Pharmaceutical Distribution Security Alliance
Questions & Answers on DSCSA

These questions and answers have been prepared by the Pharmaceutical Distribution Security Alliance (PDSA), a multi-stakeholder coalition with membership that spans the entire spectrum of the U.S. pharmaceutical distribution system, including manufacturers, wholesale distributors, third-party logistics providers, and pharmacies. This document includes a number of operational questions that have been identified by PDSA with regard to the provisions of the Drug Supply Chain Security Act (DSCSA) that take effect November 27, 2023. The answers provided in this document reflect PDSA's understanding of the DSCSA and are being provided to the FDA for its consideration. Where appropriate, we ask that FDA clarify its position on these issues through guidance documents, regulations or its preambles, or other proper means.

The viewpoints in this document do not represent legal interpretations by PDSA or its members. This document, in its current form, is being presented for discussion purposes only and is not intended for use by an individual or entity other than FDA.

1. **Can a human-readable three-segmented NDC on the front panel of a package serve as the NDC component of the human-readable product identifier on a separate panel?**

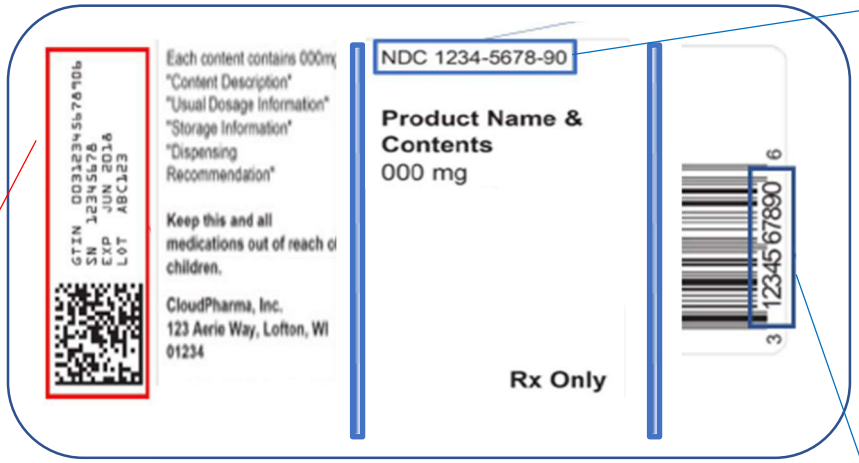
Yes, a human-readable three-segmented NDC on the front panel of a package can serve as the NDC component of the human-readable product identifier on a separate panel. The NDC forms the basis for the GTIN,[1] which is the global standard industry has implemented for product identifiers and exchange of serialization data and is part of the GS1 system of standards.[2] The GTIN is foundational to the implementation of global standards as required by the statute[3] and in combination with inclusion of the NDC elsewhere on the product packaging, the reference to the NDC in the statutory definition of product identifier is adequately fulfilled. In addition, the NDC is regulatorily required to be included in the linear barcode[4], and the three-segment NDC that the draft guidance is requesting as part of the product identifier is almost always included as part of the product artwork at all packaging levels. The product identifier required by the DSCSA does not define proximity to the barcode and should not modify existing practices and uses of product NDCs.

It is recognized that the NDC number underpins many regulatory pharmaceutical supply chain activities, particularly among dispensers. Accordingly, the NDC is included as part of the linear barcode on all levels of product packaging and the human readable NDC is part of the pre-submitted product artwork to the FDA. The NDC should already be printed on the product package in a three segmented human readable format in a location familiar to regulators and dispensers which is generally on the front label

[1] Due to the NDC format being the subject of the proposed rule, Revising the National Drug Code Format and Drug Label Barcode Requirements, this is subject to change. Additionally, there will likely be a derivation method issued by a standards body that further changes how trading partners use the NDC.
[2] 21 U.S.C. § 581(14). "The term 'product identifier' 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 standard numerical identifier, lot number, and expiration date of the product."
[3] Global Trade Item Number (GTIN), GS1, https://www.gs1.org/standards/id-keys/gtin.
[4] 21 C.F.R. §§ 201.25, 610.67 (2011).

panel, and the addition of a product identifier that utilizes the GTIN should not alter the NDC information currently available on the label. The encoded data in the 2D Datamatrix (GTIN, SN, LOT, EXP) and the immediately adjacent human-readable data should match. Today, end users in the supply chain are deriving the NDC via the linear product barcode scan and/or human readable NDC printed on the product packaging (see image below). While the human readable NDC may not be located in immediate proximity to the 2D DataMatrix (e.g., NDC on the front label panel rather than the side label panels), the human readable NDC is prominently displayed in a three segmented fashion, typically on the front panel label next to the product name in close proximity to the 2D barcode. In short, the NDC must be included on the package in human readable form, but its immediate proximity to the product identifier is not necessary (especially if space constrained), nor must it be encoded in the 2D DataMatrix.

Side Panel **Front Panel** **Side Panel**



NDC typically included per 21 CFR 201.2. Not altered by DSCSA.

New DSCSA product identifier using GTIN; does not alter existing NDC information.

NDC already required to be included per 21 CFR 201.25(c). Not altered by DSCSA.

2. Is the enhanced "system" for tracing a single, shared system?

No, the enhanced "system" will be multiple networks of independent and interoperable systems without a central communication hub.

A distributed database architecture provides superior functionality compared to alternative models. First and foremost, it leverages existing infrastructure for capturing and storing serialization information (i.e., stakeholder databases), rather than requiring the development of additional infrastructure (e.g., a large central database capable of housing all the supply chain's data). The use of existing infrastructure will ease implementation and will also serve as a cost-effective approach to supply chain security enhancement. Additionally, a distributed model enhances security by having many points of entry for data

queries, each company provides a separate layer of proprietary security measures and can better contain the threat of illegal access. The use of distributed databases allows individual companies to control storage of, access to, and maintenance of their own data.

If there were one common repository system, every trading partner would be inherently interoperable by virtue of using that one single system. Instead, the DSCSA emphasizes interoperability in recognition of the distinct and unique business systems and processes maintained and controlled by each trading partner.[5] Furthermore, the DSCSA clearly articulates the provision of "alternative methods of compliance,"[6] which is contrary to a "single over-arching system" approach and ensures that trading partners are free to choose how they wish to comply with the DSCSA's interoperability requirements. A distributed model enables communication and data query across multiple data storage sites, formats, and communication methods. A distributed database model also minimizes the potential for data errors by maintaining a single source of truth.

The DSCSA was designed to ensure that every link in the complex supply chain achieves interoperable data exchange, unit-level verification, and tracing.[7] Trading partners will utilize processes to achieve the 2023 interoperability requirements but will not require a single system. Complex data sharing and interoperability requirements promote the legitimacy of each package of prescription drugs, and systems to enable each package to be verified by its manufacturer and to be traced through the supply chain further enhance security. While achieving interoperability among supply chain members in a distributed model is challenging, interoperability can be achieved with clear guidance from, and standards set by the Agency.

Establishing an interoperable system should be grounded in two core components: (1) common data formats and structures, and (2) standardized communication protocols to support the exchange of that data between distributed systems. Common data formats and structures promote consistency across distributed data repositories and enable interoperability. Recognizing that it is critically important that each trading partner maintain control of its own data, standardized communication protocols will support efficient, interoperable exchange of that consistent data to achieve the goals of the DSCSA. FDA recently revised guidance to accomplish this goal by recommending the use of EPCIS as a data exchange method among trading partners.

3. Will the enhanced system for tracing allow regulators and other trading partners direct access to tracing information?

No, the enhanced system will be an interoperable request and response protocol and each company will define their gatekeeping function and provide responses within their own gatekeeping function. A method by which appropriate regulators can request tracing information should be available, but direct access to trading partner data via the systems and processes for tracing will not be available to regulators (nor to other trading partners).

[5] Establishing interoperability of various systems via secure, standardized communication protocols requires the collaboration among all of those distinct system stakeholders in an open collaborative way to develop those protocols. We encourage the Agency to engage in such collaboration to advance interoperability in this way.
[6] § 582(g)(2)(B).
[7] § 582(g)(4)(A)(ii).

Regulators are an important stakeholder in suspect product investigations and tracing. The DSCSA gives the FDA and other appropriate regulators the authority to request product tracing information.[8] However, trading partners have the statutory responsibility for facilitating the gathering of transaction information for tracing.[9] Accordingly, the systems and processes for tracing are expected to provide the trading partners with the ability to gather the necessary transaction information for tracing, and in turn provide that gathered information to FDA (or other appropriate officials) in an interoperable manner, as required. Metadata regarding TI data elements is typically contained in disparate systems, so a gatekeeper, or human in the loop, is necessary to access these and construct a complete and accurate response to a regulators query. Direct regulator access to independently gathered information held by trading partners will not be available, however. Such access would go beyond the statute and add significant complexity to the processes needed for user authentication and the rules for data access and use.

4. **Will the tracing process accommodate a human-in-the loop process?**

Yes, companies have the flexibility to choose to automate, semi-automate, or use human processes to assess and develop responses to tracing requests. While trading partners will have systems and processes in place to provide verification responses within 24 hours, many trading partners will continue to rely on more manual processes for tracing. Some trading partners are expected to use a hybrid approach, relying on a human "gatekeeper" to manage the process. Greater automation may be developed over time as a business value, but automation is not foreseen as a regulatory requirement. It is important to recognize the distinction between the tracing request and response message between each trading partner and the trading partner or regulator gathering the tracing information versus each individual trading partners evaluation of the request and decision as to how it will respond. Regardless of the choice in automation or manual processes for its internal assessment of the request, it is important that the request and response protocol is standardized to meet the statutory requirements for electronic interoperability.[10] How each company processes that standardized request/response *internally* is at their discretion.

5. **If a trading partner purchases product prior to November 27, 2023, and the accompanying TI does not include the product identifier, then further transacts the product on or after November 27, 2023, must the latter TI include the product identifier?**

After November 27, 2023, most wholesale distributors intend to structure their process for generating outbound TI to include two steps (among others). First, they will scan the relevant product identifiers on the products being sold to build the TI with those product identifiers. Second, they will confirm that outbound product identifier information corresponds to inbound TI the wholesaler previously received for their purchase of the product. This second step helps to add valuable reliability and quality to the TI. During a transition period on and after November 27, 2023, wholesale distributors would have the ability to execute that first process, but they will not have the ability to execute that second process for inbound

[8] § 582(a)(9)(b)(1)(B).
[9] § 582(g)(1)(E).
[10] FD&C Section 582(a)(2)(A) defines interoperability as the ability (1) exchange transaction history,15 transaction information, and transaction statements accurately, efficiently, and consistently among trading partners; and (2) for a subsequent purchaser's system, process, or practice to successfully capture and maintain the transaction history, transaction information, and transaction statements, regardless of whether they are provided in a paper or electronic format.

TI they received prior to November 27, 2023, that may not include product identifier information. While wholesaler's ability to create outbound TI by scanning and compiling product identifiers will allow technical compliance with the statutory requirement to include the product identifier in the TI, it is important for stakeholders to understand that the TI will not—and cannot—be tied to a related inbound TI at the product identifier level if that level of detail was not received from upstream manufacturer customers.

6. Is it appropriate to provide both TH and serialized TI as part of a transition process?

No, selling trading partners should not provide TH in parallel to serialized TI on and after November 27, 2023.

Beginning November 27, 2023, each authorized trading partner must provide serialized TI for all transactions for all DSCSA products.[11] On that date, the exchange of transaction history (TH) also sunsets.[12] While there is no prohibition on trading partners choosing to continue to exchange TH as a business practice, doing so would be operationally difficulty and create undue challenges. TH is typically provided by the selling trading partner via an advance ship notice (ASN). With the additional of serialized product identifier information on November 27, 2023, after that date, TI will typically be provided by the selling trading partner via EPCIS message. The ASN and EPCIS are technologically distinct methods of exchanging data. The parallel exchange of both the TH via ASN and the TI via EPCIS would be operationally challenging, particularly for the purchasing trading partner, which would be receiving and need to manage two data streams in their receiving process. Given these operational challenges, it is recommended that the TH *not* continue to be provided on and after November 27, 2023.

7. How should data errors be handled?

The transition to serialized data in 2023 will exponentially increase the amount and granularity of data exchanged between trading partners as TI. Data errors should be investigated and communicated between trading partners to support the continued flow of legitimate products to patients. Multiple types of errors are likely to occur for legitimate products to include:

- Clerical errors (e.g., inaccurately entered master data)
- Product data is available but did not accompany product
- Product with no data
- Data with no product

Many types of data errors will be inevitable and require investigation. Some errors will be minor and remedied promptly especially in the short term. Ultimately, there will be some data errors associated with legitimate product that cannot be adequately understood through investigation, and the trading partners may have no choice but to treat those products as illegitimate (even though in actuality they are legitimate). If these are common, this situation could result in backlogs of products being investigated and ultimately shortages.

[11] § 582(g)(1)(A).
[12] § 582(k)(1).

Manufacturers should strive to develop efficient aggregation process that minimize the number of errors that occur in the aggregation process. Despite best efforts, it is recognized that aggregation errors will occur. Even at very high rates of accuracy in the automated aggregation process, the volume of data errors will be significant given that more than 4 billion units are distributed every year.[13] These data errors will have a ripple effect through the supply chain—an error in one shipment may indicate a corresponding error in another shipment (e.g., product is sent to one trading partner, but the data is sent to a different trading partner) or data errors may carry forward to subsequent trading partners (e.g., a wholesale distributor buys and sells a full, sealed homogenous case relying on inference). Data errors must not impede the distribution of legitimate product. Therefore, it is critical that regulatory requirements provide the flexibility necessary to allow trading partners to work efficiently to resolve data errors and ensure the distribution of valid product—ultimately to patients—is not disrupted.

When a data exception or error has been identified and the ATP with ownership has determined it is not suspect product, flexibility around the resolution and documentation of the exception so that distribution can proceed without disrupting patient access. This may include issues such as barcode readability challenges that prevent data-product reconciliation.

8. **Who is responsible for providing TI to the dispenser in a drop shipment, the manufacturer or the wholesale distributor?**

Section 582(f) provides an exemption for drop shipments wherein the wholesale distributor that does not physically handle or store product is exempt from providing the dispenser the TI if the manufacturer includes both the TI and the wholesale distributor's contact information directly to the dispenser.[14] This exemption is not mandatory, and if the manufacturer does not provide TI directly to the dispenser and include the wholesale distributor's contact information, the exchange of TI would occur for each change of ownership (manufacturer to wholesaler as well as wholesaler to dispenser), as in any ordinary transaction. It should be noted, however, that if the exemption in Section 582(f) is not leveraged, the exchange of TI for each change of ownership will--operationally--slow the exchange of TI and change of ownership, potentially delaying patient access.

9. **Who is responsible for filing a 3911 when multiple ATPs are part of the investigation of illegitimate product?**

Collaboration among trading partners is essential to the effective investigation of suspect and illegitimate product and trading collaboration in filing Forms 3911 can improve their value, but each trading partner is responsible for determining whether it has a regulatory obligation to file a Form 3911 and how it will meet that obligation.

Each ATP who has exposure to a suspect or illegitimate product while it moves through the supply chain has an obligation to collaborate with other ATPs connected to the product. This includes coordination

[13] Kaiser Family Foundation, "Total number of retail prescription drugs filled at pharmacies," accessed at: https://www.kff.org/health-costs/state-indicator/total-retail-rx-drugs/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

[14] § 582(f)(1).

with investigations and initiating, filing, following up, and terminating a Form 3911.[15] This is aligned with the DSCSA, which requires that all investigations are "in coordination with trading partners."[16]

Trading partners must have systems and procedures in place to quickly notify trading partners who have sent or received suspect or illegitimate product along with the unique incident number on the first 3911 filing for the incident.[17] When multiple ATPs file a Form 3911 for a single incident, each filing ATP must share the unique incident number with other ATPs involved so that subsequent filings are tied to the original filing and incident. For the other ATPs involved, each must independently make its determination as to what it means for it to work "in coordination" with the filing ATP. This determination will establish the conditions under which the ATP is required to file a Form 3911 and how it will do so.

10. What is the process for closing a Form 3911 that cannot be resolved due to unrecoverable product?

An ATP that files a Form 3911 must keep the Form open if the investigation is ongoing and must maintain the product information to assist in a complete and collaborative investigation by law enforcement. If a product has been lost or stolen and is never recovered, then the ATP cannot resolve the Form 3911 for that product. Regardless, the DSCSA requires that trading partners must retain data related to each transaction for six years.[18] To avoid having 3911s open indefinitely, ATPs should be permitted to close an unresolvable 3911 after six years. If the investigation is exhausted and the product was not found investigators should terminate the 3911, providing FDA with an explanation for the termination. If further information is discovered in the future the 3911 should be reopened with a reference to the 3911 number.

We encourage the FDA to clarify in rule or guidance that a Form 3911 is subject to the data retention requirement of the DSCSA and that an ATP that files a Form 3911 for an unresolved or unresolvable Form 3911 may close that Form 3911 after six years.

11. Is TI required for clinical trial product, and if so, how should TI be exchanged?

Clinical trial products are generally outside the scope of DSCSA requirements because there typically is no change in ownership once the product enters the clinical distribution chain.

"Clinical trial products" exist in a variety of situations. First, traditional, investigational new products not yet licensed and used in authorized clinical trials are a "clinical trial product." Second, "clinical trial product" may include marketed product studied post-approval (e.g., phase IV studies). Third, some manufacturers supply "clinical trial product" in commercial packaging (i.e., the product has been FDA-

[15] § 582(c)(4)(B).
[16] §§ 582(b)(4)(A)(i)(II), (c)(4)(A)(i)(II), (d)(4)(A)(i)(II), (e)(4)(A)(i)(II).
[17] "A trading partner who determines that a product in its possession is illegitimate must also notify all immediate trading partners that they believe may have received such illegitimate product not later than 24 hours after the determination is made." Notifications to Trading Partners of an Illegitimate Product or Product with High Risk of Illegitimacy, 83 Fed. Reg. 45,254 (Sept. 6, 2018). Form FDA 483, U.S. Food & Drug Admin., Audit of McKesson Corp. (July 3, 2018), https://www.fda.gov/media/120780/download.
[18] § 582(b)(1)(A)(ii).

approved) to investigators who have purchased the product to use in their own "investigator initiated" clinical studies. Fourth, a manufacturer may purchase another manufacturer's existing commercial product, either directly from that manufacturer or from a wholesale distributor, and such product may be used as a comparator or a combination product in an authorized clinical trial. In each of these instances, the trial sponsor typically retains ownership of the product from the time it acquires the product through patient use.

"Transaction" is defined in the DSCSA as "the transfer of product between persons in which a change of ownership occurs."[19] Once a product enters a trial sponsor's ownership to be used in a clinical trial, the product remains under the ownership of the sponsor. Accordingly, there are no further transactions that trigger the TI exchange requirements for clinical products.

We encourage the FDA to clarify in rule or guidance, or if necessary, clarify through an exemption under 582(a)(3)(A)(iii), that clinical trial products, as described above, are outside the scope of the requirements of the DSCSA.

12. Is TI required when finished product is transacted for later use in compounding?

Yes, a finished product that will be later used in compounding is a still a product at the time of the transaction, therefore TI for that product is required.

The DSCSA defines a "product" as "a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing."[20] Further, the DSCSA defines "transaction" as the transfer of ownership between persons and exempts the dispensing of a product pursuant to a prescription.[21] The practice of lawful compounding is when a licensed pharmacist combines ingredients of a drug to meet the needs of an individual patient.[22] Compounded drugs are exempt from the definition of 'product.'[23]

Often DSCSA "products" are used in the compounding process. While the *compounded drug* is not subject to the DSCSA, the sale of finished product up to the point of compounding is the transaction of a product and is subject to all DSCSA requirements. There is no applicable DSCSA exemption prior to the point the product is consumed in compounding activities. The security of the product prior to compounding is as important as any other product, and all DSCSA should apply. Further, upstream trading partners have no way of knowing or identifying which product will later be used in compounding, so there is no way to distinguish that product from other DSCSA product even if there were a rationale for exempting the product.

[19] § 581(24)(A).
[20] § 581(13).
[21] §§ 581(A), 581(B)(iv).
[22] *Human Drug Compounding,* U.S. Food & Drug Admin. (Apr. 26, 2021), https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding.
[23] § 581(13).

13. The FDA's Wholesale Distributor Verification Requirement for Saleable Returned Drug Product—Compliance Policy Guidance for Industry established enforcement discretion for the verification of saleable returns prior to November 27, 2023. Must all saleable returns to a wholesale distributor be verified after that date?

Yes. FDA does not intend to take action prior to November 27, 2023, against a wholesale distributor who has not verified saleable returns pursuant to Sec. 582(c)(4)(D).[24] However, the wholesale distributor verification requirements of the DSCSA will become enforceable on November 27, 2023, for saleable returns.[25]

14. In addition to verification, an ATP accepting a saleable return must also "associate" the return to prior transaction information. How should an ATP associate a return in this manner?

For a trading partner to accept returned product, the trading partner must be able to associate the returned package with the TI and TS associated with that product. During a transition period following November 27, 2023, serialized product may be returned, but the TI to which it should be associated may not include serial-level data. In that event, trading partners may associate the serialized product to a non-serialized TI to satisfy the association requirements. This will be a transition issue only, and this type of non-serialized association occurs today, typically by association at an invoice level.

Manufacturers who intend on selling returns must verify the product identifier including the SNI, for each sealed homogeneous case of such product or, if such product is not in a sealed homogeneous case, verify the product identifier, including the standardized numerical identifier, on each package.[26]

Wholesale distributors may distribute returned product from a dispenser or repackager only if the wholesale distributor can "associate" returned product with the transaction information and transaction statement associated with that product. Beginning 6 years after enactment of the DSCSA (November 27, 2019) all transactions must include the transaction history to begin with the wholesale distributor that accepted and verified the returned product. TI and TH will not include transaction dates if it is not "reasonably practicable" to obtain such dates. [27]

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[24] "Upon receipt of a returned product that the wholesale distributor intends to further distribute, before further distributing such product, the wholesale distributor shall verify the product identifier, including the standardized numerical identifier, for each sealed homogeneous case of such product or, if such product is not in a sealed homogenous case, verify the product identifier, including the standardized numerical identifier, on each package." § 582(c)(4)(D).

[25] *Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product—Compliance Policies*, U.S. Food & Drug Admin. (Oct. 2020), 4–5, https://www.fda.gov/media/131005/download.

[26] § 582(b)(4)(E)

[27] § 582(c)(1)(B)(i)(II).

15. Will the introduction of serial-level TI force companies to change their saleable return practices?

Possibly. Section 581(17) of the statute defines a return as "providing product to the authorized immediate trading partner from which such product was purchased or received . . . ." This requirement that product only be returned to the trading partner from which it was purchased is further reinforced in 2023. Beginning November 27, 2023 "[e]ach person accepting a saleable return shall have systems and processes in place to allow acceptance of such product and may accept saleable returns only if such person can associate the saleable return product with the transaction information and transaction statement associated with that product."

Under current lot-level traceability, trading partners are only able to confirm prior purchase of a returned product at the lot level. A wholesaler (for example) has no ability to determine whether a specific serialized package that is returned to it was previously sold to that returning trading partner; the wholesaler can only determine whether *some* package within a given lot was sold to the party initiating the return. With the addition of serial-level TI beginning November 27, 2023, trading partners will have the ability to tie a specific returned serialized product to a prior transaction between those parties. Operationally this will preclude a trading partner from returning one specific serialized package to a wholesaler or manufacturer when they originally purchased a different serialized package from that wholesaler or manufacturer. This change may impact common practices related to the return of product under the 340B program.

Wholesale distributors are required to verify the product identifier upon receipt of a returned product that the wholesale distributor intends to further distribute under section 582(c)(4)(D) of the FD&C Act. However, the FDA announced it does not intend to take action against wholesale distributors who do not, prior to November 27, 2023, verify the product identifier prior to further distributing returned product as required under section 582(c)(4)(D) of the FD&C Act.[28]

16. Does the requirement for manufacturers to verify saleable return product sunset on November 27, 2023? Is verification effectively part of the "association" processes the manufacturer will undertake?

According to the manufacturer requirements of the DSCSA, "upon receipt of a returned product that the manufacturer intends to further distribute, before further distributing the product, the manufacturer shall verify the product identifier."[29] However, the sunset provision of the DSCSA states that this requirement will be eliminated.[30]

Despite that sunset, however, sec. 582(g)(1)(F) requires each entity accepting saleable returns to have "systems and processes in place to allow acceptance of such product and may accept saleable returns only

[28] FDA Guidance, "Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product— Compliance Policies," October 2020.
[29] § 582(b)(4)(E).
[30] § 582(k)(2).

if such person can associate the saleable return product with the transaction information and transaction statement associate with that product."[31] This requirement becomes effective November 2023 and, because the TI will include the product identifier information (starting in 2023), the TI validation process effectively includes verification (and more).[32]

17. Is a health care practitioner a dispenser subject to the related requirements of the DSCSA?

A health care practitioner licensed to dispenser or administer drugs is a dispenser but has limited obligation under the DSCSA.

The DSCSA defines a dispenser as any "person authorized by law to dispense or administer prescription drugs,"[33] which clearly includes a health care practitioner licensed to dispense or administer drugs (e.g., a physician, most nurse practitioners). Dispensers generally have four main sets of obligations under the DSCSA: (1) exchange TI and TS and make that information available to regulators upon request, (2) only purchase products to which a DSCSA product identifier is affixed, (3) engage in transaction only with authorized trading partners, and (4) maintain systems and process to identify, investigate, and report suspect and illegitimate products. Section 582(d)(5) exempts dispenser from the first and fourth of those obligations. Accordingly, the health care practitioners are only required to (i) purchase only those products with a DSCSA product identifier affixed, and (ii) engage in transaction only with authorized trading partners.

There are no parallel exemptions for trading partners selling to dispensers (manufacturers, repackagers, and wholesale distributors), however. Trading partners selling product to a health care practitioner therefore is obligated to provide TI and TS (and TH prior to November 27, 2023) to the health care practitioner, but the healthcare practitioner has no corresponding obligation to capture and maintain that information. To meet these obligation, many upstream trading partners have made the TI and TS available to the health care practitioner via a web portal. This is consistent with the Agency's guidance in the "DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information," which explained that web-based platforms, such as portals, are acceptable means to "transmit or access product tracing information." Interoperable tracing can be achieved regardless of whether TI and TS are provided through a push or pull method. Which of these two methods an individual company chooses is a business decision to be made between trading partners.

[31] § 582(g)(1)(F).
[32] While association of the TI effectively includes verification of the product identifier elements, the inverse is not true; verification of the product identifier alone is not sufficient to associate the TI.
[33] "The term 'dispenser' means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a whole distributor." § 581(3)(A).

18. Did the DSCSA eliminate the "five percent" rule that many states historically used to determine whether a dispenser is engaged in wholesale distribution?

Yes, the DSCSA makes clear that a pharmacy is acting as a wholesale distributor and must be licensed as such when it sells product to another pharmacy unless that sale is a minimal quantity sold *to a health care practitioner for in-office use*.[34]

The "five percent" rule allows for the sale of prescription drugs by a pharmacy to a licensed practitioner's office to be considered minimal and not subject to wholesale distribution requirements, so long as the dollar amount of the sales are less than the pharmacy's annual prescription sale. FDA has limited this rule to apply only to pharmacy sales for office use. If a pharmacy sells above five percent or to any wholesale distributor, the pharmacy must be licensed as a wholesale distributor and regulated accordingly.[35]

The statute also excludes certain narrow types of transactions from the TI and TS exchange requirements. Specifically, the TI and TS requirements do not apply to "sales by a dispenser to another dispenser to fulfill a *specific patient need*."[36] This requires the specific patient to be named in the transaction. Accordingly, even though this activity is "wholesale distribution" requiring licensure, TI and TS exchange requirements are exempted *if the sale is for a specific individually named patient*.

19. Is a reverse logistics provider subject to the same licensure requirements as a 3PL?

Reverse logistic providers and returns processors in most instances are subject to 3PL licensure if processing sellable returns and should obtain a 3PL license.

The statute defines both "reverse logistics providers" and "returns processors" as any organization that "processes saleable or nonsaleable product received from an authorized trading partner such that the product may be processed for credit to the purchaser, manufacturer, or seller or disposed of for no further distribution."[37] The agency has clarified that these organizations are to be considered 3PLs because their activities include the provision of logistic services to authorized trading partners without taking ownership of the product or directly transacting with the product.[38] If the organization takes ownership of the product or is responsible for directing transactions of the product, the organization would then be subject to federal and state wholesale distributor requirements.

In July 2022 FDA revised their position on entities which handle products at the end of their lifecycle, not intended to re-enter the supply chain.[39] Entities which handle products intended for destruction, for

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[34] § 581(23)(B)(vii).
[35] National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers, 87 Fed. Reg. 6,711–12 (Feb. 4, 2022) (to be codified at 21 C.F.R. pts. 10, 12, 16, and 205).
[36] § 582(d)(1)(A)(ii).
[37] § 581(18).
[38] *Identifying Trading Partners Under the Drug Supply Chain Security Act*, U.S. Dep't Health & Hum. Servs. 11, (August 2017), https://www.fda.gov/files/drugs/published/Identifying-Trading-Partners-Under-the-Drug-Supply-Chain-Security-Act-Guidance-for-Industry.pdf.
[39] *Identifying Trading Partners Under the Drug Supply Chain Security Act*, U.S. Dep't Health & Hum. Servs. 11, (July 2022), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/identifying-trading-partners-under-drug-supply-chain-security-act.

example, are not considered to be 3PLs. However, if an entity is conducting activities for saleable returns that allow a product back into the supply chain, it generally would be considered a 3PL, and 3PL requirements for licensure and reporting under section 584 of the FD&C Act would apply. If an entity takes ownership of the product or is responsible for the sale or disposition of the product, FDA this activity to fall under the definition of wholesale distribution, subject to all the requirements for WDDs under the DSCSA. Therefore, a returns processor or reverse logistics provider may be considered a 3PL, a WDD, or neither depending on the activities it performs.

20. Is donated product or product sold for charitable purposes subject to Section 582 requirements?

Generally, yes, donated product and product sold for charitable purposes is typically subject to Section 582 requirements.

Section 582 requirements generally apply to any transactions of a product. Section 581(24) defines a transaction as the "transfer of product between persons in which a change of ownership occurs." Requirements, therefore, attach to the change of ownership, and the statute makes no distinction as to whether that transfer of ownership is accompanied by a financial exchange. Whether the product was donated, sold at a reduced price, or sold at full price is generally irrelevant to determining whether a transaction has occurred.

The statutory definition of a transaction goes on to provide that "the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug ***by*** a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1986 to a nonprofit affiliate of the organization" is <u>not</u> a transaction that triggers DSCSA obligations. It is important to note that the plain language of the statute only exempts sales, purchases, and trades *by the charitable organization*. It is not clear that a non-charitable organizations sale of product *to* a charitable organization is exempt. For this reason, most trading partners choose to treat their sale or transfer of product to a charitable organization as subject to the requirements of section 582.

21. Are products donated by a patient assistance program (PAP) subject to Section 582 requirements?

Transactions by IRS 501(c)(3) non-profit entities are not considered transactions and are therefore exempt from Section 582 requirements only if the program a 501(c)(3) entity. If entities are not 501(c)(3) entities DSCSA requirements are required.

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