharmaceutical supply chain stakeholders who have expressed interest in our recommendations. We expect other entities will support our *Phased Approach*.

Please contact me or Elizabeth Gallenagh (egallenagh@hda.org) if you have any questions.

Sincerely,



Patrick Kelly
Executive Vice President, Government Affairs

A PHASED APPROACH TO ACHIEVING INTEROPERABLE ELECTRONIC EXCHANGE OF PRODUCT IDENTIFIERS IN TRANSACTION INFORMATION

Overview

The Healthcare Distribution Alliance (HDA) submits the attached recommendations to the Food and Drug Administration (FDA) to achieve traceability of drug packages in the pharmaceutical supply chain under the Drug Supply Chain Security Act (DSCSA). After careful consideration, HDA and its wholesale distributor members suggest implementing the final requirements of the DSCSA in phases in order 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. This stepwise approach would include an FDA grant of enforcement discretion limited to certain DSCSA requirements and trading partners, with full implementation phased in over a period of 2 years. Trading partners would continue current business practices needed to move medicines to patients safely and securely while also continuing the push toward the package-level tracing and enhanced supply chain security Congress envisioned when it enacted the DSCSA ten years ago.

* * *

The DSCSA mandates that all trading partners in the drug supply chain meet its final requirements no later than November 27, 2023. By that date, under the law, prescription drug manufacturers must provide to their purchasing customers – usually wholesale distributors – certain Transaction Information (TI) in a secure, electronic, and interoperable manner. In turn, each wholesale distributor must provide this TI to its purchasing customers – usually dispensers – in a similar secure, electronic, and interoperable manner. The FDA has stated that providing and receiving these data in an Electronic Product Code Information Services (EPCIS) event file satisfies this DSCSA requirement. EPCIS is a global standard for business-to-business exchange of product data.

These EPCIS event files that manufacturers and wholesale distributors provide to their purchasing customers must include in the TI the Product Identifier (a unique serial number affixed to each package) of each package that is sold – referred to as "serialized data." No downstream authorized trading partner can purchase and accept ownership of a prescription drug package if its supplier does not provide these serialized data. Additionally, that purchasing trading partner may only resell the prescription drug package if it provides serialized data to its trading partner customer.

With each trading partner providing, receiving, and maintaining records of purchases and sales that include each transacted package's Product Identifier in an EPCIS event file, tracing at the package level becomes possible. This capability does not exist today in the U.S. pharmaceutical supply chain. Rather, today, products can only be traced at the lot level, not the individual package level.

HDA's wholesale distributor members and their trading partners continue to make progress to meet these final DSCSA deadlines. However, many manufacturers will not be completely ready by November 27. Many have not yet established the business-to-business electronic connections with their customers that are necessary for the sending and receipt of the required EPCIS event files with serialized data. Separately, many manufacturers that can send EPCIS event files are finding that their serialized data are inaccurate and/or incomplete, which means that the serialized data they can send may not match the prescription drugs delivered to the customer. Though some manufacturers are ready (or will be) and would be compliant with the DSCSA on November 27, many are not.

This lack of readiness poses enormous problems for wholesale distributors and real risks to continued access to needed medicines for dispensers, healthcare providers, and, most importantly, patients. The package-level interoperable data exchange Congress envisioned is both interdependent and becomes effective for all trading partners at the same time. Adding to the complexity is that the ability of wholesale distributors and dispensers to purchase and resell needed medicines from manufacturers is wholly dependent upon a manufacturer's provision of this serialized data.

Without receipt of the requisite serialized data from its supplier, a wholesale distributor may not lawfully accept ownership of a covered drug product package or resell the package, which could lead to delivery disruptions to dispensers and even outright shortages of needed medicines. The only alternative would be to accept and distribute a drug package without the required serialized data, thereby risking enforcement action for non-compliance with DSCSA.

Neither option is desirable. Given the lack of broad manufacturer readiness and the DSCSA's single compliance date for all trading partners, HDA recommends that FDA enable the supply chain to reach the DSCSA's final requirements in phases. Those phases should build serialized data capacity in the supply chain, stabilize the interoperable exchange of accurate serialized data, and keep needed medicines flowing to patients. Additionally, a phased approach should keep in place existing safeguards, maintain pressure on unprepared trading partners, and not excessively burden those trading partners prepared to fully implement the DSCSA. HDA has developed such a pathway. It relies on a combination of FDA-granted exemption requests, limited enforcement discretion for defined time periods, and defined trading partner actions that are phased in over time.

Throughout our interactions with FDA, in our advocacy, and now in the phased approach explained below, HDA has consistently opposed an FDA grant of broad enforcement discretion that simply moves the compliance date for all trading partners another six months or a year, or more. Our opposition to such an approach is rooted in three critically important factors:

- For Congress's vision of interoperable tracing of prescription drug products at the package level to be realized, ***we urge FDA to keep the pressure on trading partners to ensure full implementation of the DSCSA.*** Broad enforcement discretion, without conditions and oversight, is likely to result in even more delay.

- There are real concerns with the stability of the data exchanges once these systems are "live" and trading partners are providing, receiving, and maintaining EPCIS event files with serialized data for every covered prescription drug transaction in the U.S. supply chain. The issues of quality and accuracy of serialized data and the ability of trading partner technology and personnel to manage the volume of transactions necessitate a slow build, not a single "on switch" with one compliance date for all trading partners. Simply extending the compliance date without a rational phase-in just moves the date on which the problems and issues become apparent once again.

- Last, and most important, a blanket grant of enforcement discretion ***would be catastrophic*** for wholesale distributors if it allows some manufacturers to provide serialized data in EPCIS event files while others are permitted to continue current practice to provide lot-level data (typically in an Advance Ship Notice or ASN). ***Once wholesale distributors convert from receipt of lot-level data to receipt of EPCIS event files for DSCSA compliance, they cannot continue to rely on the ASN as their DSCSA compliance document.***

    - Our wholesale distributor members spent millions of dollars and years of work to build their DSCSA technology systems to meet their 2023 obligations with the reasonable assumption that manufacturers would similarly meet their statutory obligations. Accordingly, wholesale distributor systems were not designed to ***concurrently*** maintain and employ two compliance methods for accepting transaction data. If any enforcement discretion period permits manufacturers to provide ***either*** EPCIS events files ***or*** ASNs as their means of complying with DSCSA TI requirements, we understand that wholesale distributors ***cannot***, at this date, rebuild their systems to accommodate both. They ***cannot*** operate two compliance systems simultaneously.

    - ***As such, a fundamental premise of our recommendations is that, during the first two phase-in periods, suppliers must continue the current practice of providing lot-level data (typically ASNs) to their customers while simultaneously working to ensure the provision of accurate serialized data in accurate, complete, and stable EPCIS event files.***

To summarize our recommendations for a 2-year phase-in to full DSCSA implementation and tracing of covered prescription drug products at the package level:

Phase 1, November 27, 2023 – November 26, 2024

- Manufacturers ramp up and stabilize their provision of package-level data to wholesaler distributors with each prescription drug transaction or obtain an exemption from FDA for package-level compliance until they can do so.
- To ensure that prescription drugs can continue to move in the supply chain to patients and to avoid crippling expenses and burdens for wholesale distributors, manufacturers must also continue the current practice of providing lot-level data with each prescription drug transaction to wholesale distributors.
- Wholesale distributors and dispensers maintain their current lot-level DSCSA business processes.

Phase 2, November 27, 2024 – May 26, 2025

- Manufacturers must comply with all DSCSA requirements and provide package-level data to wholesale distributors for each prescription drug transaction or must obtain an exemption from FDA if they cannot. Manufacturers would continue to provide lot-level data as well.
- Wholesale distributors would receive package-level data from manufacturers.
- Wholesale distributors would ramp up and stabilize their provision of package-level data to dispensers with each prescription drug transaction and would also continue providing lot-level data to dispensers so that prescription drugs continue to move in the supply chain to patients.
- Dispensers would continue to maintain their current lot-level DSCSA business processes.

Phase 3, May 27, 2025- November 26, 2025

- Manufacturers and wholesale distributors must comply with all DSCSA requirements and provide package-level data to their customers (including dispensers) with each prescription drug transaction.
- Dispensers work on stabilizing their business processes for receipt of package-level data from wholesale distributors and manufacturers.

At the conclusion of Phase 3, all supply chain trading partners would be expected to be in full compliance with DSCSA's package-level data requirements.

Key Terms And Concepts In This Document

"ASN" is the "Advance Ship Notice." It is an electronic data interchange (EDI) message sent from a shipper to the receiver prior to the departure of the shipment from the shipper's facility and has been used by many trading partners since 2015 as the DSCSA compliance document for provision, maintenance, and receipt of lot-level data.

"DSCSA compliance document" refers to the DSCSA-required transaction data that a trading partner must provide, receive, and maintain. The DSCSA compliance document is intended to satisfy DSCSA requirements for the interoperable exchange of TI and TS beginning November 27, 2023, and, depending on the phase of implementation described herein, may be provided in an ASN, in an EPCIS event file, posted to a portal, or made available by some other appropriate means.

"Exclusive distributor" as defined in §581(6) means "the wholesale distributor that directly purchased the product from the manufacturer and is the sole distributor of that manufacturer's product to a subsequent repackager, wholesale distributor, or dispenser."

"Lot-level data" refers to the transaction data that trading partners are currently exchanging and maintaining to meet DSCSA requirements. When required by §582, lot-level data may include lot numbers of the packages in the transaction. Lot-level data, unlike serialized data, does not include the product identifier for each package in a transaction. When provided by a manufacturer, lot-level data is typically provided to a wholesale distributor in an ASN; when provided to a dispenser, lot-level data may be provided via an ASN, in a portal, or other appropriate means.

"Manufacturer" collectively means both manufacturers and repackagers as defined in §581(10) and §581(16), respectively, and further described in the *Draft Guidance for Industry, Identifying Trading Partners Under the Drug Supply Chain Security Act* (July 2022).

"NDC" means National Drug Code, a unique, three-segment number that FDA uses to identify drugs.

"Product Identifier" (PI) as defined in §581(14), means "a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product."

"Serialized data" is provided via an EPCIS event file and means transaction data that includes

- The product identifier for each package in the transaction

- The product identifier for each sealed homogeneous case in the transaction ***and*** the product identifier for each package within the case – the contents of a case are aggregated to the case identifier.

"Transaction data" means TI and TS. For purposes of this document, TS also includes the direct purchase statement when required.

"TI" means Transaction Information as defined in §581(26).

"TS" means Transaction Statement as defined in §581(27) and for purposes of this document, also includes the direct purchase statement, required by §582(c) to be provided by a wholesale distributor to a purchaser in certain transactions.

"Verification" or "Verify" means the definition in §581(28) which states that "The term "verification" or "verify" means determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager, as applicable in accordance with [§582]." For purposes of this document, "Verification" is limited only to this determination of whether the product identifier on a package or homogenous case is one that the manufacturer or repackager assigned. This document and the phased approach it describes are not intended to propose any alteration to the existing, pre-November 27, 2023 requirements regarding the verification systems and processes trading partners must have to identify, investigate, and quarantine suspect products and to make illegitimate product notifications as set forth in §582(b)(4), (c)4), (d)(4) and (e)(4).

"WEE" means a Waiver, Exception, or Exemption from certain DSCSA requirements that must be obtained from FDA. For purposes of this document, the WEE most likely to be relevant is an Exemption, as described in §582(a)(3).

Phase 1

Summary of Phase 1

- **Length of time HDA recommends: 12 months**
- **For manufacturers**: All manufacturers must provide serialized data to customers or obtain a WEE from FDA exempting their NDC(s) from serialized data exchange requirements. Regardless, manufacturers continue to also provide lot-level data to customers.
- **For wholesale distributors**: Wholesale distributors continue current practices and receive enforcement discretion for purposes of receiving and providing serialized data and related DSCSA requirements.
- **For dispensers**: Dispensers continue current practices and receive enforcement discretion for purposes of receiving serialized data and related DSCSA requirements.

I. Manufacturers

A. If a manufacturer ***cannot*** provide serialized data for an NDC, it ***must*** obtain a WEE from FDA for that specific product/NDC.

   1. Receipt of a WEE would exempt a manufacturer from §582(g)(1)(A), (B), (D), (E), and (F) (but not from (C)). Specifically:

      a. A manufacturer would be exempt from §582(g)(1)(A) and (B) – providing serialized data in an EPCIS data file.
      b. A manufacturer would be exempt from §582(g)(1)(D) and (E) – tracing at the package level.
      c. A manufacturer would be exempt from §582(g)(1)(F) – association of saleable returns at the package level.
      d. A manufacturer would be expected to be able to comply with §582(g)(1)(C) and be able to Verify the product identifier at the package level via email, phone communication, the Verification Router Service (VRS), or other appropriate means.

   2. The WEE would be time-limited, with a deadline by when the manufacturer must provide serialized data to all customers.

   3. As a condition of the grant of the WEE, the manufacturer must continue working with its trading partners towards achieving interoperable, electronic product tracing at the package level.

   4. As a condition of the grant of the WEE (and throughout Phase 1), the manufacturer must continue to provide lot-level data to customers following current practices (i.e., typically in an ASN) to satisfy transaction data and tracing requirements.

   5. During this initial phase, as serialized data is not being provided, received, or maintained, product cannot be traced at the package level.

B. If a manufacturer ***can*** provide serialized data for an NDC in an EPCIS event file, ***it must also*** continue current practice and provide lot-level data (typically in an ASN) to customers. A wholesale distributor will then be able to receive product based upon the lot-level data and accept ownership of, and resell products even if it were to discover an EPCIS data or file-related problem, or serialized data-related error (e.g., data quality problem, missing product identifiers in the data file, etc.).

As explained in the accompanying overview, wholesale distributors cannot simultaneously operate dual systems in which they physically receive, and accept ownership of, products (i) based upon lot-level data (typically in an ASN) for some manufacturers ***and*** (ii) based upon serialized data (in an EPCIS event file) from other manufacturers. This means a wholesale distributor can operate ***only one system,*** that is, it can only receive and maintain ***either*** the ASN ***or*** an EPCIS event file as its DSCSA compliance document for all products, but ***not both***.

1. The manufacturer continues to work with its customers to achieve accurate serialized data in accurate, complete, and stable EPCIS event files.

2. If the manufacturer receives a tracing request, it will be able to trace at the package level the sale of the package to its direct customers; other trading partners will not yet be able to do so.

II. Wholesale distributors

A. During Phase 1, because EPCIS event files will not serve as the DSCSA compliance document, wholesale distributors receive enforcement discretion from FDA limited to §582(g)(1)(A), (B), (C), (D), (E), and (F). Wholesale distributors would be excused from:

   1. §582(g)(1)(A) and (B) – receiving, providing, and maintaining serialized data in an EPCIS event file.

   2. §582(g)(1)(C) – Verification at the package level.[1]

   3. §582(g)(1)(D) and (E) – tracing at the package level.

   4. §582(g)(1)(F) – association of saleable returns at the package level.

B. Because they cannot operate dual systems, wholesale distributors must continue receiving lot-level data (typically within an ASN) from all manufacturers, even if a manufacturer also provides serialized data in an EPCIS event file.

C. The ASN (or other similar lot-level document) remains a wholesale distributor's DSCSA compliance document and is maintained for 6 years.

D. The wholesale distributor continues to work with manufacturers to assess the accuracy, completeness, and stability of all EPCIS event files received and the accuracy of the serialized data within them.

E. By continuing to receive lot-level data, a wholesale distributor will be able to accept ownership of products based upon that lot-level data and resell those products even if it were to discover an EPCIS data or file-related problem, or

[1] *See* definition of "Verification" in "Key Terms and Concepts." As further stated in Section IV below, Phase 1 is intended only to extend enforcement discretion to the determination of whether a product identifier on a package or homogenous case is one that the manufacturer or repackager assigned. *See* §581(28). It is assumed that all other existing requirements continue, such as systems and processes for suspect product investigations and notifications of illegitimate products.

serialized data-related error (e.g., data quality problem, missing product identifiers in the data file, etc.).

F. As to the outbound transaction data a wholesale distributor provides to its customers:

1. The wholesale distributor continues to provide lot-level data (in an ASN, a portal, or other means appropriate for the customer).

2. The ASN (or other similar lot-level document) remains the wholesale distributor's DSCSA compliance document and is maintained for 6 years.

3. The wholesale distributor also continues to onboard customers for EPCIS file exchange and prepare for the provision of serialized data.

G. Because a wholesale distributor is not yet receiving serialized data from the manufacturer as the DSCSA compliance document, certain functionalities will not yet be present.

1. For saleable returns, a wholesale distributor cannot "associate" a product at the package level and so will continue current practices of associating a return based upon lot-level information.

2. A wholesale distributor will not be able to trace products at the package level.

III. Dispensers

A. Until manufacturers and, in turn, wholesale distributors can achieve electronic, interoperable data exchange with accurate serialized data in accurate, complete, and stable EPCIS event files, dispensers receive enforcement discretion from FDA limited to §582(g)(1)(A), (B), (C), (D), (E), and (F).

B. Dispensers continue current practices while also being excused from the requirements of §582(g)(1).

C. Dispensers continue receiving lot-level data from their suppliers via an ASN, in a portal, or other appropriate means. The ASN (or other similar lot-level document) remains the dispenser's DSCSA compliance document and is maintained for 6 years. The lot-level data remains the DSCSA compliance document even if a dispenser begins the process of receiving serialized data in an EPCIS event file from any of its suppliers.

D. Because a dispenser is not yet receiving serialized data from its wholesale distributor supplier as its DSCSA compliance document, the dispenser will not be able to trace the product at the package level.

IV. Other Requirements

Phase 1 assumes enforcement discretion that is limited to the requirements of §582(g)(1)(A), (B), (C), (D), (E), and (F) for wholesale distributors and dispensers. All other §582 requirements not dependent upon the provision, receipt, and maintenance of serialized data continue. DSCSA requirements remaining in effect include, among other things, all packages and homogenous cases must bear compliant product identifiers, all trading partners must be authorized, all trading partners must maintain records, and all trading partners must have systems and processes for suspect product investigations and notifications of illegitimate products.

V. End of Phase 1

A. HDA recommends that Phase 1 last 12 months.

B. At the conclusion of Phase 1, manufacturers must have achieved electronic, interoperable data exchange with accurate serialized data in accurate, complete, and stable EPCIS event files to all customers for all NDCs. [NOTE: If a manufacturer uses an exclusive distributor, the exclusive distributor would be expected to achieve electronic, interoperable data exchange with accurate serialized data in accurate, complete, and stable EPCIS event files to all customers for all NDCs by the end of Phase 1.]

C. If any manufacturer (or exclusive distributor) is still not compliant at the end of Phase 1, it must obtain a WEE from FDA.

1. As emphasized previously, wholesale distributors cannot simultaneously operate dual systems in which they physically receive products based upon lot-level data (typically in an ASN) for some manufacturers and receive based upon serialized data (in an EPCIS event file) from other manufacturers.

2. Once Phase 1 ends, wholesale distributors should be receiving serialized data in EPCIS event files from manufacturers (and exclusive distributors), but manufacturers (and exclusive distributors) will continue to also provide lot-level data. ***Any*** covered products a manufacturer (or exclusive distributor) seeks to transact without serialized data must be exempted from the DSCSA ***entirely***. Such products would have to be treated like

other DSCSA-exempt products (e.g., certain intravenous products, blood products), with ***no*** transaction data provided, received, and maintained.

3. The WEE would be time-limited, with a deadline by when the manufacturer must be providing serialized data to all customers for that NDC. However, for each package of product that enters the supply chain under the WEE, the exemption would have to follow that package for its life in the supply chain, until expiry.

Phase 2

Summary of Phase 2

- **Length of time HDA recommends: 6 months after the conclusion of Phase 1**
- **For manufacturers**: All manufacturers must ensure electronic, interoperable data exchange by providing accurate serialized data in accurate, complete, and stable EPCIS event files and continue to provide lot-level data. Those manufacturers that cannot provide serialized data must obtain a WEE from FDA exempting their NDC(s) entirely from the DSCSA, including all transaction data requirements.
- **For wholesale distributors**: Enforcement discretion ends for purposes of receipt of serialized data from manufacturers (and exclusive distributors). Enforcement discretion continues for purposes of providing serialized data to dispensers and related DSCSA requirements. For the first 3 months of Phase 2, a wholesale distributor may decide whether the EPCIS event file or lot-level data is its DSCSA compliance document for purposes of product receipt; during the second 3 months of Phase 2, the EPCIS event file will be the wholesale distributor's DSCSA compliance document for purposes of product receipt.
- **For dispensers**: Dispensers continue current practices and receive enforcement discretion for purposes of receiving serialized data and related DSCSA requirements.

I. Manufacturers[2]

A. All requirements of §582(g)(1) for electronic, interoperable data exchange apply to manufacturers. For all covered transactions, manufacturers must achieve electronic, interoperable data exchange by providing accurate serialized data in accurate, complete, and stable EPCIS event files to all customers for all NDCs.

[2] In Phase 2, the expectations described for manufacturers also would apply to exclusive distributors.

B. If a manufacturer **cannot** provide accurate and complete serialized data in accurate, complete, and stable EPCIS event file for an NDC to all customers, it ***must*** obtain a WEE from FDA for that specific NDC as described in Phase 1.

C. All manufacturers ***must also*** continue current practice and provide accurate and complete lot-level data (typically in an ASN) to all customers in order to accommodate transactions with dispensers and wholesale distributor transactions with other wholesale distributors.

II. Wholesale distributors

A. During Phase 2, wholesale distributors receive enforcement discretion for some §582(g)(1) requirements and enforcement discretion ends as to other §582(g)(1) requirements.

1. As to §582(g)(1)(A) and (B) – receiving, providing, and maintaining serialized data in an EPCIS event file:
    a. A wholesale distributor does not have enforcement discretion and must receive and maintain serialized data in an EPCIS event file from all manufacturers for each covered transaction.
    b. For transactions between wholesale distributors,
        i. the selling wholesale distributor must provide EPCIS event files by the end of the 3rd month of Phase 2 (and lot-level data before then and thereafter), and
        ii. the purchasing wholesale distributor has enforcement discretion during the same 3-month period to receive and maintain serialized data in an EPCIS event file for each covered transaction.

    c. A wholesale distributor has enforcement discretion whereby it is excused from providing serialized data to dispensers, but must continue to provide lot-level data.

2. A wholesale distributor is expected to comply with §582(g)(1)(C) and be able to Verify at the package level.

3. As to §582(g)(1)(D) and (E) – tracing at the package level:
    a. If it received accurate serialized data in accurate, complete, and stable EPCIS event files from the manufacturer, a wholesale distributor is expected to be able to trace such packages at the package level back to the manufacturer and would not have enforcement discretion as to this requirement.

b. A wholesale distributor has enforcement discretion as to tracing products at the package level forward (that is, to downstream customers).

4. §582(g)(1)(F) – association of saleable returns at the package level: A wholesale distributor has enforcement discretion as to association of saleable returns at the package level.

B. As to the inbound transaction data a wholesale distributor receives from its suppliers, during the first 3 months of Phase 2, a wholesale distributor may choose whether the EPCIS event file or lot-level data is its DSCSA compliance document for purposes of product receipt. At 3 months, the EPCIS event file received from the supplier is the wholesale distributor's DSCSA compliance document for receipt of transaction data and is maintained for 6 years. [This approach helps to accommodate transactions between distributors when the purchasing wholesale distributor also sources products directly from manufacturers. See the earlier discussion on the inability of wholesale distributors to operate dual systems for receipt of products.]

C. As to the outbound transaction data a wholesale distributor provides to customers:

1. The wholesale distributor continues to provide lot-level data (in an ASN, a portal, or other means appropriate for the customer).

2. For outbound transaction data, the ASN (or other similar lot-level document) remains the wholesale distributor's DSCSA compliance document and is maintained for 6 years.

3. The wholesale distributor also continues to onboard dispensers for EPCIS file exchange or other means appropriate for each dispenser and prepare for the provision of serialized data.

D. Because a wholesale distributor is receiving serialized data from the manufacturer, but not yet providing serialized data to its dispenser customers, certain functionalities will not yet be present.

1. A wholesale distributor will be able to trace products at the package level back to the manufacturer but will not be able to trace products at the package level forward to dispensers.

2. For saleable returns, a wholesale distributor will not be able to "associate" a product at the package level and so will continue current practices.

III. Dispensers

A. Until manufacturers and, in turn, wholesale distributors can achieve electronic, interoperable data exchange with accurate serialized data in accurate, complete, and stable EPCIS event files, dispensers receive enforcement discretion from FDA limited to §582(g)(1)(A), (B), (C), (D), (E), and (F), while continuing current practices.

B. Dispensers continue receiving lot-level data from their suppliers via an ASN, in a portal, or other appropriate means. The ASN (or other similar lot-level document) remains the dispenser's DSCSA compliance document (even if a dispenser begins the process of receiving serialized data in an EPCIS event file) and is maintained for 6 years.

C. Because a dispenser is not yet receiving serialized data from its wholesale distributor suppliers as its DSCSA compliance document, the dispenser will not be able to trace the product at the package level.

IV. Other Requirements

Phase 2 assumes enforcement discretion that is limited to some of the requirements of §582(g)(1)(A), (B), (C), (D), (E), and (F) for wholesale distributors and dispensers. All other §582 requirements not dependent upon the provision, receipt, and maintenance of serialized data continue. DSCSA requirements remaining in effect include, among other things, all packages and homogenous cases must bear compliant product identifiers, all trading partners must be authorized, maintenance of records, and all trading partners must have systems and processes for suspect product investigations and notifications of illegitimate products.

V. End of Phase 2

A. HDA recommends that Phase 2 last 6 months.

B. At the conclusion of Phase 2, wholesale distributors are interoperably and electronically exchanging transaction data at the package level by providing accurate serialized data in accurate, complete, and stable EPCIS event files to all customers or otherwise providing serialized data by posting it to a portal or some other appropriate means. (Manufacturers would have already been providing and wholesale distributors would have already been receiving accurate serialized data in accurate, complete, and stable EPCIS event files at the beginning of Phase 2).

C. If any manufacturer or wholesale distributor is still not compliant at the end of Phase 2, it must obtain a WEE from FDA as described in Phase 1.

Phase 3

Summary of Phase 3

- **Length of time HDA recommends: 6 months after the conclusion of Phase 2**
- **For manufacturers**: All manufacturers must achieve electronic, interoperable data exchange by providing accurate serialized data in accurate, complete, and stable EPCIS event files or a manufacturer must obtain a WEE from FDA exempting their NDC(s) entirely from the DSCSA, including all transaction data requirements.
- **For wholesale distributors**: Enforcement discretion ends for wholesale distributors. All wholesale distributors must receive, maintain, and provide serialized data and comply with all related DSCSA requirements or obtain a WEE.
- **For dispensers**: Dispensers are receiving serialized data but otherwise continue current practices and receive enforcement discretion.

I. Manufacturers

A. All requirements of §582(g)(1) for electronic, interoperable data exchange apply to manufacturers. For all covered transactions, manufacturers must achieve electronic, interoperable data exchange by providing accurate serialized data in accurate, complete, and stable EPCIS event files to all customers for all NDCs. In turn, wholesale distributors can lawfully ***only*** receive EPCIS event files to satisfy requirements for receipt of transaction data.

B. If a manufacturer ***cannot*** provide accurate and complete serialized data in accurate, complete, and stable EPCIS event file for an NDC to all customers, it ***must*** obtain a WEE from FDA for that specific NDC as described in Phase 1 that removes the product from the DSCSA ***entirely***.

II. Wholesale distributors

A. All requirements of §582(g)(1) for electronic, interoperable data exchange apply to wholesale distributors. Wholesale distributors must achieve electronic, interoperable data exchange by receiving, providing, and maintaining accurate serialized data in accurate, complete, and stable EPCIS event files for all transactions.

B. Enforcement discretion ends for wholesale distributors and all requirements of §582(g)(1)(A), (B), (C), (D), (E), and (F) apply.

III. Dispensers

A. Dispensers are in compliance with § 582(g)(1)(A) and (B) because they are receiving from manufacturers and wholesale distributors accurate serialized data in accurate, complete, and stable EPCIS event files or by other appropriate means for all transactions. Nevertheless, to give time for systems and processes associated with receipt and maintenance of serialized data to mature and stabilize, dispensers will receive enforcement discretion from FDA as to §582(g)(1)(A), (B), (C), (D), (E), and (F).

B. For covered product sales, the EPCIS event file (or other appropriate document) provided to the dispenser is the dispenser's DSCSA compliance document and is maintained for 6 years.

IV. Other Requirements

Phase 3 assumes enforcement discretion that is limited to the requirements of §582(g)(1)(A), (B), (C), (D), (E), and (F) for dispensers. All other §582 requirements not dependent upon the provision, receipt, and maintenance of serialized data continue. DSCSA requirements remaining in effect include, among other things, all packages and homogenous cases must bear compliant product identifiers, all trading partners must be authorized, maintenance of records, and all trading partners must have systems and processes for suspect product investigations and notifications of illegitimate products.

V. End of Phase 3

A. HDA recommends that Phase 3 last 6 months.

B. At the conclusion of Phase 3, the systems and processes associated with the receipt and maintenance of serialized data for dispensers have matured and stabilized.

C. If any trading partner is still not compliant at the end of Phase 3, it must obtain a WEE from FDA as described in Phase 1.

At the conclusion of Phase 3, DSCSA requirements are expected to be fully implemented. The phased approach permits the orderly implementation of the DSCSA's 2023 requirements without jeopardizing patient safety or the supply of needed medicines.