Identifying Trading Partners Under the Drug Supply Chain Security Act

Guidance for Industry

DRAFT GUIDANCE

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

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Procedural

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

The Food and Drug Administration (FDA or the Agency) is issuing this guidance to assist industry and State and local governments in understanding how to categorize the entities in the drug supply chain in accordance with the Drug Supply Chain Security Act (DSCSA).[2] DSCSA establishes product tracing requirements for certain trading partners in the drug supply chain, including manufacturers, repackagers, wholesale distributors, and dispensers. DSCSA also requires that trading partners of manufacturers, wholesale distributors, dispensers, and repackagers must meet the applicable requirements for being "authorized trading partners."[3] DSCSA also requires FDA to issue regulations that establish Federal standards for the licensing of wholesale drug distributors (WDDs) and third-party logistics providers (3PLs). The Agency is currently drafting these regulations. This guidance, when finalized, will explain FDA's current thinking on how licensing and certain other requirements apply to entities that may be considered trading partners in the drug supply chain.

This guidance is intended to (1) assist industry and State and local governments in understanding the applicability of DSCSA requirements to the various types of entities that take part in the distribution of prescription drugs in the United States, and (2) help clarify for industry whether they are engaged in activities that require licensure and annual reporting, as well as other requirements related to being an authorized trading partner in the drug supply chain. The guidance does not address all requirements described in DSCSA, but is limited to describing the activities that would determine what type of trading partner an entity may be and the applicable requirements under DSCSA.

[1] This guidance has been prepared by the Division of Drug Supply Chain Integrity in the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER) and the Office of Regulatory Affairs at the Food and Drug Administration.

[2] Title II of Public Law 113-54. In particular, see sections 503(e), 581, and 584 of the Food, Drug & Cosmetic Act (FD&C Act) (21 U.S.C. 353(e), 360eee, and 360eee-3).

[3] See sections 582(b)(3), (c)(3), (d)(3), and (e)(3) of the FD&C Act (21 U.S.C. 360eee-1).

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

On November 27, 2013, DSCSA was signed into law. It outlines new requirements to develop and enhance drug distribution security by 2023. In part, these changes include defining the types of entities in the drug supply chain (i.e., manufacturers, repackagers, wholesale distributors, 3PLs, and dispensers), requiring that the trading partners of manufacturers, repackagers, wholesale distributors, and dispensers meet the applicable requirements to be *authorized* trading partners, and establishing national standards for the licensing of WDDs and 3PLs.

A. Definitions of Drug Supply Chain Entities Under DSCSA

DSCSA identifies and defines five types of entities in the prescription drug supply chain: manufacturers, repackagers, dispensers, wholesale distributors, and 3PLs. DSCSA defines these entities in section 581 of the FD&C Act (21 U.S.C. 360eee).

A *manufacturer* is defined in section 581(10) of the FD&C Act to mean:

> [W]ith respect to a product -- (A) a person that holds an application approved under section 505 or a license issued under section 351 of the Public Health Service Act for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product; (B) a co-licensed partner of the person described in subparagraph (A) that obtains the product directly from a person described in this subparagraph or subparagraph (A) or (C); or (C) an affiliate of a person described in subparagraph (A) or (B) that receives the product directly from a person described in this subparagraph or subparagraph (A) or (B).

Section 581(16) of the FD&C Act defines a *repackager* to mean "a person who owns or operates an establishment that repacks and relabels a product or package for – (A) further sale; or (B) distribution without a further transaction."

The term *dispenser*, as defined in section 581(3) of the FD&C Act:

> (A) 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 wholesale distributor; and (B) does not include a person who dispenses only products to be used in animals in accordance with section 512(a)(5).

DSCSA defines *wholesale distributor* in section 581(29) of the FD&C Act to mean "a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider,

or repackager) engaged in wholesale distribution (as defined in section 503(e)(4) of the FD&C Act, as amended by [DSCSA])." Section 503(e)(4) of the FD&C Act (21 U.S.C. 353(e)(4)) defines *wholesale distribution* as "distribution of a drug subject to [section 503(b) of the FD&C Act (21 U.S.C. 353(b))] to a person other than a consumer or patient, or receipt of a drug subject to [section 503(b) of the FD&C Act (21 U.S.C. 353(b))] by a person other than the consumer or patient," but exempts several specific activities.

DSCSA adds *third-party logistics providers (3PLs)* as a new entity in the drug supply chain,[4] and requires 3PL facilities to be licensed and regulated separately from wholesale distributors.[5] DSCSA defines a *3PL* in section 581(22) of the FD&C Act to mean:

> [A]n entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor has responsibility to direct the sale or disposition of the product.

The key distinction between wholesale distributors and 3PLs is that, unlike a wholesale distributor, a 3PL does not take ownership of the product, and does not direct the sale or disposition of the product.

B. Authorized Trading Partners Under DSCSA

DSCSA restricts access to the distribution system for prescription drug products by requiring trading partners of manufacturers, wholesale distributors, dispensers, and repackagers meet the applicable requirements for being authorized trading partners.[6] DSCSA includes definitions for *authorized*[7] and *trading partner*[8] with respect to each entity in the drug supply chain as follows:

- To be considered an authorized trading partner, a *manufacturer* or *repackager* must have a valid registration in accordance with section 510 of the FD&C Act and accept or transfer direct ownership of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser.

- To be considered an authorized trading partner, a *wholesale distributor* must have a valid license under State law or section 583 of the FD&C Act, in accordance with section 582(a)(6) of the FD&C Act , comply with the licensure reporting requirements in section 503(e) of the FD&C Act, as amended by DSCSA, and accept or transfer direct ownership of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser.

- Similarly, to be considered an authorized trading partner, a *3PL* must have a valid license under State law or section 584(a)(1) of the FD&C Act, in accordance with section

[4] Section 581(22) of the FD&C Act.
[5] See section 585(b)(2) of the FD&C Act(21 U.S.C. 360eee-4).
[6] See sections 582(b)(3), (c)(3), (d)(3), and (e)(3) of the FD&C Act (21 U.S.C. 360eee-1).
[7] See section 581(2) of the FD&C Act.
[8] See section 581(23) of the FD&C Act.

582(a)(7) of the FD&C Act, comply with the licensure reporting requirements under section 584(b) of the FD&C Act (21 U.S.C. 360eee-3), and accept or transfer direct possession of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser.

- A *dispenser* must have a valid license under State law and accept or transfer direct ownership of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser.

C. Licensure and Reporting Requirements for WDDs and 3PLs

DSCSA also establishes new licensure and reporting requirements for wholesale distributors and third-party logistics providers.

Section 503(e) of the FD&C Act (as amended by DSCSA) establishes licensure requirements and adds reporting requirements for WDDs. Specifically, section 503(e)(1) prohibits a person from engaging in wholesale distribution of prescription drugs in any State unless such person is licensed by the State from which the drug is distributed, or by FDA if such State from which the drug is distributed has not established a licensure requirement. Furthermore, under certain circumstances,[9] such person must also be licensed by the State into which the drug is distributed. Section 503(e)(2) of the FD&C Act requires WDDs to report certain information to FDA on an annual basis, including State licensure information for each license, the name and address of each licensed facility, and any significant disciplinary actions taken by a State or the Federal government.[10]

DSCSA adds section 584 to the FD&C Act; the section sets forth requirements for licensure and reporting by 3PL facilities. Specifically, section 584(a) prohibits a 3PL in any State from conducting activities in any State unless each facility of the 3PL is licensed by the State from which the drug is distributed by the 3PL, or by FDA if the State from which the drug is distributed by the 3PL has not established a licensure requirement. Furthermore, under certain circumstances,[11] the 3PL must also be licensed by the State into which the drug is distributed. Section 584(b) of the FD&C Act requires 3PL facilities to report certain information to FDA, including State licensure information for each facility and the name and address of each facility.

III. IDENTIFYING WHO IS A TRADING PARTNER

[9] See section 503(e)(1)(A)(ii) – in relevant part, "if the State into which the drug is distributed requires the licensure of a person that distributes drugs into the State."

[10] More information about reporting is on the Wholesale Distributor and Third-Party logistics Providers Reporting web page (http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm423749.htm).

[11] See section 584(a)(2) – in relevant part, "if such State licenses third-party logistics providers that distribute drugs into the State and the third-party logistics provider is not licensed by the Secretary."

FDA has received comments and inquiries about which entities meet the definitions of the various trading partners. Whether an entity meets the statutory definition of a particular trading partner that would trigger the applicable requirements depends on the activities in which it engages. This may be particularly applicable to entities, such as private-label distributors,[12] who may have a variety of business models and may meet the definitions of a variety of trading partners. Please see the discussion below for each type of trading partner for more information.

There has also been confusion about how the definitions of *wholesale distributor* and *wholesale distribution* changed upon enactment of the DSCSA. Regulations enacted prior to DSCSA defined the term *wholesale distributor* to include manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.[13] Some of these listed entities are not included as wholesale distributors in the DSCSA.

In addition, section 581 of the FD&C Act defines different types of trading partners in the drug supply chain, including manufacturers, repackagers, WDDs, 3PLs, and dispensers. Neither section 503(e) nor section 581 of the FD&C Act lists the other types of entities included in the regulations discussed above, at 21 CFR 203.3(dd). Consequently, several types of activities that may fall within the definition of wholesale distribution under 21 CFR part 203 are not directly addressed by the statutory definition of wholesale distribution in section 503(e) of the FD&C Act, as amended by DSCSA. This may leave questions regarding the status of certain entities under the DSCSA. For example, there has been confusion as to whether DSCSA licensure and reporting requirements apply to certain types of entities, such as but not limited to jobbers, brokers, and certain contractors and solution providers. To address some of the confusion expressed by industry and the States, FDA is providing its current thinking on each of the trading partners.

A. Manufacturers as Trading Partners Under DSCSA

DSCSA defines a *manufacturer* in section 581(10) of the FD&C Act as:

> [W]ith respect to a product -- (A) a person that holds an application approved under section 505 or a license issued under section 351 of the Public Health Service Act for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product; (B) a co-licensed partner of the person described in subparagraph (A) that obtains the product directly from a person described in this subparagraph or subparagraph (A) or (C); or (C) an affiliate of a person described in subparagraph (A) or (B) that receives the product directly from a person described in this subparagraph or subparagraph (A) or (B).

An entity that falls within the definition of *manufacturer* in section 581(10) of the FD&C Act must comply with the requirements under section 582(b) of the FD&C Act.

[12] 21 CFR 207.1 (2016).
[13] 21 CFR 203.3(dd) (1999).

FDA has received comments and inquiries about how to determine whether a manufacturer is an authorized trading partner. FDA believes that most of the confusion[14] is related to the inclusion of entities that hold drug approvals (aka NDA-, BLA-, or ANDA-holders[15]), co-licensed partners, and affiliates of such entities in the definition of *manufacturer* in section 581(10) of the FD&C Act, and the interaction of this definition with the requirement to register under section 510 of the FD&C Act to be "authorized" according to section 581(2).

1. Manufacturing Establishments

Under section 510 of the FD&C Act, and part 207 (21 CFR part 207), with some limited exceptions, any person who owns or operates any establishment that manufactures, prepares, propagates, compounds, or processes drugs in the United States, or that are offered for import into the United States, must be registered with the FDA.[16] Thus, under section 581(2)(A), such manufacturer establishments must be registered in accordance with section 510 of the FD&C Act to be considered an authorized trading partner.

2. NDA-, BLA-, or ANDA-Holder, or Co-Licensed Partner of a Manufacturer

An NDA-, BLA-, or ANDA-holder or co-licensed partner of a manufacturer might not engage in the manufacturing, preparation, propagation, compounding, or processing of a drug, but could still meet the definition of manufacturer in section 581(10) in the FD&C Act. There has been confusion as to whether such manufacturers should register under section 510 of the FD&C Act to be considered an authorized trading partner. FDA believes such an entity would be an authorized trading partner without being registered under section 510 so long as the NDA-, BLA-, or ANDA-holder, or co-licensed partner is compliant with its obligations under section 510 of the FD&C Act and with any other obligations under the DSCSA. We note, however, that any person who owns or operates any establishment manufacturing, preparing, propagating, compounding, or processing drugs in the United States, or that are offered for import into the United States, must have a valid registration in accordance with section 510 to comply with the FD&C Act.

3. Affiliate of a Manufacturer (Section 581(10)(C))

Affiliate is defined in section 581(1) of the FD&C Act as:

> [A] business entity that has a relationship with a second business entity if, directly or indirectly—
>
> (A) one business entity controls, or has the power to control, the other business entity; or
>
> (B) a third party controls, or has the power to control, both of the business entities.

[14] Part 207 (21 CFR part 207) defines *manufacturers* for purposes of registration requirements under section 510 of the FD&C Act, while section 581(10) defines *manufacturers* differently for purposes of DSCSA.

[15] This refers to holders of an approved new drug application (NDA), biologics license application (BLA), or abbreviated new drug application (ANDA).

[16] 21 U.S.C. 360(b), (c), (d), and (i).

FDA considers the situation described in paragraph (A) to be similar to a parent/subsidiary business relationship (i.e., the parent has the power to control the business of the subsidiary). FDA considers the situation described in paragraph (B) as describing a business relationship where a third party controls the business of several entities, such as controlling both the parent and the subsidiary. In other words, an *affiliate* is a business entity that legally controls another business entity, directly or indirectly, or is controlled by another business entity; mere business links or relationships are not sufficient to meet the definition of an *affiliate*.[17] Manufacturers and their affiliates retain responsibility for carrying out the activities and requirements under section 582(b) of the FD&C Act. To be considered a manufacturer under DSCSA, an affiliate of a manufacturer as defined in 581(10)(A) or (B) of the FD&C Act must have received the product directly from such a manufacturer.[18]

B. Repackagers as Trading Partners Under DSCSA

DSCSA defines *repackager* in section 581(16) of the FD&C Act as "a person who owns or operates an establishment that repacks and relabels a product or package for – (A) further sale; or (B) distribution without a further transaction." Under section 510 of the FD&C Act, and under part 207, with some limited exceptions, any person who owns or operates any establishment that manufactures, prepares, propagates, compounds, or processes drugs in the United States or that are offered for import into the United States must be registered with the FDA.[19] This includes repackagers of drugs.[20] Thus, such repackager establishments must be registered in accordance with section 510 to be considered authorized trading partners.

An entity that falls within the definition of *repackager* in section 581(16) of the FD&C Act must comply with the requirements under section 582(e) of the FD&C Act. However, FDA does not consider a dispenser, specifically a pharmacy, that is solely engaged in packaging and labeling drug product(s) for dispensing to an identified individual patient after the receipt of a valid prescription for that patient (e.g., repackaging product into unit-dose packages for administration to an identified individual patient), to be a repackager under DSCSA. Therefore, the requirements in section 582(e) of the FD&C Act would not apply.

C. WDDs as Trading Partners Under DSCSA

DSCSA defines *wholesale distributor* in section 581(29) of the FD&C Act to mean "a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution (as defined in section 503(e)(4) of the FD&C Act, as amended by [DSCSA])." Section 503(e)(4) of the FD&C Act (21 U.S.C. 353(e)(4)) defines *wholesale distribution* as "distribution of a drug subject to [section 503(b) of the FD&C Act (21 U.S.C. 353(b))] to a person other than a consumer or patient, or receipt of a drug subject

[17] This interpretation is consistent with the interpretation of *affiliate* previously described in 66 FR 59138 at 59146 (November 27, 2001).
[18] See section 581(10)(C) of the FD&C Act.
[19] 21 U.S.C. 360(b), (c), (d), and (i).
[20] 21 U.S.C. 360(a)(1).

to [section 503(b) of the FD&C Act (21 U.S.C. 353(b))] by a person other than the consumer or patient," but exempts several specific activities. An entity that falls within the definition of *wholesale distributor* in section 581(29) of the FD&C Act must comply with the requirements under section 582(c) of the FD&C Act.

FDA has received comments and inquiries about how to determine whether a WDD is an authorized trading partner. Comments have stated that one source of confusion is that DSCSA provides a definition of *wholesale distribution* in section 503(e) of the FD&C Act and a definition for *wholesale distributor* in section 581 of the FD&C Act that differ from the respective definitions in the regulations promulgated pursuant to sections 503(c), (d), and (e) of the FD&C Act, as enacted by the Prescription Drug Marketing Act of 1987 (PDMA).[21] Several types of entities are not considered to be WDDs under DSCSA that were under these regulations. Many of these entities are now considered to be 3PLs under DSCSA, and are discussed in the next section.

Another source of confusion stems from uncertainty as to whether a manufacturer can also be licensed as a WDD. The definition of *wholesale distribution*, as set forth in section 503(e)(4) of the FD&C Act, as amended by DSCSA, excludes the distribution of a manufacturer's own drug (section 503(e)(4)(H)). As a result, if a manufacturer is only distributing its own drug, it would not be engaged in wholesale distribution under DSCSA, and would not be required to comply with the licensure and reporting requirements for WDDs under DSCSA.

Generally, but with exclusions enumerated in section 503(e)(4), an entity engaged in the distribution of a drug subject to section 503(b) of the FD&C Act (21 U.S.C. 353(b)) to someone other than a consumer or patient and that the entity did not manufacture, would be engaged in wholesale distribution and subject to all the WDD requirements under DSCSA.

Jobbers: FDA considers a *jobber* to be a person or entity that owns or operates an establishment that engages in wholesale distribution on a small scale, or sells product solely to retailers and institutions. Jobbers engage in *wholesale distribution* because they own and direct the sale or distribution of product to, and receive product from, a person other than a consumer or patient, and are not otherwise excluded from the definition under section 503(e)(4) of the FD&C Act. Jobbers are thus considered WDDs and are subject to the requirements for WDDs under DSCSA.

D. 3PLs as Trading Partners Under DSCSA

DSCSA defines *3PLs* broadly to include any entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.[22]

There has been confusion as to what activities would be considered "other logistics services" within the definition of *3PL*. FDA's current thinking is that *other logistics services* means

[21] Public Law 100-293; codified at 21 U.S.C. 321 et seq.
[22] See section 581(22) of the FD&C Act.

services provided by entities that accept or transfer direct possession[23] of products from that entity's facility within the United States and its territories on behalf of a trading partner (i.e., manufacturer, repackager, WDD, or dispenser). FDA also considers "other logistics services" to include services provided by entities that accept or transfer direct possession of products from that entity's facility within the United States and its territories on behalf of a repackager of products for further sale or a repackager acting on behalf of a manufacturer, WDD, or dispenser.

Trading partner, with respect to 3PLs, is defined in part as having direct possession of product.[24] Those 3PLs that do not accept or transfer direct possession of product are thus not considered trading partners. Therefore, the "authorized trading partner" provisions of section 582 of the FD&C Act would not apply when manufacturers, wholesale distributors, dispensers, and repackagers engage 3PLs who are not trading partners.[25]

Furthermore, FDA considers the section 584 requirement that "each facility of such [3PL]" [26] be licensed "in accordance with the regulations" to mean that 3PLs without a facility are not required to be licensed. Section 584 provides that FDA will establish licensure standards that centrally include requirements relating to storage of product. These standards address issues with access and maintenance that presuppose the existence of a physical facility wherein product is maintained.

Accordingly, FDA considers a *facility* to be an establishment, warehouse, structure, or structures under common ownership at one general, permanent, physical location used to store or handle prescription drug products. FDA would not consider a truck or shipping container used to transport product to constitute a facility for purposes of DSCSA because such trucks or containers are not consistently located at one physical location and would not sensibly be covered by the storage requirements specific to 3PL facility licensure. Likewise, FDA would not consider an establishment, warehouse, or structure that is not used to store or handle prescription drug products to constitute a facility for purposes of section 584.

1. *Entities That Warehouse But Do Not Own or Direct the Sale or Disposition of Product*

An entity that owns, rents, or leases a facility where it warehouses product, but does not take ownership of, nor direct the sale or disposition of the product, is a 3PL under DSCSA. An entity that owns, rents, or leases a facility under common ownership or control with another trading partner, where it warehouses product but does not take ownership of, nor direct the sale or disposition of the product, is also a 3PL under DSCSA. These entities could be engaged in activities that include storage of products distributed by *consignment*.[27]

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[23] FDA considers *direct possession* to mean having physical, direct contact with the product.
[24] See section 581(23)(B) of the FD&C Act.
[25] See sections 582(b)(3), (c)(3), (d)(3), and (e)(3) of the FD&C Act (21 U.S.C. 360eee-1).
[26] FDA interprets the language in section 584(a) of the FD&C Act, "facility of such third-party logistics provider," to mean a facility owned, rented, or leased by the 3PL.
[27] FDA's current understanding of *consignment* involves the sale of a product by the manufacturer directly to the consumer where the product is stored and shipped by an entity on behalf of the manufacturer.

2. Brokers

FDA considers a *broker* to be a person or entity, who facilitates business transactions between two other trading partners, but does not take ownership of the product nor direct the sale or disposition of a product. A broker does not provide or coordinate warehousing and does not accept or transfer direct possession of the product and, therefore, is not considered a 3PL under DSCSA. Thus, FDA generally would not consider the 3PL licensure requirements under DSCSA to cover brokers.

However, if a person or entity acts as a seller or buyer, or directs the sale, purchase, or trade of a product, such person or entity is a principal party to the transaction and is considered to be involved in directing the sale or disposition of the product. FDA does not consider the lack of direct possession of the product as a sufficient reason to preserve broker status because, as the seller or buyer, the person or entity is accepting or transferring ownership of the product. A person or entity engaged in this activity would not be considered a broker, but would likely meet the definition of a manufacturer, WDD, repackager, or dispenser, depending on the circumstances, and would be required to meet all of the applicable requirements under DSCSA.

3. Solution Providers

FDA considers a *solution provider* to be a person or entity that provides other entities hardware, software, or systems solutions to help achieve compliance with the requirements under DSCSA. A solution provider does not take ownership of the product nor direct the sale or disposition of a product. Furthermore, a solution provider does not provide or coordinate warehousing and does not accept or transfer direct possession of the product and, therefore, is not considered a 3PL under DSCSA. Thus, FDA would not consider the 3PL licensure requirements under DSCSA to cover solution providers.

4. Common Carriers

As it relates to the distribution of prescription drug products subject to DSCSA, FDA considers a *common carrier* to be an entity that solely provides transportation services,[28] but does not take ownership of the product nor direct the sale or disposition of the product. Common carriers do not provide or coordinate warehousing for the products they transport. Although common carriers accept and transfer direct possession of product, they do not store and handle product from a facility, as defined above. Therefore, FDA would not consider the services provided by common carriers to constitute other logistics services, and FDA would not consider common carriers to be covered by the 3PL licensure requirements under DSCSA. The owner of the product would remain responsible for compliance with any applicable storage and handling requirements and for the product's safety and integrity during transit, and should select common carriers that can provide appropriate safeguards.

[28] Such transportation services may include the transport of product from one location to another, and cross-docking of product en route to its destination, but does not include the warehousing of a product that lacks an identified consignee or delivery destination.

5. Logistics or Administrative Services Contractors

FDA is also aware that some entities that solely contract with other trading partners to provide labor, logistic, or administrative services in the other trading partner's facility, but do not take ownership nor direct the sale or disposition of product, have identified themselves as 3PLs. These entities do not themselves provide or coordinate the warehousing of product; rather, the trading partner with which the entity is contracting provides or coordinates the warehousing. Although such contractors may accept and transfer direct possession of product, they do not store and maintain product at their own facility, and thus would not meet the *facility* requirement of the *other logistics services* definition above. Therefore, FDA would not consider such entities to be 3PLs under DSCSA. FDA expects the trading partner with which such a contractor is contracting to be responsible for its activities. For example, if an entity is engaged in the provision of its services as a contractor in a wholesale distribution facility that is not under common ownership or control of the contractor and WDD, the contractor's activity would be captured by the wholesaler's license and obligations for compliance.

6. Returns Processors and Reverse Logistics Providers

A *returns processor* or *reverse logistics provider* is defined in section 581(18) of the FD&C Act as:

> [A] person who owns or operates an establishment that dispositions or otherwise 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.

FDA considers *returns processors* and *reverse logistics providers* to be 3PLs because they are entities that provide *other logistics services* on behalf of other trading partners in a facility the returns processor or reverse logistics provider owns, rents, or leases, and they do not take ownership of nor direct the sale or disposition of the product. As indicated in the definition, such entities may execute the dispositioning of product, whether it is as a return, recall, or for disposal, but they are not responsible for directing whether the product is to be sold or dispositioned. This activity may include activity that has been referred to as "reverse distribution." However, if an entity takes ownership of the returned or dispositioned product or is responsible for directing the sale or disposition of the product, such entity does not meet the definition of a returns processor or reverse logistics provider, but rather is engaged in wholesale distribution, subject to all the requirements for WDDs under DSCSA.

E. Dispensers as Trading Partners Under DSCSA

Section 581(3) of the FD&C Act states that *dispenser*:

> (A) 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 wholesale distributor; and (B) does not include a person who dispenses only products to be used in animals in accordance with section 512(a)(5).

Under this definition, a dispenser is a pharmacy that does not act as a WDD, or any other person authorized to dispense or administer human prescription drugs. Furthermore, this definition redefines dispenser-affiliated warehouses and distribution centers as dispensers (these were previously considered to be WDDs under PDMA). Such warehouses and distribution centers are no longer considered WDDs, unless such facilities are also engaged in wholesale distribution activities.

An entity that falls within the definition of *dispenser* in section 581(3) of the FD&C Act must comply with the requirements under section 582(d) of the FD&C Act. The statutory requirement for dispensers to exchange product tracing information became effective on July 1, 2015.[29] However, dispensers are not required to provide the product tracing information prior to, or at the time of, a transaction if the product is dispensed to a patient or if it is a sale by a dispenser to another dispenser to fulfill a "specific patient need."[30, 31] The term *specific patient need* refers to the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. This 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.[32] Although a dispenser that sells a product to another dispenser to fulfill a specific patient need is not required to provide product tracing information, other requirements of section 582(d) and the FD&C Act may apply to the transferring and receiving pharmacies. Accordingly, such sales or transfers should be documented by each pharmacy in a manner that would facilitate appropriate actions by the pharmacy in the event of an investigation of suspect or illegitimate product, recall, or notification of illegitimate product. Transfers of product to another dispenser without a specific patient need may constitute wholesale distribution, subject to the requirements for wholesale distributors in sections 503(e), 582, and 583 of the FD&C Act.

To be considered an authorized trading partner, a *dispenser* must have a valid license under State law and accept or transfer direct ownership of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser.

[29] FDA issued guidance explaining that the Agency did not intend to object to the failure to comply with certain requirements of section 582(d) of the FD&C Act, relating to the exchange of product tracing information before March 1, 2016. See FDA guidance for industry *DSCSA Implementation: Product Tracing Requirements for Dispensers — Compliance Policy (Revised)*. We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA Drugs guidance Web page at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

[30] See section 582(d)(1)(A)(ii) of the FD&C Act.

[31] The term *specific patient need* is defined in section 581(19) of the FD&C Act.

[32] *Id*.

Table 1. Summary of Authorized Trading Partners*

Entity Type	Description of Activity	Other Entities Included	Entities Generally Not Included	Entity is a Trading Partner When It	Entity is Authorized When It is
Manufacturer	Manufactured the product			Accepts or transfers direct ownership of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser	Registered with FDA in accordance with section 510 of the FD&C Act
	Approved application holder, or co-licensed partner of the approved application holder who obtained the product directly from the application holder or person who manufactured the product				Compliant with its obligations under section 510 of the FD&C Act
	Affiliate[1] of manufacturer who obtained the product directly from the application holder or person who manufactured the product				Compliant with its obligations under section 510 of the FD&C Act
Repackager	Owns or operates an establishment that repacks and relabels a product or package for further sale or distribution without a further transaction		A dispenser, specifically a pharmacy, that is solely engaged in packaging and labeling a product for dispensing to an identified individual patient pursuant to a valid prescription	Accepts or transfers direct ownership of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser	Registered with FDA in accordance with section 510 of the FD&C Act

491 Table 1 (cont'd). Summary of Authorized Trading Partners*

Entity Type	Description of Activity	Other Entities Included	Entities Generally Not Included	Entity is a Trading Partner When It	Entity is Authorized When It/It is
Wholesale Distributor[2]	Engaged in distribution of a drug to, or receipt of a drug by, a person other than a consumer or patient, with certain exceptions	Jobbers, *i.e.*, those engaged in wholesale distribution on a small scale or that sell product solely to retailers and institutions; dispensers who transfer product to another dispenser without a specific patient need	A manufacturer distributing its own drug; a manufacturer's co-licensed partner, a 3PL, a repackager, entities excluded from "wholesale distribution" pursuant to section 503(e)(4), a dispenser, a dispenser-affiliated warehouse or distribution center, or a dispenser who transfers product to another dispenser for a specific patient need	Accepts or transfers direct ownership of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser	Has a valid license under state law or section 583 of the FD&C Act, in accordance with 582(a)(6) of the FD&C Act, as amended by DSCSA; in compliance with reporting requirements under section 503(e)
3PL	Provides or coordinates warehousing or other logistics services with regard to a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product	Returns processors or reverse logistics providers[3] that do not take ownership of the product and are not responsible for directing the sale or disposition of the product	Brokers,[4] solution providers,[5] common carriers,[6] logistics or administrative services contractors[7]	Accepts or transfers direct possession of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser	Has a valid license under state law or section 584(a)(1) of the FD&C Act, in accordance with 582(a)(7) of the FD&C Act, as amended by DSCSA; in compliance with reporting requirements under section 584(b)

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Table 1 (cont'd). Summary of Authorized Trading Partners*

Entity Type	Description of Activity	Other Entities Included	Entities Generally Not Included	Entity is a Trading Partner When It	Entity is Authorized When It
Dispenser	Retail pharmacy, hospital pharmacy, or group of chain pharmacies under common ownership and control that do not act as a wholesale distributor		Person who only dispenses products to be used in animals in accordance with section 512(a)(5)	Accepts or transfers direct ownership of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser	Has a valid license under state law
	Person authorized by law to dispense or administer prescription drugs				
	Affiliated warehouses or distribution centers of a dispenser under common ownership and control that do not act as a wholesale distributor				

* Content in merged cells applies to all the rows that run across those merged cells for each entity type.

[1] See §581(1) of the FD&C Act.

[2] See discussion in section III.C. above, pp. 7-8.

[3] See §581(18) of the FD&C Act, and discussion in section III.D.6. above, p. 11.

[4] See discussion in section III.D.2. above, pp. 9-10.

[5] See discussion in section III.D.3. above, p. 10.

[6] See discussion in section III.D.4. above, p. 10.

[7] See discussion in section III.D.5. above, pp. 10-11.