



Healthcare Distribution Alliance

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Enhanced Drug Distribution Security Traceability in 2023 and Beyond Position Statement¹ September 29, 2020

Introduction

In the Drug Supply Chain Security Act (DSCSA), the requirements for traceability as of November 27, 2023 are set out in § 582(g)(1) of the Federal Food, Drug and Cosmetic Act (FDC Act).² Below, the Healthcare Distribution Alliance (HDA) summarizes the 2023 requirements that, together, implement a highly protective, electronic system in support of the safe, secure and efficient movement and tracing of prescription pharmaceuticals through the supply chain in the United States. The system described here may evolve as technology and capabilities mature.

The DSCSA's 2023 enhanced drug distribution security provisions exist within the larger framework of pharmaceutical regulation in the U.S., touching upon manufacturing, labeling and National Drug Codes (NDCs), drug shortages, importation, and many other matters of concern. In the global market for pharmaceuticals that are manufactured and distributed by multinational entities, another important priority for stakeholders is that implementation of existing DSCSA requirements be aligned, when possible, with international standards and compliance obligations.

The essential pillars of this enhanced traceability system are as follows:

- Authorized trading partners exchange transaction information (TI) and a transaction statement (TS) in a secure, interoperable, electronic manner;
- With all products uniquely serialized and identified, unless excluded, authorized trading partners provide and maintain serialized product data in all DSCSA-covered transactions, resulting in “one up, one down” unit-level traceability;
- Each trading partner holds, owns, and controls its own transaction data and, in response to appropriate requests, is able to promptly respond with that data and/or facilitate the gathering of that data;
- Robust systems for the identification, investigation and handling of suspect and illegitimate products;
- Robust systems for verifying product identifiers in suspect and illegitimate product investigations and for the resale of returned products;
- A system that uses aggregation and inference to enhance efficiency; and
- Business processes in place to address and reconcile transaction data errors.

¹ This Position Statement is intended to inform and stimulate discussion and is not intended to offer legal advice. Readers should consult with their own legal and regulatory counsel to determine any applicable federal and state laws and regulations.

² The citations to § 581 and § 582 referenced in this document refer to sections of the FDC Act as amended by the DSCSA and are codified at 21 U.S.C. § 360eee and § 360eee-1 respectively.

Some of these elements, such as those related to suspect and illegitimate product, serialization, and transactions only with authorized trading partners, are already in effect and will continue to 2023 and beyond. Others, such as the inclusion of a product's identifier in TI, will not go into effect until 2023.

Technologies, industry understanding and sophistication, and patient needs are always evolving. Thus, this vision for 2023 and implementation of it will continue to mature over time.

We elaborate upon each of these pillars below.

1. There will be a secure, interoperable, electronic system between authorized trading partners through which TI and TS will be exchanged.

- The requirement for interoperable, electronic tracing of pharmaceutical products at the package level goes into effect on November 27, 2023. In this system, for each pharmaceutical product transaction, an authorized trading partner provides TI and a TS to another authorized trading partner “in a secure, interoperable, electronic manner” in accordance with standards established by guidance. § 582(g)(1)(A).
- The standards for this interoperable exchange of transaction data shall comply with a form and format developed by a widely recognized international standards development organization. § 582(a)(2)(A); § 582(h)(4)(A)(i).
- Trading partners must be authorized and may only engage in transactions with other authorized trading partners.³ §§ 582(b)(3), (c)(3), (d)(3), (e)(3).
- Currently, EPCIS⁴ is the only internationally recognized standard that will meet DSCSA requirements⁵ for this interoperable electronic exchange of product tracing information. Though still immature for the pharmaceutical and healthcare industries, EPCIS is expected, when fully implemented, to provide seamless, stable, consistent, compatible, electronic connections between trading partners throughout the pharmaceutical supply chain.

³ The requirements regarding transactions only with authorized trading partners have been in place since January 1, 2015.

⁴ Electronic Product Code Information Services (EPCIS) is a GS1 standard that enables trading partners to share information about the physical movement and status of products as they travel throughout the supply chain.

⁵ See, e.g., § 581(14); § 582(a)(2)(A); § 582(h)(4)(A)(i).

- In a separate document entitled *Getting Ready for EPCIS*, HDA describes a suggested timeline for EPCIS readiness and implementation for meeting the 2023 deadline.
- Once 2023 requirements are met and implemented for a fully interoperable, electronic system based upon EPCIS standards, the system could likely be enhanced with additional functionalities and utilities.
- Beyond EPCIS, it is important to remain open to other technologies which could support 2023 interoperability as they develop and mature.

2. Under the DSCSA, authorized trading partners provide and maintain serialized product data in all transactions, resulting in “one up, one down” unit-level traceability.

- Product identifiers must be affixed to all covered products, and homogeneous cases of such products, packaged by manufacturers and repackagers after November 27, 2018.⁶ By November 27, 2023, that product identifier must be included as part of the TI for every product transaction. § 582(g)(1)(B).
- For each DSCSA-covered drug product transaction (that is, for each covered change in ownership of a product)⁷, the authorized owner of the product must, prior to or at the time of, each transaction, provide the subsequent owner with TI and TS for that transaction. The buyer of the product may not accept ownership of that product unless the previous owner (*i.e.*, the seller), prior to or at the time of the transaction, provides the TI and TS. §§ 582(b)(1)(A), (c)(1)(A), (d)(1)(A), (e)(1)(A).
- As noted above, each trading partner must receive, maintain, and provide a TS for each DSCSA-covered product transaction. In the TS that accompanies a DSCSA transaction, the supplier attests, among other things, to compliance with the DSCSA, that it did not knowingly ship a suspect or illegitimate product, and that the supplier is authorized. § 582(g)(1)(A)-(B).

⁶ The product identifier is a standardized graphic in human-readable form and on a machine-readable carrier that conforms to international standards and includes the product’s unique standardized numerical identifier (SNI), lot number, and expiration date. § 581(14) (definition of product identifier); § 581(20) (definition of SNI). *See Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy, Final Guidance for Industry* (September 2018) available [here](#).

⁷ A “transaction” is “the transfer of product between persons in which a change of ownership occurs.” § 581(24)(A). Various exchanges are exempted from this definition, including intracompany distributions, dispensing of the product to a patient, and distributions of product samples by a manufacturer or licensed wholesale distributors. § 581(24)(B)(i),(iv), and (v). For simplicity and clarity, terms such as “buy,” “purchase” and “sell” are used here but the DSCSA applies to any transfer of ownership of a covered product unless otherwise exempt.

- The TI and TS will be provided in a secure, interoperable, electronic manner reflecting only the current ownership and sale. § 582(g)(1)(A); § 582(k)(1).⁸ Thus, for every transaction of a covered product, a trading partner will be able to go “one up” to identify the transaction in which it acquired the product, and go “one down” to identify the transaction in which (and if) it transferred ownership of the product. This ability to go “one up and one down” achieves unit-level traceability between trading partners. As technology and capabilities evolve over time, this “one up and one down” process may eventually become more or even fully automated, assuming controls can be put in place to assure limited access to, and security of, transaction data.
- Trading partners must maintain, for 6 years, the transaction data that they provide and receive.⁹

3. Under the DSCSA, each trading partner holds, owns, controls, and is wholly responsible for its own transaction data. The circumstances under which a trading partner must share its transaction data with others are prescribed and well-defined.

- At the present time, there appears to be consensus in industry for a distributed model or models,¹⁰ in which, as discussed below, each trading partner holds,¹¹ owns, and controls the transaction data it provides and receives.¹²

⁸ Transaction history (TH) is not exchanged between trading partners as of November 27, 2023 as this requirement sunsets and has “no force or effect” as of that date. § 582(k)(1).

⁹ See § 582(b)(1)(A)(ii) (manufacturers); § 582(c)(1)(A)(v)(I) (wholesale distributors); § 582(d)(1)(A)(iii) (dispensers); § 582(e)(1)(A)(iii) (repackagers).

¹⁰ There also appears to be consensus among stakeholders that a centralized model would not be implementable. Unlike, for instance, with the database of wholesale distributor licensure information, § 503(e)(2), the DSCSA says nothing about FDA or any other entity undertaking development and management of a centralized database of all data for all drug product transactions in the U.S. In the absence of a governmental body statutorily charged with the development and administration of a centralized database, and a mandate for supply chain partners to participate in it, we believe there are enormous practical, legal, and security concerns associated with creating and maintaining a centralized system and to achieving voluntary industry-wide participation in a centralized system.

¹¹ It is assumed that arrangements with third parties to capture and/or maintain the required data are acceptable, as long as such arrangements recognize that the trading partner employing such a service remains ultimate responsibility for the data and for meeting DSCSA requirements.

¹² HDA encourages the continued examination and development of innovative technologies to meet the 2023 interoperability requirements of the DSCSA.

- The DSCSA requires trading partners to maintain their product tracing/transaction data and suspect and illegitimate product investigations information for 6 years.¹³ These data, particularly a company’s suppliers, customers, and product volumes, are proprietary, highly confidential commercial information and may include or constitute trade secrets. The DSCSA is very concerned with the security of these data and the circumstances under which a trading partner must disclose these confidential data are prescribed and well-defined.
 - Manufacturers, wholesale distributors, dispensers and repackagers may each develop its own “secure electronic database” to meet the verification requirements of § 582 (or use a secure database operated by a third party). § 582(b)(4)(D); § 582(c)(4)(C); § 582(d)(4)(C); and § 582(e)(4)(D).
 - Dispensers may have third parties “confidentially maintain[er]” their transaction data. § 582(d)(1)(B); § 582(g)(2)(A).
 - Wholesale distributors must “maintain the confidentiality” of transaction data. § 582(c)(1)(A)(v)(II).
 - In developing guidance documents on unit-level tracing and standards for interoperable data exchange, FDA must, among other things, ensure the protection of confidential commercial information and trade secrets. § 582(h)(3)(iii); § 582(h)(4)(iv).
 - In the circumstances (discussed below) in which a trading partner may request from another trading partner the information necessary to “facilitate gathering” the TI for a product, the systems and processes for making and responding to a request must be “in a secure manner that ensures the protection of confidential commercial information and trade secrets.” § 582(g)(1)(E)(ii).
- Each trading partner will need to be satisfied with the content of its DSCSA data before engaging in any applicable transactions.
- Given the importance of data security and confidentiality as set forth above, the DSCSA is also very specific about when a trading partner must provide those data to others. The circumstances under which a trading partner must share its data with another entity are well-defined – during recalls and suspect and illegitimate product investigations. In such instances, the trading partner is able to provide (and required to provide) the data in its possession (*i.e.*, the transaction data that it received from its supplier and the transaction data that it provided to its customer), keeping in mind that the TH requirement sunsets in 2023.

¹³ See § 582(b)(1)(A)(ii), § 582(b)(4)(A)(iii), (B)(v) (manufacturers); § 582(c)(1)(A)(v)(I), § 582(c)(4)(A)(iii), (B)(v) (wholesale distributors); § 582(d)(1)(A)(iii), § 582(d)(4)(A)(iv), (B)(v) (dispensers); § 582(e)(1)(A)(iii), § 582(e)(4)(A)(iii), (B)(v) (repackagers).

- A trading partner must have systems and processes necessary to promptly respond with the TI and TS for a product upon a request by FDA or other appropriate state or federal official in the event of a recall or for purposes of investigating a suspect or illegitimate product. § 582(g)(1)(D).
- A trading partner must have systems and processes necessary to promptly facilitate gathering the information in its possession necessary to produce the TI going back to the manufacturer, as applicable,
 - Under § 582(g)(1)(E)(i), in the event of a request by the Secretary (including FDA) or other appropriate state or federal official on account of a recall or for the purposes of investigating a suspect product or an illegitimate product; or
 - Under § 582(g)(1)(E)(ii), in the event of a request by an authorized trading partner,
 - for purposes of investigating a suspect product, or
 - for purposes of assisting the Secretary (including FDA) or other appropriate Federal or State official on account of a recall or for the purposes of investigating a suspect product or an illegitimate product.
 - Requests by an authorized trading partner shall be in a secure manner that ensures the protection of confidential commercial information and trade secrets. § 582(g)(1)(E)(ii).
- The trading partner is able to provide only the TI in its possession.
- The processes by which a trading partner provides transaction data in response to appropriate requests in order to enable and achieve traceability may evolve over time as technologies mature and become more sophisticated.

4. Trading partners must have robust systems and processes to identify, investigate and manage suspect and illegitimate products.

As of January 1, 2015, and continuing onward to 2023 and beyond, trading partners must have systems and processes in place to prevent suspect and illegitimate products from entering the legitimate U.S. pharmaceutical supply chain. Sections 582(b)(4), (c)(4), (d)(4), and (e)(4) require trading partners to have the following:

- A system to enable them to identify and determine whether a product is a suspect product.

- A system to quarantine and investigate a product that has been determined to be a suspect product and to coordinate with trading partners, as applicable, in making the determination as to whether that product is illegitimate.
- A system to clear a product for distribution, as appropriate, if, after investigation, it is determined that the suspect product is not an illegitimate product. The trading partner is required to notify FDA of cleared products, if applicable (that is, if the product was subject to a previous notification to or from FDA).
- For products determined to be illegitimate, a system for:
 - Quarantine;
 - Disposition;
 - Taking reasonable and appropriate steps to assist another trading partner to disposition the illegitimate product;
 - Retaining samples for examination and laboratory analysis by the manufacturer and/or FDA or other appropriate Federal or State official; and,
 - Providing notifications to FDA and other trading partners and, termination of those notifications.
- A system for a manufacturer to notify its immediate trading partners and FDA of a product that has a high risk of illegitimacy.
- A system with procedures for taking appropriate action when the trading partner has received an illegitimate product notification or a manufacturer's notification of a high risk of illegitimacy.
- A system for the creation and maintenance of records for a minimum of 6 years.

5. Verification of product identifiers is an important part of supply chain security.

- 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 (SNI) or lot number and expiration assigned to the product by the manufacturer or the repackager. § 581(28).
- By November 27, 2023, trading partners must have systems and processes for verification of products at the package level, including the SNI. § 582(g)(1)(C).

- Since November 27, 2017, manufacturers and repackagers have had important obligations regarding the “verification” of the identifier on serialized products. Upon receiving a request for verification from an authorized repackager, wholesale distributor or dispenser, a manufacturer or repackager must, within 24 hours, notify the person making the request whether the product identifier, including the SNI, corresponds to a product identifier affixed or imprinted by the manufacturer (§ 582(b)(4)(C)) or repackager (§ 582(e)(4)(C)).
- Trading partners are required to verify a product identifier, including the SNI, in two circumstances:
 - Manufacturers, wholesale distributors, repackagers,¹⁴ and dispensers¹⁵ must verify product identifiers in suspect product investigations; and
 - Returns are verified prior to resale under some circumstances.
 - Beginning November 27, 2017, manufacturers and repackagers were required to verify any returned product prior to reselling it. § 582(b)(4)(E); § 582(e)(4)(E). This requirement sunsets on November 27, 2023. § 582(k)(2).
 - Wholesale distributors were required to begin verifying a product’s identifier prior to resale beginning November 27, 2019. § 582(c)(1)(B)(i)(II); § 582(c)(4)(D).¹⁶ FDA, however, granted enforcement discretion for this requirement until at least November 27, 2020.¹⁷ Once FDA lifts its enforcement discretion, a wholesale distributor

¹⁴ Upon making a determination that a product is suspect, or upon receiving a verification request FDA, manufacturers, wholesale distributors, and repackagers must be able to “promptly conduct an investigation in coordination with trading partners” to determine whether the product is an illegitimate product; the investigation shall include validating any applicable TI and TH the manufacturer, wholesale distributor, or repackager possesses and investigating whether the product is illegitimate product. § 582(b)(4)(A)(i)(II) (manufacturer); § 582(c)(4)(A)(i)(II) (wholesale distributor); § 582(e)(4)(A)(i)(II) (repackager). As the requirements for receipt and transmission of TH sunsets in 2023, there would be no TH for a trading partner to validate after November 27, 2023.

¹⁵ A dispenser must “promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product.” § 582(d)(4)(A)(i)(II). The investigation shall include “validating any applicable” TI and TH. § 582(d)(4)(A)(ii)(III). As the requirements for receipt and transmission of TH sunsets in 2023, there would be no TH for a trading partner to validate after November 27, 2023.

¹⁶ The requirement that wholesale distributors verify returns prior to resale arises in two places in the DSCSA, § 582(c)(1)(B)(i)(II) and § 582(c)(4)(D). The entirety of § 582(c)(1)(B)(i) sunsets on November 27, 2023 pursuant to § 582(k)(2). However, § 582(c)(4)(D) and its verification of saleable returns requirements continues for wholesale distributors after November 27, 2023 and does not sunset.

¹⁷ Wholesale Distributor Verification Requirement for Saleable Returned Drug Product—Compliance Policy Guidance for Industry (September 2019) available [here](#).

must be able to verify a return prior to resale; this requirement continues after November 27, 2023. § 582(c)(4)(D).

6. Aggregation and inference are critically important for pharmaceuticals to move efficiently in the supply chain.

- Aggregation and inference are crucial to an efficient, interoperable electronic system for the secure movement of products in the pharmaceutical supply chain.
- Aggregation allows for the inference of smaller units (*e.g.*, packages) to an identifier associated with a larger unit (*e.g.*, case, pallet or tote) which is comprised of those small individual items (*e.g.*, packages packed within a case).
- Given the volume of products moving through the pharmaceutical supply chain every day and the importance of maintaining secure operations, all trading partners need the ability to infer the smaller units within a larger, aggregated unit to achieve efficient traceability.
- Without the ability to aggregate individual product identifiers to a larger unit's identifier and then infer the individual units within the larger unit, manufacturers and wholesale distributors would have to open each sealed case and scan each unit within it before shipping the larger unit.
- A dispenser similarly will need to be able to infer individual units from an aggregated larger unit when it receives a homogenous case or a tote (that contains multiple different products within that tote) from its wholesale distributor supplier.
- Opening a sealed larger unit such as a case to scan each item within it before shipping to capture product identifiers is contrary to supply chain integrity practices and would be very slow, inefficient, and highly burdensome to implement.
- The DSCSA mandates that FDA issue guidance that defines the circumstances under which the sectors within the pharmaceutical distribution supply chain may use aggregation and inference. § 582(h)(3)(A)(i). The guidance must also identify methods and processes to enhance secure product tracing, which may include the use of inference and aggregation. § 582(h)(3)(A)(ii).

7. There will need to be business processes to address and reconcile data issues.

- During transactions between authorized trading partners, there will be instances in which the product received and the data received do not match. In otherwise routine transactions between established authorized trading partners, the mismatch will most likely be due to data organization and other data-related issues rather than any problem

with the product's quality or legitimacy. The result, however, is that a trading partner has a product, and the product identifier is affixed to it, but is not able to match that identifier to transaction data in the trading partner's possession. These mismatches are inevitable given the relative immaturity of processes and the volume of product that rapidly moves between authorized trading partners. It is expected that over time, as systems mature, the rate of mismatches will decline significantly, but will not disappear completely.

- Trading partners will need to have in place business processes for reconciliation of these data issues without immediately rendering a product as “suspect.”
 - Some processes may allow for a trading partner to reconcile a data issue internally within the company.
 - Other situations will not be amenable to an internal resolution and will require that the entity seek assistance of its trading partner, likely the supplier, in order to reconcile the data issue.
- Given the volume of products involved¹⁸ and in order to avoid interruptions in patient care, it is important that there be ways to distinguish these commercially routine data reconciliations occurring between established trading partners from true suspect or illegitimate product situations.

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The vision for 2023 traceability described here will yield a highly protective, interoperable electronic system for the unit-level tracing of prescription pharmaceuticals. Accomplishment of this system and compliance with the DSCSA will require collaboration and coordination among trading partners, including an enormous commitment of industry resources and time. A safer and more secure pharmaceutical supply chain is, however, a worthy goal. Given the significant effort that is involved, at the present time HDA's wholesale distributor members are focused upon the DSCSA's requirements effective up to, and including, 2023. However, collectively, we embrace future possibilities and applications as systems mature and technology and understanding evolve.

¹⁸ HDA has “estimated that wholesale distributors receive approximately 58.7 million units of saleable returns per year, which could result in about 226,000 verification requests to manufacturers per business day.” Source: Letter to Janet Woodcock, M.D., Douglas C. Throckmorton, M.D., Donald D. Ashley, J.D., Leigh Verbois, Ph.D., and Connie Jung, R.Ph., Ph.D., U.S. Food and Drug Administration, from Anita T. Ducca, HDA; Re: Request for Additional Exercise of Enforcement Discretion as to Verification of Saleable Returned Drug Products (April 24, 2020).