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HDA Saleable Returns Pilot Study Preview

Industry Pilot to Test Methods of Verifying Saleable Returns in the Pharmaceutical Supply Chain

HDA, Distributors and Manufacturers to Assess Methods and Technologies to Support the 2019 Requirement to Verify the Product Identifier for Nearly 60 Million Saleable Items Returned Annually by Dispensers to Distributors

1. Overview of Saleable Returns Pilot

Beginning in November 2019, the Drug Supply Chain Security Act (DSCSA) will alter how wholesale distributors must process serialized saleable pharmaceutical returns from customers. HDA and its Traceability Pilot Work Group (TPWG) members believe that supply chain efficiency and security in the handling of returns could be impacted to varying degrees depending upon how the DSCSA is interpreted and implemented among trading partners.

To better understand the operational impact of the 2019 DSCSA requirements, and how the industry can best meet these requirements, HDA is sponsoring a pilot study to examine different methods for verifying product identifiers.

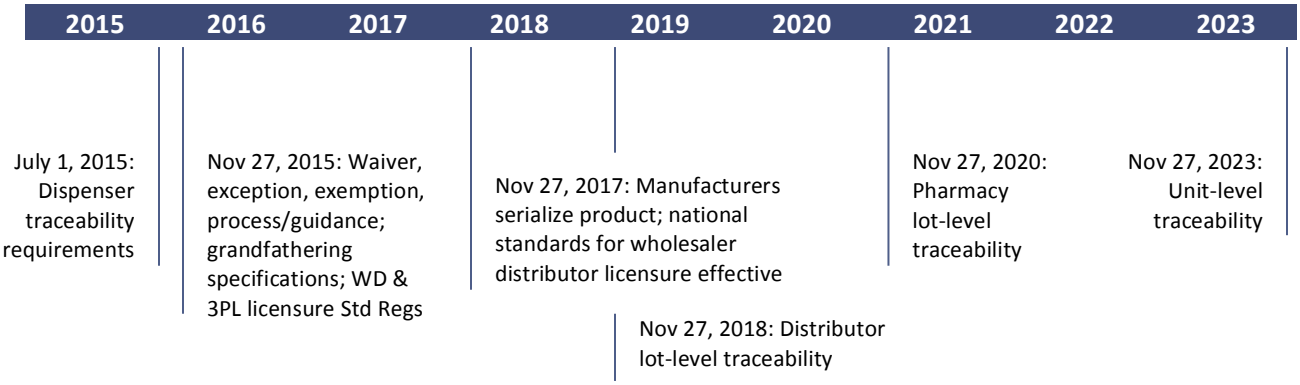
The objectives of this pilot are to gain first-hand, real-world experience with the processes and technologies required to effectively manage saleable returns from the dispenser to the distributor, and coordinate mandatory verification of product identifiers with the manufacturer. The pilot will help participants form a better understanding of how processes and technology can be used to efficiently and effectively implement this requirement and the potential impact of associated costs. The findings of this pilot will be shared broadly with the industry to provide companies with valuable information they can use as they decide how to progress toward this next compliance milestone.

Ultimately, the goal of the pilot will be to identify the most efficient method(s) for managing the verification process for saleable returns to meet the requirements of the DSCSA. This pilot is not designed to be a referendum on the nature of returns — saleable or not — or on future methods of data exchange for full DSCSA implementation in 2023.

2. Background Information on the DSCSA and 2019 Saleable Returns Requirements

a. Overview of the DSCSA

Over a period of 10 years, the DSCSA will implement a system to allow for the traceability of individual units of certain pharmaceuticals in the supply chain. Enacted on November 27, 2013, the DSCSA will be implemented in stages over the next eight years (see dates below). The DSCSA, among other things, preempts state and local laws related to product tracking and tracing requirements, mandates that all members of the supply chain be appropriately authorized and specifies information that trading partners must provide and receive in prescription drug transactions at the lowest saleable unit, from the manufacturer through the dispenser.



b. Overview of Selected Serialization and Verification Requirements

Manufacturer Serialization Beginning 11/27/17

- For each package and homogeneous case of product intended to be introduced in a transaction in commerce, manufacturers must affix or imprint a "product identifier" in both human- and machine-readable form.
    - A product identifier is a standardized numerical identifier (SNI), lot number, and expiration date. An SNI includes the NDC number and a unique alphanumeric serial number up to 20 characters.
    - Each package must have a 2D barcode.
    - A case may have a 2D barcode or a linear barcode.
- The product identifier information must be maintained ≥ six years after the initial transaction date.
- There is no requirement to include a product identifier in the transaction information (TI) until 2023.
- A manufacturer must respond within 24 hours (or such other time as determined by the Secretary) to a verification request (i.e., a request to confirm whether a product identifier corresponds to a product identifier affixed or imprinted by the manufacturer).

Wholesale Distributor Saleable Returns as of 11/27/19

- A wholesale distributor only may engage in transactions involving product bearing a product identifier (unless subject to an exemption/exception of some kind).
- A wholesale distributor only may accept saleable returns if it can "associate" the returned product with the TI/transaction statement (TS) associated with that product.
- "Associate" is not defined.
- A wholesale distributor must verify the product identifier, including the SNI, before further distribution (i.e., reselling the product).
    - Reminder: As of 2017, manufacturers must affix/imprint an identifier in both human- and machine-readable form.
    - Note: Until 2023 —
        - A manufacturer does not have to pass a TI-containing product identifier.
        - A wholesale distributor does not have to receive or pass a TI-containing product identifier.

3. Volume and Amount of Saleable Returns

To better understand the scope of saleable returns that will need to be verified, and the benefits of a pilot study to examine the issue, HDA conducted a survey of distributor members' saleable returns from dispenser customers. We received data from six pharmaceutical distributors for the period of July 2014 through June 2015. Those data showed that these six distributors handled more than 58 million units of saleable returns during the course of one year. The *HDA Factbook* consistently shows that saleable returns average between 1.6 and 2.0 percent of gross sales on an annual basis.

	Saleable Returns – Unit Quantity	Saleable Returns – Return Lines
Annual Saleable Returns Volume	58,782,871 units	30,823,602 lines
Weekly Volume	1,130,440 units	592,672 lines
Daily Volume	226,088 units	118,552 lines

In an environment in which distributors must verify the product identifier for each saleable return, these volumes look particularly large. Furthermore, the data received for the survey spanned 650 manufacturers and some manufacturers' products represented more than 2 million saleable return units in a year. The sheer volume of units, which would require 226,088 verifications each business day by these six distributors alone, demonstrates that, to continue the secure and rapid distribution of pharmaceuticals between trading partners and to patients, the industry will need to identify efficient methods for complying with the 2019 requirements while maintaining operational efficiency.

Company Categorization	Saleable Returns – Annual Unit Quantity	Saleable Returns – Daily Unit Quantity*
Total Saleable Returns Volume – Large Distributor Volume	19,118,445 units	73,532 units
Total Saleable Returns Volume – Average Distributor	475,845 units	1,830 units
Total Saleable Returns Volume – Large Generic Manufacturer	2,052,768 units	7,895 units
Total Saleable Returns Volume – Large Branded Manufacturer	1,797,219 units	6,912 units
Total Saleable Returns Volume – Average Manufacturer	86,866 units	334 units

**Assuming 260 work days per year*

Another review of the data shows the volume of saleable returns, on average, to individual companies. On average, a large distributor may have more than 19 million saleable units returned in a given year, or over 73,000 units per business day. The data also show the volume of saleable returned items for individual manufacturers. The generic manufacturers representing the highest volume of saleable returns to distributors averaged more than 2 million items in one year, while high volume brand companies had nearly 1.8 million units returned. The daily volumes approached 8,000 and 7,000, respectively.

4. Methods for Wholesale Distributors to Verify Saleable Returns with Manufacturers

In light of the DSCSA's requirements and the volume of saleable returns that would need to be verified with manufacturers, HDA's Traceability Pilots Work Group (TPWG) members developed the following list of possible methods by which distributors could verify a product identifier for the purpose of determining whether they may resell a saleable returned drug (assuming the product is otherwise acceptable for resale as determined by company procedures):

1. Manufacturer sends to wholesale distributor product identifiers for only the units purchased by the wholesale distributor.
2. Manufacturer sends to all wholesale distributors product identifiers for *all* units (not just the product identifiers for the units purchased by the wholesale distributor).
3. Central repository: All manufacturers send data to a central database, automatically verified.
4. Verification service: Each manufacturer has its own database, check external database automatically, connect through an interface.
5. Portal: Each manufacturer has its own — manual without a verification service.
6. Distributors scan product on inbound.
7. Distributors scan product on outbound.

8. Distributors manually confirm with manufacturers at time of return via phone or email.

9. Verification discovery service: Router to link to the databases (Like scenario 4 but with router service/server).

While the above suggestions are viewed as potential options, the feasibility of each depends upon various factors, including available technology, degree of reliance on manual processes and impacts upon efficiency. As the TPWG prepares to move forward with the pilot study, it will determine which methods will be tested in a live environment and which will be evaluated by other means, such as a "desktop exercise" or white paper.

Overview of Proposed Pilot Study Approach

Reporting Structure

This pilot study will be managed by HDA under the guidance of the TPWG. Ernst and Young (EY) will provide third-party support for project management, data analysis and facilitation.

Assumptions

- Only the verification of serialized saleable returns will be in scope.
- The focus will be on products that distributors purchase directly from manufacturers, although pilot scenarios may address the viability of the various methods for "non-direct purchase distributors."
- Dropships will not be included in the pilot project.

Pilot Participants

The pilot will include distributor(s) and manufacturer(s), but not dispensers as they do not have any DSCSA requirements relevant to this evaluation. Some of the methods of verification may be able to be accomplished by the wholesale distributor internally (i.e., without manufacturer participation) using the serialized product they are receiving.

Pilot Approach

To determine the most efficient method(s) possible to handle the verification process for saleable returns, the TPWG has mapped out the process for each of the verification methods described above. To evaluate the viability, advantages, disadvantages and potential costs of each method, HDA proposes that these scenarios be assessed through one of the following approaches:

1. Pilot: This will involve a live and active environment for real-world testing and execution.
2. Desktop Exercise: This will involve further time and resources to analyze and test the proposed approach in theory and articulate both the opportunities and challenges in using this approach.
3. Whitepaper: This approach will be employed to review scenarios that, for various reasons, are likely impractical given the scale, volume or complexity of industry processes.

Approach	Methods to Verify Saleable Returns
Pilot	• Manufacturer sends to wholesale distributor product identifiers for only the units purchased by the wholesale distributor (scenario 1). • Central repository: All manufacturers send data to a central database, automatically verified (scenario 3). • Distributors scan product on outbound (scenario 7).
Desktop	• Verification service: Each manufacturer has its own database, check external database automatically, connect through an interface (scenario 4). • Portal: Each manufacturer has its own — manual without a verification service (scenario 5) • Verification Discovery Service – router to link to the databases (scenario 9)
Whitepaper	• Manufacturer sends to all wholesale distributors product identifiers for all units (not just the product identifiers for the units purchased by the wholesale distributor) (scenario 2) • Distributors scan product on inbound (scenario 6) • Distributors manually confirm with manufacturers at time of return via phone or email (scenario 8)

Pilot Timeline

The following is the proposed timeline and steps within each phase of the pilot that we are proposing to execute over the next 12 months:

2015 Q4 Finalize participants and scope

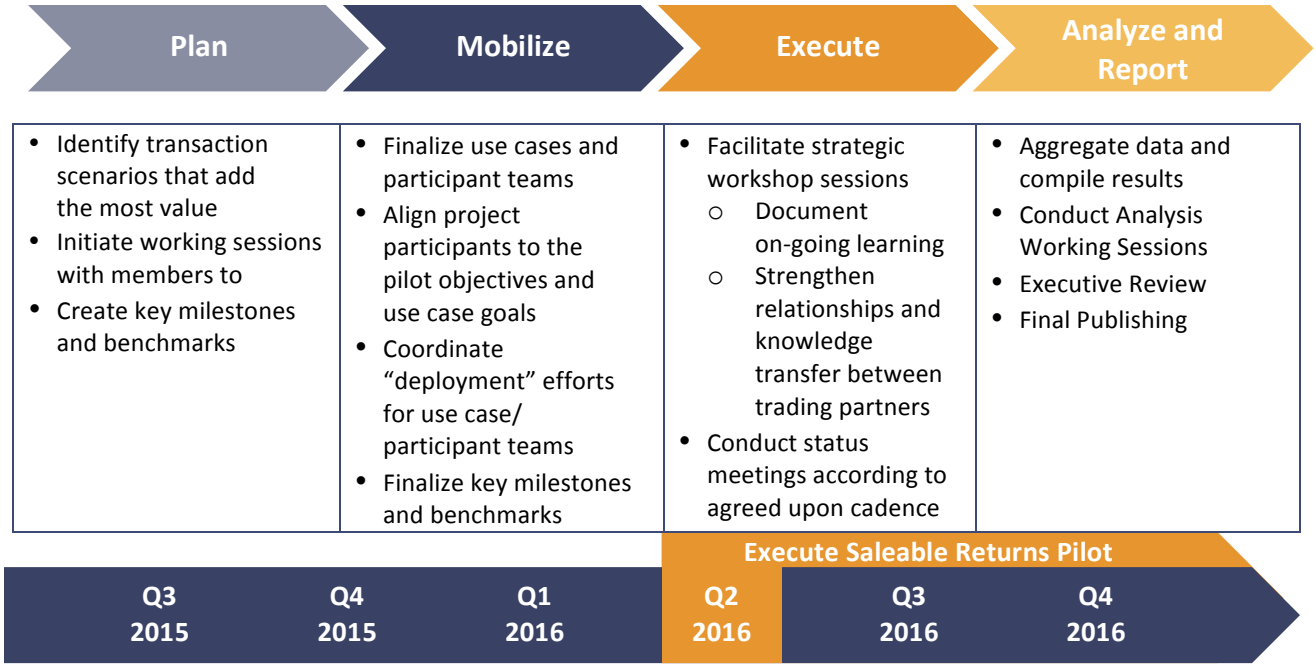
Q4 Define requirements and start development

2016 Q1 Finish solution development

Q2 Execute pilot

Q3 Gather results and finalize report

Q4 Report at HDA Traceability Seminar



Qualifications for participation

- Willingness to share pilot results broadly through HDA with industry and FDA
- Must be self-funded
- Commitments of necessary human resources
- Accept timeline
- Accountability to Traceability Pilots Work Group
- Representative sample (large, medium, small companies)
- Willingness to have a non-HDA third-party provide facilitation and data review

About HDA

HDA is the national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors. Each business day, HDA's 33 member companies ensure that 15 million prescription medicines and healthcare products are delivered safely and efficiently to more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. HDA and its members work daily to provide value and achieve cost savings, an estimated $42 billion each year to our nation's healthcare system.

Since the passage of the Drug Supply Chain Security Act, HDA has been a forum for members to come together to discuss implementation issues. Among the tools developed are *Supply Chain Product Transaction Scenarios: Drug Supply Chain Security Act Implementation, EDI Guidelines for the 856 Advance Ship Notice to Support Implementation of DSCSA, HDA ASN Exceptions Guidelines for the Drug Supply Chain Security Act* and *HDA Guidelines for Bar Coding in the Pharmaceutical Supply Chain: Quick Start Guide*.

Contacts

HDA: Perry Fri, Executive Vice President, Industry Relations, Membership and Education, pfri@hda.org

EY: Ryan Kelly, Senior Manager, Advisory Consulting Services, Ryan.Kelly2@ey.com

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