

HDA Qs and As on the Drug Supply Chain Security Act (DSCSA)

VERSION 4.0

June 2016

This document, the HDA Qs and As on the Drug Supply Chain Security Act (DSCSA), has been prepared by the Healthcare Distribution Alliance (HDA) in consultation with its Traceability Implementation Work Group (Work Group). This document discusses how the DSCSA applies to several areas of wholesale distributor operations and the pharmaceutical supply chain generally.

These Qs and As should be reviewed with reference to the DSCSA and the Food and Drug Administration's (FDA) implementing regulations and guidance. They should also be considered in conjunction with other documents provided by HDA such as the Transaction Scenarios, ASN Guidelines, ASN Business Examples, ASN Exceptions Guidelines and other documents.

These materials are not legal advice and are based on evolving requirements. As such, they may change as FDA issues guidance and regulations implementing the DSCSA. Each company must make its own business decisions about DSCSA implementation. Please consult your operations, regulatory and information technology staff, consultants and legal counsel as well as your trading partners for further implementation guidance.

NOTE 1: Version 4.0 June 2016, is a revision of the Version 3.0 October 2015 Qs and As. We have amended this document based on our evolving understanding of the DSCSA, additional questions we have received as implementation of the statutory requirements continues, and to address information provided by FDA. Generally, the intent or interpretation of the questions has not changed. As Note 4 explains, Version 4.0 includes new questions related to guidance recently released by FDA. In a few instances, modifications to update and/or refine existing Qs and As, such as by clarifying FDA's view of data transmission requirements for drugs that are part of the 340B Program, have been incorporated.

NOTE 2: On December 24, 2014, FDA issued a guidance document entitled, "DSCSA Implementation: Product Tracing Requirements – Compliance Policy" ("Compliance Policy Guidance").¹ In the Compliance Policy Guidance, FDA announced that it would exercise enforcement discretion with respect to the DSCSA's product tracing requirements until May 1, 2015 for manufacturers, wholesale distributors and repackagers. This enforcement discretion did not extend to other requirements in § 582 of the Federal Food, Drug and Cosmetic Act (FD&C Act), such as verification related to suspect and illegitimate product (including quarantine, investigation, notification and recordkeeping) and requirements related to engaging in transactions only with authorized trading partners.

¹ 79 Fed. Reg. 78874 (Dec. 31, 2014), *The Drug Supply Chain Security Act Implementation: Product Tracing Requirements – Compliance Policy; Guidance for Industry; Availability*.

Accordingly, although some of the responses below identify a statutory implementation date of January 1, 2015, we recognize that FDA stated that it intended to exercise “enforcement discretion” and did not intend to begin enforcing the product tracing requirements of the DSCSA until May 1, 2015. We have added an asterisk (*) to those Qs and As below related to product tracing requirements that, though effective on January 1, 2015, were subject to FDA’s exercise of enforcement discretion until May 1, 2015. However, the May 1, 2015 enforcement discretion extension does not apply to all sections of DSCSA, therefore January 1, 2015 remains the implementation date for some sections.

As of May 1, 2015, the enforcement discretion expired and the product traceability requirements applicable to manufacturers, wholesale distributors and repackagers on January 1, 2015 are in effect and enforceable.

NOTE 3: On July 1, 2015, FDA issued a guidance document entitled, “DSCSA Implementation: Product Tracing Requirements for Dispensers– Compliance Policy.” (“Dispenser Compliance Policy Guidance”). The Dispenser Compliance Policy Guidance announced that FDA would exercise enforcement discretion until November 1, 2015 with respect to the DSCSA’s product tracing requirements that would otherwise be applicable to dispensers on July 1, 2015. Specifically, the Agency stated, “FDA does not intend to take action against dispensers who, prior to November 1, 2015, accept ownership of product without receiving the product tracing information, as required by section 582(d)(1)(A)(i) of the FD&C Act.” FDA emphasized the limited scope of this enforcement discretion, stating: “this compliance policy does not extend to transactions in which dispensers must provide the subsequent owner with product tracing information, including transaction history, as required by section 582(d)(1)(A)(ii).”

On October 28, 2015, FDA issued a guidance document entitled, “DSCSA Implementation: Product Tracing Requirements for Dispensers – Compliance Policy (Revised)” (“Revised Dispenser Compliance Policy Guidance”).² The Revised Dispenser Compliance Policy Guidance announced that FDA would extend its enforcement discretion until March 1, 2016 with respect to DSCSA’s product tracing requirements that would otherwise have been applicable to dispensers on November 1, 2015.

Because the traceability requirements for dispensers did go into effect on July 1, HDA uses this original statutory deadline in any questions or answers described below, recognizing that FDA has stated that it will not begin enforcing those requirements until March 1, 2016.

As discussed in Note 4, FDA has chosen to continue to exercise enforcement discretion to a limited group of transactions, that is, certain transactions with first responders.

² *DSCSA Implementation: Product Tracing Requirements for Dispensers- Compliance Policy; Updated Guidance for Industry, Availability*, 80 Fed. Reg. 67408 (November 2, 2015) available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM453225.pdf>

Note 4: On February 29, 2016, FDA announced the release of a guidance, effective immediately, that describes the circumstances under which the Agency would exercise enforcement discretion and not enforce certain provisions of § 582 of the FD&C Act. The Guidance is entitled “Requirements for Transactions with First Responders under Section 582 of the Federal Food, Drug, and Cosmetic Act – Compliance Policy Guidance for Industry” (“First Responder Guidance”)³. In the First Responder Guidance, FDA explains that it will exercise enforcement discretion and not take action against parties to certain transactions with first responders if certain conditions are met. FDA states (footnotes omitted):

Specifically, FDA does not intend to take action against a dispenser who transfers ownership of a product directly to a first responder without providing product tracing information to the first responder, as required by sections 582(c)(1)(A)(ii)-(iv) and (d)(1)(A)(ii) of the FD&C Act, provided that the conditions enumerated in Section IV. A of this guidance are met. FDA also does not intend to take action against trading partners who conduct business with a first responder that is not “authorized” as a dispenser within the meaning of section 581(2)(D) of the FD&C Act. In addition, FDA does not intend to take action against a first responder who: (1) accepts ownership of product without first receiving the product tracing information as required by section 582(d)(1)(A)(i) of the FD&C Act and does not capture and maintain product tracing information as required by section 582(d)(1)(A)(iii) of the FD&C Act; or (2) does not comply with the dispenser requirements for verification of suspect or illegitimate product described in section 582(d)(4) of the FD&C Act.

FDA states that the First Responder Guidance is in effect “until further notice.” Thus, Version 4.0 of this Q and A is modified to reflect this guidance. Three new dispenser-related questions to Section VII are added and additional discussion of transactions where a dispenser sells product to a first responder is also provided in Sections VII and X. If you have further questions about FDA’s First Responder Guidance, HDA urges you to closely review the Guidance and consult with your own legal and regulatory advisors.

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³ *Requirements for Transactions with First Responders under Section 582 of the Federal Food, Drug, and Cosmetic Act – Compliance Policy Guidance for Industry*, 81 Fed. Reg. 10260 (Feb. 29, 2016), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM488240.pdf>

I. DEC 31, 2014 COMPLIANCE POLICY GUIDANCE

1. Does the Compliance Policy Guidance released by FDA on December 31, 2014 extend the deadline to implement DSCSA?

No, it does not. FDA has granted enforcement discretion for one part of the DSCSA, which means that the law is still in effect and should be implemented. However, FDA is intending to exercise enforcement discretion for trading partners that meet the description in the Policy Guidance. For additional information, see Note 1 above in the cover page.

2. Does the Compliance Policy Guidance grant enforcement discretion for implementation of the entire DSCSA until May 1, 2015?

No, the Compliance Policy Guidance only affects the data transmission portion (the Transaction Information (TI), Transaction History (TH) and Transaction Statement (TS) data elements) of the DSCSA. It does not change or modify the implementation dates or deadlines of any other DSCSA requirements including but not limited to submitting licensure registration, suspect and illegitimate product, etc. For additional information, see Note 1 above in cover page.

II. GENERAL

4. Will wholesale distributors be required to provide lot number (in TI and TH) to downstream trading partners starting January 1, 2015*?

Under the DSCSA, a “direct purchase wholesale distributor” [*i.e.*, one that acquired the product directly from the manufacturer, exclusive distributor or repackager (in the case of a repackager, only if the repackager purchased directly from the manufacturer)] is NOT required to pass lot number. If a wholesale distributor is not a “direct purchase wholesale distributor,” it must pass lot number as part of TI and TH when transferring ownership of the product. For additional information, see the separate HDA ASN Business Examples Document.

5. What transaction data (TI/TH/TS) needs to be passed in the following scenario: Affiliate Manufacturer to Affiliate Repackager to Wholesale Distributor? In this scenario, one affiliate manufactures the finished product and sells to the other affiliate, who is the repackager. The repackager packs into NEW finished product packaging and sells to wholesale distributors.

First, because the manufacturer and repackager are affiliates, the manufacturer’s transfer of product to the repackager qualifies for an exemption from the definition of “transaction.” Thus, the manufacturer would not have to pass TI/TH/TS to the repackager. Second, the repackager would have to pass TI/TH/TS to the wholesale distributor, with TH starting with the repackager. Finally, § 582(c)(1)(A)(ii) creates the “direct purchase option” under which purchases made directly from (i) the manufacturer, (ii) the exclusive distributor, or (iii) a repackager that purchased direct from the manufacturer, qualify for abbreviated TI and TH. Under this transaction scenario, because the wholesale distributor is purchasing from a direct-purchase repackager, the wholesale distributor

would not have to include the lot number in TI or TH, and would not have to include the transaction date or shipment date (associated with its acquisition of product from the repackager) in TH.

6. How should wholesale distributors address the gap between the requirement for wholesale distributors to provide TI/TH/TS on January 1, 2015*, and the requirement for dispensers to receive it on July 1, 2015?

Trading partners will need to decide how they wish to address this gap as a business matter. As discussed in Note 3, FDA extended the date by which dispensers must begin receiving TI/TH/TS to March 1, 2016.

7. Does shipment date need to be included in TI and TH for compliance with DSCSA?

Shipment date is only required to be included in TI/TH when the shipment date is more than 24 hours after the transaction date.

8. For a given transaction, when does ownership transfer take place?

Supply agreements may specify different points for actual transfer of title of goods, *e.g.*, title may pass when goods leave the shipper's dock, when the goods are delivered to the buyer's dock, or when the buyer opens the truck, inspects the delivery and accepts it. "Transaction" is defined in DSCSA as "the transfer of product between persons in which a change of ownership occurs." § 581(24)(A). HDA has recommended that FDA permit trading partners to use any commercially reasonable and supportable transaction date. FDA has not responded to this recommendation at this time.

9. Can you provide clarification on transaction date and shipment date as it relates to the ASN and packing list?

For the purposes of the DSCSA, transaction date is the date of ownership transfer as recognized by the trading partners. The DSCSA does not define specifically how a company is to determine transaction date. HDA has recommended that FDA permit trading partners to use any commercially reasonable and supportable transaction date in whatever document is sent, whether the ASN or a packing slip. FDA has not responded to this request at this time. In the ASN, the segment containing the transaction date is the Beginning Segment Date or "BSN".

10. When a seller prepares a packing list, the shipment date is unknown. It might ship the same day or within the next couple of days. Which date should be printed on the packing list? After the ASN is sent, the seller has an actual ship date. Does the ship date in the ASN need to match the date on the packing list? If so, how can this be achieved?

The transaction date must be included on whichever document/documents that the seller designates to satisfy the DSCSA requirement to pass TI/TH/TS (whether packing slip, ASN or other). The DSCSA does not require that the dates used on the packing slips and ASNs match, nor does HDA offer any guidance on this.

11. FDA recognizes 10-digit NDC numbers, yet certain customers require 11-digit or 12-digit NDC numbers for a variety of business reasons. What NDC number should be included in the TI/TH in order to comply with the DSCSA requirements?

Trading partners should use the same NDC number (whether 10 or 11 digits) when placing orders and sending ASNs.

12. Is there a definition of “co-licensed partner”?

The DSCSA definition of “manufacturer” includes a “co-licensed partner” of the holder of the drug product’s New Drug Application (NDA), Abbreviated New Drug Application (ANDA) or Biologics License Application (BLA), or the NDA/ANDA/BLA holder’s affiliate. However, the DSCSA does not otherwise define “co-licensed partner.” The term is commonly used in industry and has been defined in the laws of many states. These definitions may help inform how FDA should interpret “co-licensed partner” for DSCSA purposes. To help inform FDA’s interpretation, several supply chain members have communicated to FDA the view that “an entity, including a private label distributor, that receives product from the NDA/ANDA/BLA holder pursuant to a license or similar contractual agreement that confers a right on the entity to sell the product through its distribution channels is a co-licensed partner of the NDA/ANDA/BLA holder and therefore meets the DSCSA definition of ‘manufacturer’.”⁴

To date, FDA has not commented on this view.

13. What responsibility for the TI/TH/TS data does a pharmacy have if it sells or merges its pharmacy business, including its inventory of products covered by the DSCSA, to or with another pharmacy? Is the sale of a pharmacy to another that includes the products in the seller’s inventory, a “transaction” under the DSCSA? What responsibility does the new purchasing pharmacy have for the existing data of products previously purchased and sold by the selling pharmacy?

There are two considerations for the data involved:

a) When a selling pharmacy is sold to a buying pharmacy, and the sale includes the seller’s existing inventory of products, is that sale a “transaction” under the DSCSA that would require the selling pharmacy to pass TI/TH/TS to the buying pharmacy?

and

b) When a pharmacy is sold to or merges with another pharmacy, what is the appropriate disposition of the data the selling or merging pharmacy has had to maintain for six years for each product transaction?

⁴ Comment from Pharmaceutical Distribution Security Alliance (PDSA) Q and A Document May 22, 2014 submitted to Dkt. No. FDA-2014-N-0337-0002, available at <http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0337-0002>.

Generally, TI/TH/TS data must be provided for any “transaction” (*i.e.*, change in ownership) of a covered drug product. However, the DSCSA explicitly exempts from the definition of “transaction” (and thus from the requirements to pass or receive TI/TH/TS) any “distribution of a product pursuant to the sale or merger of a pharmacy or pharmacies.” § 581(24)(B)(ix). Therefore, the selling or merging pharmacy is not required to provide TI/TH/TS for the sale of the drugs in its inventory that are part of the sale of its business to the acquiring pharmacy.

Under the DSCSA, the selling pharmacy would have been required to receive TI/TH/TS data for all product transactions after July 1, 2015 (though FDA granted enforcement discretion until March 1, 2016) and that pharmacy must maintain those data for six years. As discussed above, the DSCSA exempts the selling pharmacy from passing TI/TH/TS for the inventory it sells in a merger or other corporate sale of its business to another pharmacy. The statute does not specifically address what should happen to the selling pharmacy’s existing transaction data for its acquisition of product. We believe the most prudent reading of the DSCSA is that the selling pharmacy should share with the purchasing pharmacy the historical TI/TH/TS data it received so that the purchasing pharmacy may maintain the data for six years from the original transaction date. If the selling pharmacy was using a third-party to maintain its data, the seller should inform the buying pharmacy on how to access that historical data. Without possession of or access to the historical TI/TH/TS for the inventory it acquired in the corporate transaction, the purchasing pharmacy might not be able to comply with DSCSA requirements regarding, among other things, investigations of suspect and illegitimate product, and requests for verification.

14. How can I find out if my trading partner is an “authorized trading partner”?

DSCSA requires each supply chain member to ensure that it buys products from and sells products to only “authorized trading partners.” A **manufacturer** is considered authorized if it is registered with the FDA as a drug establishment. FDA maintains a searchable database that can be checked to confirm a drug manufacturer’s registration status. See <http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm>. The DSCSA defines “manufacturer” to include an NDA/ANDA/BLA holder. If an application holder does not physically produce product, then FDA does not permit the company to register its facility. Industry stakeholders have proposed that application holders – as well as other entities that would appear to function for DSCSA purposes as manufacturers, yet are not permitted by FDA to register – be considered by FDA to be “authorized” for DSCSA purposes.⁵ The FDA has not yet commented on the stakeholders’ recommendations.

A **wholesale distributor** is considered authorized if it has a valid state license (or federal license if the state does not issue licenses) and has reported its current state licenses to the FDA. You can check state licensing websites for licensure status. For most states this information is included in the state Board of Pharmacy’s website. These websites usually make available to the public the licensed entity’s name and license number. FDA has provided a listing of state licensing authority

⁵ See Q & A # 14 PDSA Letter Pharmaceutical Distribution Security Alliance Questions and Answers Regarding the Drug Supply Chain Security Act submitted to FDA on October 24, 2014. www.pdsaonline.org

information here:

<http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm>

You may also ask that your trading partner provide documentation of their Authorization status, such as by providing a copy of a license certificate.

The DSCSA also requires wholesale distributors to report licensure and certain other information for each facility annually to FDA and FDA must make some of that information publicly available. See § 503(e)(2). Licensure reporting data are now searchable on FDA's website at <http://www.accessdata.fda.gov/scripts/cder/wdd3plreporting/index.cfm>. The licensure information searchable from this database may be another route for helping to determine authorization status information.

A third-party logistics provider, like a wholesale distributor discussed above, is considered authorized if it has a valid state license (or federal license if the state does not issue licenses) and has reported its current state licenses to the FDA. § 584(a)-(b). You can check FDA's database for licensure status at <http://www.accessdata.fda.gov/scripts/cder/wdd3plreporting/index.cfm>.

Some members of the supply chain have proposed to FDA that this publicly available information should be allowed to be used to verify authorization status.⁶ FDA has not yet responded to this recommendation.

A dispenser is considered authorized if it/he/she has a valid license under state law. Trading partners can check state-maintained databases to confirm licensure status, or, as above, ask the dispenser to provide a copy of the applicable license certificate. Supply chain partners have also requested that FDA recognize the limited instances in which dispensers should be "authorized" but are not necessarily licensed by the state. Certain Department of Defense facilities are one example.⁷

All supply chain partners should check with their own advisors and regulatory counsel as to the most appropriate method for confirming authorization status for their individual business.

In the First Responder Guidance,⁸ FDA states that it does not intend to take enforcement action against a trading partner that transfers ownership of a product to a first responder who is not "authorized" as a dispenser as defined in § 581(2)(D).

III. SALABLE RETURNS

15. What is a "return" under DSCSA?

⁶ See Q and A #12 in the Comment from Pharmaceutical Distribution Security Alliance (PDSA) Q and A Document May 22, 2014 submitted to Dkt. No. FDA-2014-N-0337-0002, available at <http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0337-0002>.

⁷ See Q and A # 15 in the Letter Pharmaceutical Distribution Security Alliance Questions and Answers Regarding the Drug Supply Chain Security Act submitted to FDA on December 4, 2014. www.pdsaonline.org.

⁸ *Requirements for Transactions with First Responders under Section 582 of the Federal Food, Drug, and Cosmetic Act – Compliance Policy Guidance for Industry*, 81 Fed. Reg. 10260 (Feb. 29, 2016), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM488240.pdf>.

“Return” as used under the DSCSA means providing product to the authorized immediate trading partner from whom such product was purchased or received, or to a returns processor or reverse logistics provider for handling of such product. § 581(17). Sending product to a trading partner from whom the product was not purchased is a new transaction and not a return. As discussed in Question 16 below, the DSCSA provides streamlined procedures for certain product movements that meet the definition of a “return.”

16. How does DSCSA address salable returns to a wholesale distributor?

Beginning January 1, 2015*, until November 27, 2019, a wholesale distributor may accept a return from a dispenser or repackager pursuant to the terms and conditions of an agreement between the parties. The parties may agree that the dispenser or repackager does not need to provide TI, TH and/or TS with the returns it makes to its wholesale distributor supplier. The wholesale distributor may resell the returned product without providing TH that reflects the prior sales. For any subsequent resale of the returned product, the TH begins with the wholesale distributor that accepted the return. § 582(c)(1)(B)(i)(I).

After November 27, 2019, a wholesale distributor may accept returned product from a dispenser or repackager only if it can associate the returned product with the TI and TS. For all transactions after that date, the TH shall begin with the wholesale distributor that accepted and verified the returned product. However, the TH need not include transaction dates if it is not reasonably practicable to obtain those dates. § 582(c)(1)(B)(i)(II).

17. Are TI/TH/TS required if a “secondary distributor” is returning a drug product to a direct purchase distributor? Can the direct purchase distributor resell these returned products?

This transaction is a return under the DSCSA, but because it is from a wholesale distributor rather than from a dispenser or repackager, the return is not eligible for streamlined treatment under the DSCSA. Therefore, the return from the “secondary distributor” to the direct purchase distributor constitutes an independent transaction that requires full transaction data. The “secondary distributor” must provide TI/TH/TS to the direct purchase distributor. And yes, while the direct purchase distributor may resell the product, the DSCSA is unclear as to whether the TH for the subsequent sale may begin with the direct purchase distributor or whether the direct purchase distributor must show the previous sale to and return from the “secondary distributor,” as well as all prior TH back to the original manufacturer.

18. Are TI/TH/TS required if a direct purchase distributor is returning drug product to an exclusive distributor? Can the exclusive distributor resell the drug product? If so, what TI/TH/TS does the exclusive distributor have to provide with a subsequent resale of the product?

This transaction is a return under the DSCSA, because it is from a wholesale distributor to the party (the exclusive distributor) from whom it acquired the product. However, the return is not eligible for streamlined treatment under the DSCSA applicable to returns accepted by wholesale

distributors from a dispenser or repackager. Therefore, the return from the wholesale distributor to the exclusive distributor constitutes an independent transaction that requires full transaction data. The wholesale distributor must provide TI/TH/TS to the exclusive distributor.

And as in Question 17 above, while the exclusive distributor can resell the product, the DSCSA is unclear as to whether the TH for the subsequent sale begins anew with the exclusive distributor or whether it must show the previous sale to and return by the wholesale distributor, as well as all prior TH back to the original manufacturer.

19. When a dispenser changes wholesale distributor suppliers, can the new wholesale distributor (Distributor Y) accept as a return product that was originally sold to the dispenser by its initial distributor (Distributor X)?

Distributor Y can accept product from the dispenser, but the product would not be treated as a “return” under the DSCSA and thus would not be entitled to the streamlined treatment described in Question 15. The sale from the dispenser to Distributor Y would represent a new transaction for which the dispenser would have to pass TI/TH/TS (and, technically, be licensed as a wholesale distributor because it is engaging in wholesale distribution). Further, if Distributor Y makes a subsequent sale of that product, the TH it passes would need to include the transaction with the dispenser, as well as all other prior transactions. If a return is nonsalable, TI/TH/TS would not need to be passed.

20. Does the DSCSA define what a returns processor is? Can a returns processor handle both salable and nonsalable products?

Yes. The DSCSA defines returns processors (or “reverse logistics provider”) as “a person who owns or operates an establishment that disposes or otherwise processes salable or nonsalable product received from an authorized trading partner such that the product may be processed for credit ... or disposed of for no further distribution.” § 581(17). Thus, the returns processor is allowed to handle both salable product and nonsalable product under the DSCSA. However, there is no provision that permits a returns processor to sell the returned product. As a result, if the returns processor sells the returned goods, it would be acting as a wholesale distributor and would have to comply with the traceability and licensure requirements applicable to a wholesale distributor (including receiving and passing full TI/TH/TS and including TH for the product’s prior transactions).

21. Is a returns processor required to receive or provide TI/TH/TS? Is there a distinction between salable and nonsalable product?

In most circumstances, a returns processor would not be required to receive or pass TI/TH/TS.

The DSCSA defines returns processor (or reverse logistics provider) as “a person who owns or operates an establishment that disposes or otherwise processes salable or nonsalable 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.”

§ 581(18). While not explicit in this definition, the returns processor generally does not take ownership of the returned product and, therefore, would not be required to receive TI/TH/TS. Furthermore, for nonsalable product, TI/TH/TS do not need to be passed.

If the returns processor takes ownership of a salable return and resells the drugs, the returns processor would be treated as a wholesale distributor and would have to both receive and pass TI/TH/TS. If the returns processor receives a salable return from the original purchaser (“Buyer #1”) -- but does not take ownership of the drugs -- and then, at the owner’s (“Seller”) request ships the drugs to a new purchaser (“Buyer #2”), then the Seller will need to provide TI/TH/TS to Buyer #2.

Whether Seller must receive TI/TH/TS from Buyer #1 when Buyer #1 returns the drugs (through the returns processor) depends on many factors, including whether the Seller is the manufacturer or wholesale distributor, and whether Buyer #1 is a direct purchase wholesale distributor, non-direct-purchase wholesale distributor or dispenser. Please consult with your regulatory counsel for details specific to your situation.

22. What TH must a wholesale distributor provide when it resells returned product that it originally sold prior to January 1, 2015*, but seeks to resell after that date?

The answer to this question is not affected by when the product was initially sold by the wholesale distributor. A wholesale distributor may accept returns from a dispenser or repackager to whom it sold the product pursuant to the terms and conditions of an agreement between the parties. Starting January 1, 2015*, the TH the wholesale distributor provides for any subsequent sale of that product does not have to reflect the prior transactions. For any resale, the TH begins with the wholesale distributor that accepted the return.

23. Can a wholesale distributor accept returns from a repackager, and if so, what TI/TH/TS must be passed by the repackager on the return transaction, and what TI/TH/TS must be passed by the wholesale distributor if and when it resells the product?

See Question 15 above regarding the streamlined procedure under the DSCSA that permits a wholesale distributor to accept returns from a repackager (or dispenser) to whom it sold the product pursuant to the terms and conditions of an agreement between the parties. The TH the wholesale distributor provides for any subsequent sale of that product does not have to reflect the prior sale to or return by the repackager. For any resale transactions, the TH would begin with the wholesale distributor that accepted the return.

However, if the repackager has repackaged the product (*e.g.*, with new labeling, new lot number and new NDC number), this would appear to be a new product, which, we believe, would not qualify as a “return” under DSCSA; rather, the repackager’s shipment back to the wholesale distributor would constitute a new transaction involving a new product. Moreover, if the wholesale distributor sought to sell the indirectly sourced repackaged product, it would have to pass full TI/TH/TS tracing back to the original sale by the manufacturer (which would present a significant challenge).

24. What if a wholesale distributor ships a product to a licensed practitioner and the licensed practitioner returns the product? What TI/TH/TS would the wholesale distributor need to provide on a subsequent resale of the returned product?

The DSCSA includes licensed practitioners within the definition of “dispenser,” but provides that licensed practitioners are exempt from complying with the traceability requirements generally applicable to dispensers. Although the statute is far from clear, we believe returns by licensed practitioners would be treated in the same manner as returns from any other dispenser. That is, a licensed practitioner could return product to the wholesale distributor from whom he/she purchased the product (pursuant to an agreement between the parties) without having to provide TI/TH/TS, and the wholesale distributor could then resell the product by providing TH that started with the wholesale distributor’s resale.

25. Does the DSCSA affect the return of product from wholesale distributors back to the manufacturer? Or 3rd party processors? If so, what information has to be passed?

The DSCSA provides that a wholesale distributor may return nonsalable product to the manufacturer from whom it acquired the product without having to pass TI/TH/TS. Such return can be made directly to the manufacturer or through a 3rd party returns processor.

The DSCSA does not specifically address returns of salable product from a wholesale distributor to the manufacturer. Accordingly, at least arguably, such return transactions would not be exempt from the traceability requirements and the wholesale distributor would have to pass TI/TH/TS to the manufacturer (whether directly or through a 3rd party returns processor). The content of the TH would depend on the prior transactions associated with the product. [NOTE: If the product is sent back to the manufacturer prior to the wholesale distributor formally taking ownership of the product, then the movement of goods would not constitute a transaction and thus the wholesale distributor would not need to pass TI/TH/TS when shipping the goods back to the manufacturer.]

IV. NONSALABLE RETURNS

26. What requirements apply to nonsalable returns to or from a wholesale distributor?

Under the DSCSA, a wholesale distributor may return a nonsalable product to the manufacturer or repackager, to the wholesale distributor from whom such product was purchased, or to a person acting on behalf of such a person, such as a returns processor, without providing TI/TH/TS.

Further, the DSCSA does not require a dispenser to provide TI/TH/TS when it returns nonsalable product to the wholesale distributor from whom it acquired the product. Implicitly, this means that the wholesale distributor is relieved of any requirement to receive TI/TH/TS when accepting the nonsalable returned goods from the dispenser. Further, we believe this transfer may be outside the scope of the DSCSA because when a drug is nonsalable, it is not for “administration to a patient.” If a drug is not for administration to a patient, it does not meet the definition of “product” under the DSCSA in § 581(13). Therefore nonsalable returns do not have to be accompanied by TI/TH/TS.

V. SUSPECT AND ILLEGITIMATE PRODUCT

27. The DSCSA does not require wholesale distributors to report suspect product. However, DSCSA does require wholesale distributors to report to FDA if a suspect product is determined NOT to be illegitimate (thus, implicitly notifying the FDA that the wholesale distributor had considered the product suspect in the first place). How should wholesale distributors address this apparent inconsistency in the law?

The DSCSA states that the wholesale distributor shall, upon clearing suspect product, provide notice to “the Secretary, if applicable.” § 582(c)(4)(A)(ii). A wholesale distributor can make an independent determination that a product is suspect, or it can find out about suspect product through a request for verification from the Secretary.⁹ Thus, the phrase “if applicable” in the statute should be read to mean that a wholesale distributor must notify the Secretary that suspect product is cleared (*i.e.*, is NOT illegitimate) only when the investigation was initiated in response to a request for verification from the Secretary.

VI. 340B QUESTIONS

28. Does the DSCSA indicate to which entity a wholesale distributor should provide the TI/TH/TS data (*i.e.*, transaction data) for drugs purchased under the Federal Government’s 340B Drug Discount Program (“340B Program”)?

The DSCSA does not mention 340B Program drugs specifically. However, the DSCSA makes clear that when a wholesale distributor sells drugs, it must provide the transaction data to the party to which it transfers ownership of those drugs. In the case of sales made under the 340B Program (described further below), the wholesale distributor is transferring ownership of the drugs to so-called “Covered Entities” (“Covered Entities” or “CEs” such as hospitals) that are participating in the 340B Program. Thus, the plain language of the DSCSA would require the wholesale distributor to provide transaction data to each Covered Entity to which it sells (transfers ownership to) drug products.

As background, under the 340B Program, administered by the Health Resources and Services Administration (“HRSA”), wholesale distributors sell products to Covered Entities (typically hospitals). Some of the CEs contract with retail pharmacies (“Contract Pharmacies” or “CPs”) to provide dispensing services to 340B Program eligible patients.

Sometimes, a CE will purchase products from its wholesale distributor and direct the wholesale distributor to ship the drugs directly to one of the Covered Entity’s Contract Pharmacies, which then dispenses the drugs to 340B eligible patients.

⁹ § 582 (c)(4)(A)(i) “Upon making a determination that a product in the possession or control of a wholesale distributor is a suspect product, or upon receiving a request for verification from the Secretary that has made a determination that a product within the possession or control of a wholesale distributor is a suspect product...”

This “bill to/ship to” arrangement has caused some confusion regarding to which party the wholesale distributor should send the DSCSA-required transaction data. A plain reading of the DSCSA dictates that the wholesale distributor must provide the transaction data to the Covered Entity, the purchaser who is accepting ownership of the drugs from the wholesale distributor, regardless of whether the drugs themselves are shipped to the Covered Entity’s CP.¹⁰

A coalition of CEs and CPs has taken the position that they would prefer for wholesale distributors to provide transaction data to Contract Pharmacies. The coalition petitioned FDA for an exemption from the DSCSA requirements that would permit wholesale distributors to send the transaction data to the CPs.¹¹

FDA denied the CE/CP coalition’s request on March 1, 2016. Therefore, wholesale distributors must continue to provide the transaction data to the CE who is the purchaser accepting ownership of the drugs from the wholesale distributor, regardless of whether the drugs themselves are shipped to the Covered Entity’s CP. FDA suggested that CEs and CPs use third party agreements to address DSCSA responsibilities for maintaining product tracing information.

VII. DISPENSER RELATED QUESTIONS

29. Are dispensers, such as hospitals, responsible for providing TI/TH/TS when they provide or sell drugs or drug products to emergency medical services (such as fire departments or ambulances)?

There are many factors that affect whether this transfer of ownership is covered by, or exempt from, the DSCSA’s TI/TH/TS data requirements.

The hospital would not have to provide transaction data if the transfer qualifies for one of the exemptions noted in the statutory definition of “transaction” at § 581(24)(B). These exemptions include, but are not limited to:

- Intracompany distributions between affiliates;
- Distributions by a dispenser to a healthcare entity under “common control” with it;
- Distribution for “emergency medical reasons including a public health emergency declaration...” (a distribution as a result of a drug shortage not caused by public health emergency does not qualify for this exemption);
- The product is a blood or blood component intended for transfusion (discussed in Question 33 below);

¹⁰ A matrix describing the data that must be provided and a graphic depiction of this type of business model can be found in slides 5 and 7 of the HDA “Transaction Scenarios” <http://www.healthcaredistribution.org/~media/pdfs/government-affairs/traceability-resource-2014-transaction-scenarios.ashx>

¹¹ See Exemption request submitted to the Honorable Margaret A. Hamburg, M.D., Commissioner, U.S. Food and Drug Administration, March 24, 2015, by the National Association of Chain Drug Stores, Safety Net Hospitals for Pharmaceutical Access, American Society for Health-System Pharmacists, National Association of Counties, National Alliance of State and Territorial AIDS Directors, and Planned Parenthood Federation of America.

- The seller is a charitable organization described in section 501(c)(3) of the Internal Revenue Code and the purchaser is a nonprofit affiliate of the seller; and,
- The product is a medical convenience kit (discussed in Question 34 below).

Another possible exclusion from the requirement to pass TI/TH/TS could exist if one dispenser sells to another dispenser to fill a “specific patient need.” The DSCSA defines “specific patient need” as:

the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. Such term does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need. § 581(19). (emphasis added).

The DSCSA’s exclusions and exemptions are very complex and the above list is not exhaustive.

In addition, a dispenser may be relieved from providing TI/TH/TS to first responders it sells product to under certain conditions. In its First Responder Guidance¹² issued on February 29, 2016, FDA describes the circumstances under which it intends to exempt product sales to first responders from TI/TH/TS and other DSCSA requirements (footnotes omitted):

FDA does not intend to take action against a dispenser who transfers ownership of product directly to a first responder where the dispenser does not provide the first responder with product tracing information [the TI/TH/TS] as required by sections 582(c)(1)(A)(ii)-(iv) [product tracing requirements for wholesalers] and (d)(1)(A)(ii) [product tracing requirements for dispensers] of the FD&C Act, provided that:

- the dispenser captures and maintains the product tracing information for such transaction ... for not less than six years after the transaction ... and
- the dispenser provides such product tracing information to the first responder or Secretary, if requested, not less than two business days after receiving the request or in such other reasonable time as determined by the Secretary, based on the circumstances of the request.

Also, FDA does not intend to take action against a trading partner that transfers ownership of a product to a first responder who is not “authorized” under the DSCSA because the Agency recognizes that first responders may not be “authorized” “dispensers” as those terms are defined in § 581. FDA’s enforcement discretion “does not extend to the other requirements of § 582, including the requirement for manufacturers, wholesale distributors, dispensers and repackagers to verify suspect and illegitimate product (including quarantine, investigation, notification and

¹² *Requirements for Transactions with First Responders under Section 582 of the Federal Food, Drug, and Cosmetic Act – Compliance Policy Guidance for Industry*, 81 Fed. Reg. 10260 (Feb. 29, 2016), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM488240.pdf>.

recordkeeping)...” FDA’s enforcement discretion “does not extend to any other requirement of the FD&C Act that may apply, including sections 503 and 583.”¹³

It is important for dispensers to know that state laws and regulations that exempted a dispenser from the state’s wholesale distribution licensure requirements are no longer available. For example, state “five percent” rules used to permit pharmacies to sell a small quantity of drugs to other pharmacies without having to be licensed as a wholesale distributor. The DSCSA’s data transmission and licensure requirements preempt these state laws and regulations. This means that, unless otherwise exempt, the transaction is subject to the DSCSA – the selling pharmacy would have to pass TI/TH/TS, would have to store those data, would be considered a wholesale distributor for purposes of that sale, and would be subject to the DSCSA requirements applicable to wholesale distributors, including licensure. Question 31 addresses this issue further.

HDA also encourages such a review because the DSCSA contains additional requirements, including provisions about licensure, storage of data, recordkeeping, and only doing business with authorized trading partners, which may apply to a dispenser in a product transaction.

Please refer to the answers to Section X. EXCEPTIONS TO TRANSACTION DATA REQUIREMENTS of this Q and A for additional discussions of the TI/TH/TS data requirements and exclusions.

There are many forms that such transfers of ownership may take that are unique to a supply chain entity’s individual business model, practices and sales circumstances. Further, the DSCSA is very complex. HDA strongly urges each dispenser to consult with its own legal counsel if it plans on any sale, loan, or trade of product (beyond the usual dispensing to patients) that it believes is exempted from the DSCSA or subject to FDA’s enforcement discretion.

30. Is a licensed practitioner responsible for receiving or sending TI/TH/TS?

The DSCSA defines “dispenser” to include retail pharmacies, hospital pharmacies, a group of chain pharmacies under common ownership or control that do not act as a wholesale distributor and other persons “authorized by law to dispense or administer prescription drugs.” § 581((3)(A). The DSCSA does not include a separate definition for “licensed practitioner,” but clearly a licensed practitioner is one type of “dispenser.”

As a general rule, all dispensers must receive TI/TH/TS when they accept ownership of a product. However, the DSCSA provides that this requirement does **not** apply to “licensed health care practitioners authorized to prescribe or administer medication under State law or other licensed individuals under the supervision or direction of such practitioners who dispense or administer product in the usual course of professional practice.” § 582(d)(5). Certainly, physicians (and those who prescribe under their supervision) would qualify for this exclusion and would not be required to receive TI/TH/TS.

¹³ Sections 502 and 583 are the provisions of the FD&C Act requiring wholesale distributor licensure.

The DSCSA also contemplates that retail pharmacies may sell “minimal quantities” of prescription drugs to licensed practitioners for office use. Such sales are specifically excluded from the definition of “transaction,” so that the retail pharmacies are not required to provide TI/TH/TS and the licensed practitioners are not required to receive TI/TH/TS for such sales. § 581(24)(B)(vii). The DSCSA does not define “minimal quantities” and FDA has not defined the term.

If a licensed practitioner sells a DSCSA-covered product, unless the transaction is exempt from the data transmission requirements or subject to FDA enforcement discretion (*see e.g.* Question 29), the licensed practitioner not only would have to provide TI/TH/TS to its customer (regardless of whether it is selling to another licensed practitioner) and store those data, but he/she also would be considered a wholesale distributor for purposes of that sale and have to comply with the DSCSA requirements applicable to wholesale distributors (including the licensure requirement).

HDA understands that a number of entities have requested that FDA clarify the data receipt and transmission requirements for dispensers (presumably including licensed practitioners). In an exercise of enforcement discretion, FDA has granted a limited exception from the data transmission and authorized trading partner requirements for sales of products by dispensers to first responders.¹⁴ Given the multiple factors that may be involved with each transaction and some of the vague terms used in the statute, HDA strongly urges practitioners to consult with their own legal counsel if they plan on a sale or purchase they believe is exempted from the data transmission requirements or otherwise subject to FDA’s enforcement discretion.

31. When is a dispenser exempt from sending TI/TH/TS to a subsequent purchaser? Are loans and borrowing of products between dispensers covered by the DSCSA? Can a dispenser still rely on a state’s “5 percent rule” to sell product to other dispensers?

The DSCSA defines “dispenser” to include retail pharmacies, hospital pharmacies, a group of chain pharmacies under common ownership or control that do not act as a wholesale distributor and other persons “authorized by law to dispense or administer prescription drugs.” § 581(3)(A). As a general rule, a dispenser must send TI/TH/TS for each “transaction,” that is, when the dispenser transfers ownership of a product to another person. *See* § 581(24) (definition of “transaction”); § 582(d)(1)(A)(ii) (dispenser shall provide subsequent owner of product TI/TH/TS for each transaction).

The DSCSA does not distinguish among products that a dispenser sells, borrows, or loans to another entity. Unless the transaction is exempt, a dispenser transferring ownership of product via sale, loan, or borrowing to another entity would have to pass TI/TH/TS to the subsequent purchaser, would have to store those data, and would be considered a wholesale distributor for purposes of that sale and have to comply with the DSCSA requirements applicable to wholesale distributors (including the licensure requirement).

¹⁴ *See* Requirements for Transactions with First Responders under Section 582 of the Federal Food, Drug, and Cosmetic Act – Compliance Policy Guidance for Industry, 81 Fed. Reg. 10260 (Feb. 29, 2016), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM488240.pdf>.

The DSCSA contains certain exemptions that may apply to dispensers when they transfer ownership of product to another entity. These exemptions include the following:

- The dispenser does not have to supply TI/TH/TS when dispensing to a patient, § 582(d)(1)(A)(ii).
- A licensed retail pharmacy may sell “minimal quantities” of product to a licensed practitioner for office use without providing TI/TH/TS to the licensed practitioner. § 581(24)(B)(vii). (Note: The DSCSA does not define “minimal quantities” and FDA has not defined the term.)
- A dispenser may sell product to another dispenser to “fulfill a specific patient need” without providing TI/TH/TS to the purchasing dispenser. § 582(d)(1)(A)(ii). The DSCSA defines “specific patient need” as “the transfer of a product from one pharmacy to another to fill a prescription for an identified patient.” § 581(19). “Specific patient need” “does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need. § 581(19).
- A dispenser does not need to supply TI/TH/TS if it distributes product for emergency medical reasons, including when a public health emergency has been declared. However, a drug shortage “shall not constitute a public health emergency” unless the public health emergency caused the shortage. § 581(24)(B)(iii) (emphasis added).
- Intracompany distribution of product between members of an affiliate are not transactions under the DSCSA and so do not require the sending and receipt of TI/TH/TS. § 581(24)(B)(i).
- The distribution of product among hospitals or other health care entities under common control are not transactions under the DSCSA and so do not require the sending and receipt of TI/TH/TS. § 581(24)(B)(ii).
- Transfers of ownership of some products, such as medical devices, medical convenience kits, and blood and blood components, are not covered by the DSCSA and are exempt from sending and receipt of TI/TH/TS (see Questions 33 and 34 below).

Given the multiple factors that may be involved with each transaction and some of the vague terms used in the statute, HDA strongly urges practitioners to consult with their own legal counsel if they plan on a sale or purchase they believe is exempted from the data transmission requirements or otherwise subject to FDA’s enforcement discretion.

32. What TI/TH/TS data must a dispenser provide and/or receive if/when it sells or loans a prescription drug product to another entity?

If a dispenser sells a product that they did not directly purchase from a manufacturer, the dispenser must provide the same data that any other non-direct purchase distributor must provide (For data required of non-direct purchasers, see “Multiple Distributors, Slides 16 and 17, – Distributor Y” in the HDA Transaction Scenarios). Further, a loan (including instances where the dispenser refers to the transaction as a “borrow” or “trade”) of a prescription drug product to another entity is still considered to be a “transaction” in most such instances because the products being loaned will

change ownership from the loaning dispenser to the “borrowing” dispenser. (*See also* Questions 29, 30, and 31 above for additional information on requirements and exclusions for dispensers.)

VIII. EXEMPT PRODUCTS

33. What types of products are considered to be blood components and therefore exempt from DSCSA requirements?

The DSCSA requires TI/TH/TS to be passed/received when “products” are the subject of a “transaction” (*i.e.*, change ownership). The law includes a number of exemptions from the definition of “product” and from “transaction.” Both the definition of “product” and “transaction” exempt “blood and blood components intended for infusion”. Thus, the transfer of ownership of blood and blood components (intended for infusion) does not trigger the requirement to pass or receive TI/TH/TS.

The DSCSA does not define further “blood and blood components”. Manufacturers of these types of products have made determinations as to whether their product is a blood product, blood component or other product that is exempt from DSCSA requirements. If you are unsure if a product is blood or a blood component intended for transfusion, or otherwise exempt from DSCSA requirements, we would recommend that you contact the manufacturer to find out how it has classified its product.

34. (a) Are medical devices exempt from DSCSA requirements? (b) Are combination products exempt from DSCSA requirements? (c) Are medical convenience kits exempt from DSCSA requirements?

(a) Medical devices are not included within the definition of “product”, and are thus transactions involving medical devices and not subject to DSCSA requirements.

(b) Combination products (*e.g.*, medical device and a drug or biologic) are exempt from the DSCSA definition of “transaction” and thus their sale does not require the passage or receipt of TI/TH/TS as long as the combination product is not approved under an NDA, ANDA or BLA. Unless it is otherwise exempt, a prescription combination product approved under an NDA, ANDA or BLA would be covered by the DSCSA. If you are unsure if a product is covered by the DSCSA, contact the manufacturer to find out how it has classified its product.

(c) Finally, certain medical convenience kits also are exempt from the DSCSA definition of “transaction”(and thus exempt from the requirements to pass TI/TH/TS. Medical convenience kits qualifying for this exemption must meet a number of conditions, including that:

- The kit is assembled at a facility registered with FDA as a medical device manufacturer;
- The kit does not contain a controlled substance;
- If the kit contains a product, the kit manufacturer
 - Purchased the product from the manufacturer or a direct purchase wholesale distributor, and

- Did not alter the label or primary container the product was packaged in;
- and;
- The product contained in the kit is
 - An IV solution for replenishment of fluids and electrolytes;
 - Intended to maintain the equilibrium of water and minerals in the body;
 - Intended for irrigation or reconstitution; or
 - An anesthetic, anticoagulant, vasopressor, or sympathomimetic.

The DSCSA provisions regarding medical convenience kits and other products and transactions that are exempt from the DSCSA requirements are complicated. If you are unsure whether a product or transaction is exempt from DSCSA requirements, contact the manufacturer, which, in the case of a medical convenience kit, would be the entity that assembled the kit.

IX. DATA TRANSMISSION, ASN¹⁵ AND ADDITIONAL TECHNICAL QUESTIONS

35. How should wholesale distributors handle a shipping discrepancy, such as a shortage, damage, or overage?

FDA has not addressed discrepancies or the need for changes to correct information in TI/TH/TS. Certainly the DSCSA requires that accurate TI/TH/TS be passed, received and stored, so if errors are discovered, they need to be corrected. In the HDA ASN Exceptions Guidelines for the Drug Supply Chain Security Act (“ASN Exceptions Guidelines”), HDA describes various scenarios in which there is a discrepancy or error in TI/TH/TS, and proposed responses/corrective actions.

36. If a wholesale distributor receives more product than it receives data for (e.g., it orders 150 units but only receives TI/TH/TS for 100 units), how does the wholesale distributor handle the 50 units for which it does not have data? How should the manufacturer correct the missing data?

The DSCSA provides that a wholesale distributor may not accept ownership of a product (that is, accept product into inventory) unless, prior to or at the time of product receipt, it has also received sufficient transaction data (TI/TH/TS). So, in the above example, the wholesale distributor could accept ownership of 100 units because it received transaction data for 100 units. Before the wholesale distributor could accept ownership of the final 50 units, the manufacturer would need to send the transaction data for those 50 units to the wholesale distributor. The ASN Exceptions Guidelines addresses this and other discrepancy issues in more detail.

37. If a wholesale distributor receives less product than it receives data for (e.g., it orders 300 and receives TI/TH/TS for 300 units but only 200 units are shipped), how should the wholesale distributor handle the discrepancy? How should the manufacturer correct the missing units ordered?

¹⁵ Please contact HDA’s Industry Relations team for additional technical detail the use of the ASN at: 703-787-0000.

As noted elsewhere in these responses, the DSCSA prohibits a wholesale distributor from accepting ownership of a product unless it has received sufficient transaction data. In the present example, the wholesale distributor received transaction data for the 200 units shipped, so the wholesale distributor may accept ownership of the 200 units. For the quantity not shipped, the parties would use standard business practices to resolve the shortage. The ASN Exceptions Guidelines addresses this and other discrepancy issues in more detail.

38. For a particular transaction, Company Y is the seller and the “ship from” within the TI, and Company X is the buyer and the “ship to”. In the ASN, does Company Y need to send the information in four different segments or can Company Y just send it in two segments?

Company Y should send all four segments, even if the information is the same. In the ASN Guidelines, HDA intentionally created this structure to make clear (i) the buyer and seller information for DSCSA compliance, and (ii) the logistical movement of product. Even though the buyer and “ship to” are the same in this scenario, the buyer is not the same entity as the “ship to” in all transactions.

39. Has FDA approved of the transaction statement language used in HDA’s ASN Guidelines?

HDA’s legal interpretation is that the example language in the ASN Guidelines is sufficient. The transaction statement can be sent or exchanged in one Yes/No Question (“YNQ”) segment per the guidelines.

40. Can you use more than one YNQ segment in the ASN to provide the transaction statement?

HDA recommends that trading partners use one YNQ segment for the TS.

41. Has FDA approved of the direct purchase statement language in HDA’s ASN Guidelines?

HDA’s legal interpretation is that the language in the ASN Guidelines is sufficient.

42. My shipment contains items that are exempt from DSCSA. Can I use the same ASN?

Yes, you can; however, you only need to send TI/TH/TS for products covered by DSCSA. Distributors typically ‘flag’ exempt items in their internal systems based on information from the manufacturer for each product. (For example, manufacturers will be prompted when completing the HDA Standard Product Information Form for Pharmaceutical Products [the ‘HDA New Item Form’] to indicate if that particular product is exempt from DSCSA requirements.)

43. Where in the ASN is the transaction date identified?

In the ASN, there is a spot at the Beginning Segment for Ship Notice (BSN) segment for transaction date. The date the trading partners choose as the ownership transfer date should be inserted there by the seller.

44. Would an ASN from a manufacturer include more than one product/different lots, etc.? If there are different products/different lots, do they provide the TS at the item/line level?

Yes, an ASN can still accommodate multiple products and different lots. There is line item detail which can provide a TS, including direct purchase statements and other detailed information (name, NDC#, lot #, container size, number of containers, etc.) about the product. The TS at the shipment level directs the receiver to line level for detailed direct purchase statements.

45. Does TH require only an additional N1 loop or a new ASN attached to the previous one in the chain?

HDA believes that all of the required information can be sent in the one ASN between the two trading partners. Furthermore, the ASN does *not* have the capability to “follow” a single product or single lot through the supply chain. Each shipment generates a new ASN.

For example, the manufacturer generates an ASN for a case of drug product; the ASN and the product are then provided to the purchasing wholesale distributor. Once the case is received, the wholesale distributor typically removes the individual units from the case and warehouses them. For its customers, the wholesale distributor then creates a new ASN, from the wholesale distributor to the dispenser, to accompany the shipment that identifies all of the different drugs, from all of the different suppliers, and other relevant shipment information.

46. What will the receiving party do if an ASN is not received at the time the shipment arrives at the receiving party’s dock? Hold-off on formal receipt?

The law states that “A wholesale distributor shall not accept ownership of a product unless the previous owner prior to, or at the time of, the transaction provides the transaction history, transaction information, and a transaction statement for the product, as applicable under this subparagraph.” § 582(c)(1)(A)(i). This means that the wholesale distributor must have TI/TH/TS at the time of or before the change of ownership. Trading partners will need to determine how the seller will provide TI/TH/TS to the receiving party (whether by paper, ASN or other form) so that the receiving party may accept ownership of the product.

Because the time at which an ownership change occurs varies based upon commercial agreements between the parties, if product were to arrive at a buyer’s warehouse without TI/TH/TS, holding off on the physical receipt of product would be a business decision of the individual trading partners. Certainly if the buyer physically receives the product prior to receiving TI/TH/TS, the goods would need to remain quarantined until receipt of TI/TH/TS so that ownership could lawfully be accepted. See HDA’s ASN Exceptions Guidelines for more details.

47. If Distributor X does not supply the lot number to Distributor Y, how should Distributor Y pass that information to the dispenser?

Distributor Y should check the label of the product for the lot number, which is usually included on the unit-level product's external packaging, and/or on the label affixed to the bottle. HDA has identified the DSCSA required transaction data for different transaction scenarios among trading partners. This information can be found in the [HDA Transaction Scenarios](#).

48. If the “ship to” and “bill to” addresses are different for a dispenser, does the wholesale distributor need to show both addresses in the transaction data?

No. The DSCSA requires a seller to provide TI to the buyer. The law specifies that the TI must include “the business name and address of the person to whom ownership is being transferred” (*i.e.*, the buyer). When the seller provides TI/TH/TS data in an electronic ASN or on other transmission documents, such as invoices or packing slips, the purchaser's address is referred to as the “bill to” address. In some cases, the “bill to” addresses for the purchaser are different from the physical location – or “ship to” address – where a product is being delivered.

For business reasons, many buyers and sellers also provide this “ship to” address to the purchaser. If the “bill to” and “ship to” addresses are different -- for example, if the purchaser's main business office handling the transaction's payment is in a hospital's main building, but the product will be physically delivered, stored and used in a separate outpatient department -- the recipient will likely receive both a “bill to” address and a “ship to” address reflecting each separate address. Note that if a “bill to” address and a “ship to” address are different locations, the DSCSA does not require retention of the “ship to” address (which is not part of the TI).

49. Is EPCIS a US standard or a global standard?

EPCIS as a GS1 Standard. This fits with the DSCSA language. EPCIS is published as an ISO/IEC standard - ISO/IEC 19987. (And for CBV, ISO/IEC 19988). CBV = Core Business Vocabulary

There is no “US version” of any GS1 standard. GS1 standards are global standards.

The proper way to refer to any GS1 standard is as a “GS1 standard”. This implies it was ratified by the entire GS1 community through the GS1 Global Standards Management Process (GSMP).

In the case of EPCIS is published as an ISO/IEC standard, namely ISO/IEC 19987. (And for CBV, ISO/IEC 19988)

In the case of DSCSA, GS1 is recommending the use of EPCIS, CBV, and also the GS1 US implementation guideline. These things layer atop one another: EPCIS establishes a data framework and XML schema, CBV provides identifier structures that populate that framework (in conjunction with the GS1 General Specifications and the EPC Tag Data).

X. EXCEPTIONS TO TRANSACTION DATA REQUIREMENTS

50. Are free-of-charge items subject to TI/TH/TS requirements? There is change of ownership but no exchange of money.

There are a variety of scenarios under which products change ownership, but do not trigger the requirement for passing TI/TH/TS. Specifically, if the transfer of goods is exempt from the statutory definition of “transaction” (§ 581(24)), then the change in ownership does not trigger the TI/TH/TS requirement (similarly, if the distribution of product is excluded from the statutory definition of “wholesale distribution” (new FDCA § 503(e)(4)), TI/TH/TS would not be required to be passed/received). For example, the distribution of product samples by a manufacturer or licensed wholesale distributor is exempt from the definition of “transaction” (§ 581(24)(B)(v)) and, therefore, the transfer of samples would not need to be accompanied with TI/TH/TS.

51. Are donated items subject to TI/TH/TS requirements? There is a change of ownership but no exchange of money.

As noted in the response to the previous question, if the distribution of product is excluded from the statutory definition of “transaction” or “wholesale distribution”, TI/TH/TS would not be required to be passed/received. For example:

- **Charitable Organizations:** The distribution of product by a 501(c)(3) charitable organization to a non-profit affiliate is exempt from the definition of “transaction” (§ 581(24)(B)(viii)). [Please note that the transfer of ownership from a manufacturer (or wholesale distributor) to a charitable organization – even if the product is donated – would constitute a “transaction” and, therefore, the transfer would require the transmission of TI/TH/TS.]
- **Specific Types of Products and Specific Parties:** The definition of “transaction” excludes the distribution of a number of types of products (*e.g.*, convenience kits that contain certain specified drugs), regardless of the parties involved in the transfer, as well as distributions to specific parties (*e.g.*, transfers among affiliates, or transfers to or from a facility licensed by the Nuclear Regulatory Commission), regardless of the product involved. *See* § 581(24)(B) for details.

52. Are products designated for destruction subject to TI/TH/TS requirements? There is a change of ownership but no exchange of money.

Products designated for destruction are covered by the DSCSA’s “nonsalable returns” provisions. Under DSCSA, the transfer of product by a manufacturer, wholesale distributor or dispenser (with or without the use of a returns processor) for destruction is exempt from the requirements to pass TI/TH/TS.

53. Are items distributed for emergency medical reasons subject to TI/TH/TS requirements?

The distribution of product for emergency medical reasons (which does not include a drug shortage) is exempt from the definition of “transaction” (§ 581(24)(B)(iii)), and thus exempt from the requirements to pass TI/TH/TS.

54. Are products a dispenser sells to first responders subject to TI/TH/TS requirements?

As discussed in Section VII, Dispenser Related Questions, FDA has granted a limited exception from the data transmission and authorized trading partner requirements for sales of products by dispensers to first responders.¹⁶

XI. GRANDFATHERED PRODUCT

55. What are a wholesale distributor's obligations with respect to passing TI/TH/TS for product that was received prior to January 1, 2015*, but sold after January 1, 2015*?

[NOTE: FDA's guidance mentioned in Note 2 above does not specifically address how, if at all, the "grandfathering" provision of the DSCSA (discussed further below) would be affected, but the only logical assumption is that the provision would be affected because it addresses product tracing requirements.]

Accordingly, while the response below includes the statutory implementation date of January 1, 2015, FDA should agree that the "cut-off date" for grandfathered product is now May 1, 2015. For consistency, HDA has continued to use the statutory deadline of January 1, 2015 (with an asterisk) which can be read as May 1, 2015 if the guidance applies to grandfathering.]

Starting January 1, 2015*, the DSCSA requires a seller to pass transaction data (TI/TH/TS) when it transfers ownership of its drug products. The DSCSA includes a provision (entitled, "Grandfathering Product") that describes the TI/TH/TS requirements for products entering the supply chain before January 1, 2015.* See § 582(a)(5)(B). With respect to transaction data requirements, this provision provides as follows:

For a product that entered the pharmaceutical distribution supply chain prior to January 1, 2015*:

- (i) authorized trading partners shall be exempt from providing transaction information as required under subsections (b)(1)(A)(i), (c)(1)(A)(ii), (d)(1)(A)(ii), and (e)(1)(A)(ii) [these are citations to the transaction data requirements for manufacturers, direct purchase wholesale distributors, dispensers and repackagers, respectively];
- (ii) transaction history required under this section shall begin with the owner of such product on such date; and
- (iii) the owners of such product on such date shall be exempt from asserting receipt of transaction information and transaction statement from the prior owner as required under this section.

¹⁶ See Requirements for Transactions with First Responders under Section 582 of the Federal Food, Drug, and Cosmetic Act – Compliance Policy Guidance for Industry, 81 Fed. Reg. 10260 (Feb. 29, 2016), at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM488240.pdf>.

This section of the DSCSA is not particularly clear, and in the absence of any FDA guidance, we interpret this provision to mean:

Prior to January 1, 2015*:

- When engaging in wholesale distribution of a drug, a company must comply with the requirements of the Prescription Drug Marketing Act (PDMA) and pass a pedigree when appropriate.

Starting January 1, 2015*, for any drug that entered the supply chain prior to January 1, 2015*:

- The entity that owns the product on January 1, 2015* is not required to pass, receive or store any transaction data that it was not required to receive.

When engaging in a new transaction after January 1, 2015*:

- It is not clear from the statutory provision set forth above whether the seller is required to pass TI. Because TI can be generated by the seller in a new transaction and is not dependent on the information that the seller received prior to January 1, 2015* for the product, FDA likely would interpret the statutory provision as requiring the seller to pass TI.
- The seller must pass TH, but the TH can start with the entity that owns the product on January 1, 2015*.
- The entity that owns the product on January 1, 2015* must pass TS when it sells the drug, but is not required to assert that it received TI and TS from the prior owner (two of the elements of a full TS). All subsequent owners must pass full TS.