PDSA
Pharmaceutical Distribution Security Alliance

February 11, 2025

Since enactment of the Drug Supply Chain Security Act (DSCSA), members of PDSA have identified a number of questions regarding different provisions of the DSCSA. Working together, members from all sectors of the supply chain have developed answers to these outstanding questions that PDSA believes constitute reasonable and appropriate interpretations of the statutory text and account for the operational realities faced by supply chain participants.

PDSA is a multi-stakeholder coalition established in 2011 with a membership that spans the entire spectrum of the U.S. pharmaceutical distribution system, including manufacturers, repackagers, wholesale distributors, third-party logistics providers, and pharmacies. More than 25 companies are formal members of PDSA, while many other external stakeholders provide additional policy and technical support through industry trade associations. Our primary goal is to ensure patients have uninterrupted access to safe, authentic, FDA-approved medicine.

There are several questions that remain. Working together, members from all sectors of the supply chain have developed prospective answers to several of these questions that PDSA believes constitute reasonable and appropriate interpretations of the DSCSA statutory text and account for the operational realities faced by supply chain participants.

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1. **What data elements should be included when reporting data discrepancies to trading partners?**
   It is important to provide all relevant information in the initial communication of data discrepancies (i.e., data exceptions) to facilitate speed and efficiency in resolving the discrepancy. The HDA Exceptions Handling Guidelines For The DSCSA and related DSCSA Exceptions Handling Communication Guide identify specific information that is recommended to be included when communicating a data discrepancy. This generally includes business information about the purchase (e.g., a delivery number), the product identifier data for the packaging level at issue if available (i.e., GTIN, serial number, lot, expiry), the type and description of the exception, and relevant contact information, and other relevant business information agreed to between trading partners.

2. **Are health care practitioners required to follow DSCSA requirements?**
   Health care practitioners authorized by law to dispense or administer prescription drugs are dispensers under the DSCSA, but they are specifically excluded from some of the DSCSA's most onerous provisions. Health care practitioners *are* subject to the requirements to only transact product that is serialized and to only transact with trading partners that are authorized. However, health care practitioners are *not* subject to the product tracing or verification requirements. *See* FDCA § 582(d)(5). Accordingly, health care practitioners are not required to provide, capture, or maintain transaction information (TI) and transaction statements (TS). The carveout, however, does not relieve trading partners selling *to* health care practitioners to their obligation to capture, maintain TI and TS, nor the obligation to make it available to the health care practitioner.

   The DSCSA does not define the term "healthcare practitioner." Other parts of Federal law generally ascribe the term its common usage. For example, regulations related to the National Practitioner Data Bank define a healthcare practitioner as, "an individual who is licensed or otherwise authorized by a state to provide health care services (or any individual who, without authority, holds himself or herself out to be so licensed or authorized)." 45 CFR § 60.3.

   In assessing whether a trading partner is subject to the healthcare practitioner carveout, it is important to assess to whom ownership is being transferred and how they are licensed, as that is the entity/individual subject to the DSCSA transaction obligations. If ownership is transferred to a practice operating an in-office pharmacy, all DSCSA obligations may apply. If ownership is being transferred to the individual healthcare practitioner, the carveout may apply.

3. **Are veterinary products or sales subject to DSCSA requirements?**
   DSCSA obligations apply to "transactions" of a "product." The sale of veterinary products is, therefore, only subject to DSCSA obligations if there is a sale of a "product" that qualifies as a "transaction."

FDCA § 581(12) and (13) define a product as a prescription drug for *human* use in a finished dosage form for administration to a *patient*. Drugs intended solely for *animal* use, therefore, are not "products" and are not subject to DSCSA obligations.

The sale of *human* drugs into the veterinary setting requires a fact-dependent analysis by each trading partner to determine whether DSCSA obligations apply. When evaluating a sale of human drugs into the veterinary setting, trading partners may consider whether the veterinary setting is a trading partner, the certainty with which the product will only be used for veterinary applications, and whether the DSCSA was intended to cover product that has left the regulated supply chain.

4. **Is a manufacturer's serialization data considered cGMP data?**
Yes. Serialization data (including aggregation data) is generated to satisfy cGMP verification requirements, thereby making it cGMP data that must comply with data integrity.

Data integrity is essential through the cGMP data life cycle. FDA explained in its December 2018 Data Integrity Guidance that all data become a cGMP record when they are generated to satisfy a cGMP requirement. See 21 USC 374(a), which permits FDA to inspect manufacturing facilities for "all things therein (including records, files, papers, processes, controls, and facilities)" that bear on whether the drug is adulterated, misbranded, or otherwise may not be manufactured or sold. In the same guidance, FDA explained that, in practice, this means FDA "routinely requests and reviews records not intended to satisfy a cGMP requirement but which nonetheless contain cGMP information."

As with all cGMP data, the regulatory emphasis is on qualification of systems and process, not on data perfection. A serial number is an original data object that has a data lifecycle, whereby each step of the lifecycle is to comply with data integrity principles. A unique serial number is applied to each product, which helps to verify the integrity of that product. FDA can request serial number verification, and if it cannot be confirmed, an investigation is triggered. Therefore, serialization data is data that bears on whether a drug is adulterated or misbranded and is used by FDA when it inspects facilities or products for whether they are meeting cGMP requirements.

5. **What obligations apply to intermediate bulk drugs (*i.e.*, bulk containers of drug <u>not</u> intended for sale to a dispenser), such as a large drum of drug, sold with the intent of being packaged/repackaged?**
Under the DSCSA, serialization and traceability obligations tie to a "product." Section 581(13) defines a "product" as "a prescription drug in a finished dosage form for administration to a patient without *substantial further manufacturing* (such as capsules, tablets, and lyophilized products before reconstitution) . . . ." FDCA § 581(13). FDA

generally defines the "manufacture" of a drug to include "filling," and "packaging." 21 C.F.R. § 4.2. Therefore, a prescription drug that *requires* further packaging, such as intermediate bulk drug, is not a "product" and is generally not subject to DSCSA requirements.

For this purpose, it is important to consider whether further packaging is *required* for sale or administration to a patient. An intermediate bulk drug, such as a drum, cannot be sold or administered to a patient, and therefore is not yet a product. However, a drug that is in finished dosage form, *including packaging and labeling*, for sale or administration to a patient that is sold to a repackager, is considered product and is generally subject to DSCSA serialization and tracing requirements.

6. To whom can saleable returns be made?

The DSCSA expressly provides that saleable returns may only be made to, and only be accepted by, the trading partner from which the package of product was received. FDCA § 582(g)(1)(F). For example, if Pharmacy A purchases a package of product from Wholesaler B and wishes to return that package for credit, Pharmacy A may only return that package to Wholesaler B. That package cannot be returned by Pharmacy A to Wholesaler C.

7. Are clinical trial drugs subject to DSCSA traceability?

DSCSA traceability requirements apply to any "transaction" of a "product." In determining whether DSCSA obligations apply to a specific clinical trial drug, it is important to consider both whether the drug is a "product" and whether there has been a "transaction."

The DSCSA generally defines a "product" as a drug for human use that is subject to section 503(b)(1) in a finished dosage form for administration to a patient without substantial further manufacturing. FDCA § 581(12), (13). Certain limited exceptions apply, but they are not uniquely applicable to clinical trial drugs.

The term "transaction" generally means "the transfer of product between persons in which a change of ownership occurs." FDCA § 581(24). There is no requirement that the change of ownership be in exchange for payment; the relevant question is whether legal ownership/title of the product changes. In many instances, clinical trial drugs remain under the ownership of the trial sponsor once they enter the clinical study supply chain, but ultimately that is a legal question that must be assessed by each individual trading partner.

8. **Are physician samples subject to DSCSA requirements?**
   No, data exchange obligations apply to each "transaction" of a product, and the DSCSA statute expressly states that "the distribution of product samples by a manufacturer or a licensed wholesale distributor in accordance with section 503(d)" is not a transaction. FDCA § 581(24)(B)(v). It is important to note that FDCA § 503(d) sets forth detailed requirements for the permissible distribution of drug samples.[1]

9. **Are states obligated to recognize WEEs?**
   Yes, State regulators must recognize all FDA-established WEEs. FDA's authority to establish WEEs is an explicit part of the DSCSA.

   WEEs are an integral part of the DSCSA, and the statute expressly requires FDA to establish a process for receiving WEE requests and issuing WEEs when the Agency deems it appropriate. *See* FDCA § 582(a)(3)(A). The DSCSA's preemption provision expressly extends to WEEs. Under FDCA § 585(a), states and their political subdivisions may not "establish or continue in effect any requirements for tracing products through the distribution system . . . which are inconsistent with . . . any waiver, exception, or exemption [established by FDA]."

10. **When and how should company-specific waiver, exemption or exceptions (WEEs) be communicated to trading partners?**

    If an individual company requests and receives a WEE, the WEE recipient is responsible for notifying its direct trading partners upon FDA approval, and in any circumstance, prior to any product shipment that will rely on the WEE. Recipients should not assume a WEE request will be granted and generally should not communicate WEE applicability before the WEE is granted by FDA.

    It is important to communicate the termination of a WEE. Communication should be in advance of the termination date when possible to accommodate planning and preparation. Unless clearly communicated, trading partners of the WEE recipient should not be responsible for the obligations waived or exempted under the WEE.

11. **What must a trading partner do in order to rely on the FDA-Initiated Exemptions announced by FDA on October 9, 2024 (the "FDA-Initiated Exemptions") and in effect on November 27, 2024?**

    The FDA-Initiated Exemption announcement identifies two conditions for a trading partner to rely on the Exemptions.

[1] It is noted that 21 CFR 203.38 requires sample product to "bear a label that clearly denotes its status as a drug sample, e.g., 'sample,' 'not for sale,' 'professional courtesy package.'"

- The trading partner must have either (i) "initiated their systems and processes by successfully completing data connections with their immediate trading partners" or (ii) initiated processes and documented their "efforts to establish data connections but were not able to fully complete them with all immediate trading partners."
- The trading partner is expected to "communicate their reliance on the exemptions to their trading partners."

The decision to rely on the FDA-Initiated Exemptions and the method of communicating such reliance are individual business decisions.

12. Must both trading partners in a transaction align on whether the FDA-Initiated Exemptions apply to that transaction?

No. The decision whether to rely on the FDA-Initiated Exemptions is a business decision to be made by each trading partner individually. Both trading partners in a given transaction must make their own determinations whether to rely on the FDA-Initiated Exemptions, and one trading partner's decision to rely/not rely on the FDA-Initiated Exemptions does not impact the other trading partner's decision to rely/not rely on the FDA-Initiated Exemptions. Each trading partner has their own respective compliance obligations, and a given trading partner's reliance on the FDA-Initiated Exemptions determines only that trading partner's compliance obligations.

13. Should the FDA-Initiated Exemptions be applied at a trading partner level, product level, or an individual transaction level?

Tracking and managing the FDA-Initiated Exemptions at a product or individual transaction level would be operationally infeasible. If a trading partner decides to avail itself to the FDA-Initiated Exemption, application of the FDA-Initiated Exemption to all products and all transactions in which that trading partner engages for the duration of that exemption period, will generally support operational implementation and efficiency.

Trading partners should have flexibility to determine the time period for which they will rely on the Exemption. For example, a trading partner may initially decide to *not* rely on the Exemption and later decide to do so, or alternatively, a trading partner may choose not to rely on the Exemption for the full permissible period of time established by FDA.

14. Must lot-level transaction information continue to be exchanged through November 27, 2026[2]?

The breadth of the FDA-Initiated Exemptions and Small Business Dispenser Exemption and the recognition that each individual trading partner will determine whether to rely on the FDA-Initiated Exemptions will create a mixed environment of unit-level data

[2] Or any other date on which all broadly applicable exemptions established by FDA expire.

exchange and lot-level data exchange. To support efficiency and ease of compliance, each trading partner should continue its current methods of providing lot-level transaction information for each transaction—regardless of whether the trading partner is relying on the FDA-Initiated Exemptions—through November 27, 2026.

15. If a wholesale distributor receives product from a manufacturer without serialized traceability data between May 27, 2025 and August 27, 2025, can the wholesale distributor continue to distribute the product?

Yes. The failure by the manufacturer to provide serialized traceability data after May 27, 2025 may create non-compliance for the manufacturer, but an eligible wholesale distributor can continue to rely on its own exemption until August 27, 2025 and continue distribution of the product consistent with the conditions of the FDA-Initiated Exemptions announcement. Between May 27, 2025 and August 27, 2025, the eligible wholesale distributor minimally will need the lot-level transaction information to rely on its exemption. If that product remains in the wholesale distributor's inventory beyond August 27, 2025, the wholesale distributor may also continue to distribute the product at that time.

16. Do the DSCSA Verification System requirements apply to exempted drugs?

The DSCSA generally requires trading partners to implement systems and processes to identify, investigate, and make notifications (including Forms 3911) for suspect and illegitimate products. *See* FDCA § 582(b)(4), (c)(4), (d)(4), and (e)(4). These requirements apply to "***product*** in the possession or control of the [trading partner]" and are ***not*** based on the presence or absence of a "transaction."

Certain prescription drugs are excluded from the statutory definition of a "product" under the DSCSA. For example, blood or blood components intended for transfusion, radioactive drugs or radioactive biological products, imaging drugs, IV solutions intended for replenishment of fluids and electrolytes, medical gas, homeopathic drugs, and certain compounded drugs are not "products." FDCA § 581(13).[3] Because those drugs are not products, they are not subject to the Verification System requirements in § 582(b)(4), (c)(4), (d)(4), and (e)(4). *It is important to note, however, that other federal, state, and local laws and regulations may impose other similar investigation requirements.*

Other drugs are "products," as defined by the DSCSA but are exempted from the definition of a "transaction." For example, most physician samples are "products" but are exempted from the definition of a transaction. FDCA § 581(24). Although TI and TS exchange are generally not required for such products because there is no transaction, those drugs remain "products" nonetheless, and they generally are subject to the Verification System requirements in § 582(b)(4), (c)(4), (d)(4), and (e)(4).

[3] See Question #8 above for more information on which physician samples are exempted.