Healthcare Distribution Management Association

May 16, 2016

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RE: Pharmaceutical Distribution Supply Chain Pilot Projects; Request for Information, 81 Fed. Reg. 22279 (April 15, 2016), Dkt. No. FDA-2016-N-1114

Dear Doctor Bernstein, Doctor Jung and Mr. Bellingham:

The Healthcare Distribution Management Association (HDMA) appreciates this opportunity to provide public comments to the Food and Drug Administration (FDA) regarding the Pharmaceutical Distribution Supply Chain Pilot Projects; Request for Information, 81 Fed. Reg. 22279 (April 15, 2016).

HDMA represents the nation's primary, full-service healthcare distributors. Our members are large national companies and regional, family-owned and small businesses. HDMA member companies deliver nine million healthcare products to more than 200,000 pharmacies, hospitals, nursing homes, physician offices and clinics across the United States. This essential function is provided with little public recognition or visibility, and at great

savings to the healthcare system. HDMA members serve as the central link in a sophisticated national supply chain. HDMA members take this mission very seriously, and we support manufacturers, healthcare providers and the government in ongoing efforts to ensure the U.S. medicine supply remains secure, efficient and highly regulated.

HDMA participated in the public workshop FDA convened on April 5 and 6, 2016 regarding proposed pilot projects under the Drug Supply Chain Security Act (DSCSA). 81 Fed. Reg. 7807 (Feb. 16, 2016). We also submitted comments on April 21, 2016 regarding that workshop to Dkt. No. FDA-N-0407. Here, in response to FDA's Request for Information published on April 15, 2016, we address the following:

- Even in the 2½ years since its passage, the DSCSA has significantly strengthened supply chain security – product transactions must only be between authorized trading partners; all trading partners must exchange and maintain transaction data; and suspect and illegitimate product requirements have improved how potential product problems are identified, investigated and reported. The introduction of fully serialized product, with aggregation and inference, and then the exchange of serialized data between authorized trading partners will produce even greater benefits to pharmaceutical supply chain security and traceability that are far superior to even where we are today. However, while the product identifier will be very useful in many ways, there is no reason for creating new verification requirements that have no basis in the DSCSA.
- Varying levels of technical capability within the supply chain mean that some are better positioned than others to utilize the product identifier to enhance the tracing of a product. Because unfamiliarity with DSCSA requirements persists, HDMA believes it is very important for FDA to continue to emphasize that the statute requires a secure, interoperable, *electronic* system.
- Both HDMA and the Pharmaceutical Distribution Security Alliance (PDSA) submitted comments to Dkt. No. FDA-N-0407 regarding the April pilots workshop. PDSA suggested criteria for the evaluation of pilots that significantly overlap with the system attributes HDMA identified for a secure, interoperable, electronic system. HDMA agrees with PDSA's comment with respect to these criteria.
- FDA presented terms at the April 5 and 6 workshop and posted them at http://www.fda.gov. HDMA offers comment upon those terms.
- We provide a more detailed discussion of the HDMA Saleable Returns Pilot Study which is designed to examine certain verification requirements effective in 2019. We include a preview of the study disseminated in November 2015.
- In response to FDA providing "interested persons an opportunity to submit comments relating to FDA's implementation of the DSCSA" (81 Fed. Reg. at 22280), we discuss three matters on which there is urgent need for FDA action:
  - Issuance of a guidance on grandfathering which will address how FDA intends to treat unserialized product, and serialized product that does not have related transaction information;
  - Promulgation of regulations on licensure of wholesale distributors and third-party logistics providers, made especially critical because of lingering misconceptions

regarding requirements applicable to dispensers who act as wholesale distributors and sell product to other dispensers and wholesale distributors; and,

- Issuance of guidance on processes for obtaining waivers, exceptions, and exemptions from DSCSA requirements.

* * *

HDMA thanks you for this opportunity to provide input on FDA's Request for Information. If you have any questions, please contact me at 703-885-0240 or at aducca@hdmanet.org.

Sincerely,

Anita T. Ducca
Senior Vice President, Regulatory Affairs

Attachments:

1. Comments by the Healthcare Distribution Management Association on the FDA Federal Register Notice: Pharmaceutical Distribution Supply Chain Pilot Projects; Request for Information
2. HDMA Saleable Returns Pilot Study Preview (November 2015)

Comments by the Healthcare Distribution Management Association on the FDA Federal Register Notice Pharmaceutical Distribution Supply Chain Pilot Projects; Request for Information

81 Fed. Reg. 22279 (April 15, 2016), Dkt. No. FDA-2016-N-1114

May 16, 2016

The Healthcare Distribution Management Association (HDMA) thanks the Food and Drug Administration (FDA) for the opportunity to provide comment on the agency's Request for Information regarding Pharmaceutical Distribution Supply Chain Pilot Projects, 81 Fed. Reg. 22279 (April 15, 2016), Dkt. No. FDA-2016-N-1114. HDMA previously participated in the FDA's public Workshop on proposed pilot projects under the Drug Supply Chain Security Act (DSCSA) and, on April 21, 2016, submitted comments to that docket, No. FDA-2016–N–0407. HDMA also submitted our April 21, 2016 comments to this docket.

In the April 15 Request for Information, FDA seeks comments upon three issues:

- Utilizing the product identifier for tracing of a product, which may include verification of the product identifier, including the use of aggregation and inference;
- Technical capabilities of each sector of the supply chain to comply with systems and processes needed to utilize the product identifier to enhance the tracing of a product; and
- System attributes that are necessary to implement the requirements established under the DSCSA.

81 Fed. Reg. at 22280.

At the April Workshop, FDA posted a list of important DSCSA terms that are not defined in the statute and has since published those terms at http://www.fda.gov. We offer comment upon those terms here. Further, in the April 15 *Federal Register* notice, FDA states it is "interested in comments regarding past or present pilot projects related to enhancing the safety and security of the pharmaceutical distribution supply chain." *Id.* Last, FDA states that its notice "is intended to provide interested persons an opportunity to submit comments relating to FDA's implementation of the DSCSA". *Id.*

HDMA addresses each of these six issues below.

1. **Utilizing the product identifier for tracing of a product, which may include verification of the product identifier of a product, including the use of aggregation and inference.**

The DSCSA sets out a phased-in approach with the goal, over ten years, of achieving a secure, interoperable, electronic system. Already, measures to significantly strengthen supply chain security have been put in place – product transactions must only be between authorized trading partners; all trading partners must exchange and maintain transaction data; and suspect and illegitimate product requirements have improved how potential product problems are

identified, investigated and reported. Today, all prescription drug transactions are subject to traceability requirements and must be between authorized trading partners. Less than three years ago, this was not the case – the predecessor to the DSCSA, the Prescription Drug Marketing Act (PDMA), imposed limited "pedigree" (now traceability) requirements upon relatively few transactions. In a short period of time, the supply chain has enormously enhanced security and many improvements are still to come as serialized product begins to enter the marketplace.

A future in which there is fully serialized product, with aggregation and inference, and then the exchange of serialized data between authorized trading partners, will produce even greater benefits to pharmaceutical supply chain security and traceability that are far superior to even where we are today in the current state of lot level tracing. The serialized product and data will enable each authorized trading partner to swiftly identify[1] whether it ever received a single product and from whom. The product identifier, and verification of it, play a critical role in increasing the security of saleable returns. Serialized product and data will enable standardized data formats and better scalability. Further, with serialized product and its data, inference and aggregation are possible.

We emphasize that aggregation and inference are critically important processes to an efficient, secure supply of serialized product supported by serialized data. Without the benefit of inference, a wholesale distributor would not be able to transact in the aggregated quantities received from manufacturers, such as cases or pallets. Rapid, efficient receiving and warehousing actions would have to halt so that every sealed container holding multiple, serialized units of products, could be broken apart and individually scanned. Breaching and disturbing an otherwise sealed, intact container in order to scan individual units at the point of receipt also undermines security and makes it more difficult to identify product tampering and other potential problems. Breaking seals, opening containers and subjecting individual units of prescription drugs to needless handling also increases the risks of breakage, compromise of product integrity and otherwise rendering the product unsafe for patients. The ability of wholesale distributors to transact in aggregated sealed containers without scanning each item is critical to supply chain security, product integrity and assuring the quick and efficient provision of medicines to patients.

HDMA responded in more detail to question 1 in its previous, April 21 comments. *See* Dkt. No. FDA-2016-N-1114. We reiterate that we believe the DSCSA's verification obligations are very clear and there is no basis for expanding them to impose new, extra-statutory requirements upon authorized trading partners, as some urged at the April 5-6 pilots meeting and subsequent comments.

Moreover, the DSCSA also does not require any one segment of the supply chain (manufacturer, wholesale distributor or dispenser) to maintain complete data on the product's prior Transaction History (TH). Nor does the DSCSA require a trading partner to establish and maintain a database that may be queried to produce a complete "lookback" of this information

[1] The DSCSA requires manufacturers and wholesale distributors to respond to requests for information from FDA or other state or federal official within 1 business day, not to exceed 48 hours. § 582(b)(1)(B); 582(c)(1)(C). Dispensers must respond within 2 business days, or such other time FDA determines is reasonable. § 582(d)(1)(D).

going all the way back to the manufacturer. As stated in § 352(k)(1), after November 27, 2023, "the provision and receipt of transaction history" "shall have no force and effect" and the DSCSA does not envision that the supply chain would be subject to the electronic equivalent of producing the TH.

We addressed these and related issues in more detail in our April 21, 2016 comment.

2. Technical capabilities of each sector of the supply chain to comply with systems and processes needed to utilize the product identifier to enhance the tracing of a product.

HDMA's wholesale distributor members believe they are well-positioned with regard to overall DSCSA implementation and have or will develop the technical capabilities necessary to utilize product identifiers, participate in a secure, interoperable, electronic system for the exchange of transactional data and comply with the statute's other requirements. The vast majority of all prescription drug transactions (as "transaction" is defined in the DSCSA) in the United States involve HDMA distributor members purchasing from manufacturers or the manufacturer's exclusive distributor or repackager, and selling that product to a dispenser. Thus, as DSCSA implementation moves forward, toward 2023 and beyond, the vast majority of prescription drug transactions will move in this tightly controlled, documented, closed, electronic system between authorized trading partners.

However, as HDMA and its members continue their outreach about the DSCSA, we find that serious misinformation persists about the statute and its requirements. This is particularly true for some dispensers, small manufacturers, state regulatory authorities including the state Boards of Health or Pharmacy, and even federal field personnel. We urge FDA to continue its efforts to educate pharmaceutical supply chain stakeholders and regulators on DSCSA requirements. We believe it is especially important that FDA emphasize, convincingly and repeatedly, that the DSCSA's secure, interoperable system for the exchange of transaction data *must be electronic*. Further, we urge FDA to address the very persistent belief that State licensure and pedigree requirements and exceptions to those requirements continue in effect when, in fact, the DSCSA preempts them.

3. System attributes that are necessary to implement the requirements established under the DSCSA.

We discussed the system attributes we believe are necessary to implement DSCSA requirements in our April 21 comment. Attributes we identified included, but were not limited to, DSCSA compliance, security, reliability and cost effectiveness. In its April 21, 2016 comment to Dkt. No. FDA-2016–N–0407, the Pharmaceutical Distribution Security Alliance (PDSA) suggested criteria for the evaluation of pilots. PDSA's criteria significantly overlap with the attributes HDMA identified for a secure, interoperable, electronic system and include the following:

- Cost Effectiveness
- Retrievability

- Scalability
- Flexibility/versatility
- Reliability
- Interoperability
- Security
- Ease of Implementation/Maintainability
- Management of Data Ownership
- Patient Impact

HDMA agrees with PDSA's comment with respect to the above criteria.

4. Terms FDA identified at the pilots meeting and later published at http://www.fda.gov.

FDA began the April Workshop with a presentation that included key terms in the DSCSA. HDMA thanks FDA for publishing these terms and offers comment upon them below.

a. Aggregation

FDA Description
Physical (packing): The process of packaging a number of packages within outer layers of packaging (bundles, cases, totes, pallets, etc.)
Data: Recording the hierarchical information related to packages and any other outer layers of packaging for shipment

HDMA Suggested Changes
HDMA agrees with this explanation and suggests additions indicated in ***blue, bold, italics***:

Physical (packing): The process of packaging a number of packages within outer layers of packaging (***units***, bundles, cases, totes, pallets, etc.)
Data: Recording the hierarchical information related to packages and any other outer layers of packaging for shipment. ***Aggregation enables inference.***

b. Disaggregation

FDA Description
Physical (unpacking): The process of unpacking a number of packages from outer layers of packaging (bundles, cases, totes, pallets, etc.)
Data: Recording the hierarchical information related to packages received and unpacked in a shipment

HDMA Suggested Changes
HDMA agrees with this explanation.

c. Inference

FDA Description
Packages are deemed to be contained within outer levels of packaging (bundles, cases, totes, pallets, etc.) based on information that is provided by the seller

HDMA Suggested Changes
We suggest adding to the description of the term "inference." Our additions are indicated in ***blue, bold, italics***.

Packages are deemed to be contained within outer levels of packaging (***units***, bundles, cases, totes, pallets, etc.) based on information that is provided by the seller. Inference is only possible with aggregation.

Inference applies in instances where a collection is moved through the supply chain in an outer container (e.g., pallets, cases, totes, etc.), and less than 100% of the barcodes in that collection are read by recipients.[2]

Inference is only possible if units have been aggregated.

Inference continues as long as the aggregated outer container (e.g. pallet, case, tote, etc.) is intact and unopened. Once the most outer container is opened, inference for that outer container ceases.

d. Interoperability

FDA Description
The ability to exchange product tracing information accurately, efficiently, and consistently among trading partners (reference: FDA Guidance, November 2014) ("electronic interoperability" would involve electronic formats, methods, or systems)

HDMA Suggested Changes
HDMA agrees with this explanation.

e. System Attributes

FDA Description
System attributes are properties or capabilities of the system that are necessary to implement the requirements of section 582. The attributes of a product tracing system may include the following:

[2] The source for this sentence is GS1 Healthcare. *The Practice of Inference in the U.S. Pharmaceutical Supply Chain*. (May 2010).

- Capability to capture and maintain product tracing information
- Interoperability to enable trading partners to securely exchange product tracing data accurately and efficiently
- Capability to verify product
- Controlled access to product tracing information by trading partners, FDA and other appropriate federal and state officials
- Security of data and systems

HDMA Suggested Changes

HDMA appreciates FDA's recognition that access to product tracing information must be controlled. As we discussed above and in our April 21 comments, the provisions in the DSCSA requiring transmission of TH expressly sunset on November 27, 2023. The DSCSA also explicitly identifies the circumstances under which trading partners and government officials may access transaction data. To better clarify the parameters of access to product tracing information, we suggest the fourth bullet point under "system attributes" include the following addition, indicated in ***blue, bold, italics***.

- Controlled access to product tracing information by trading partners, FDA and other appropriate federal and state officials ***to provide information as necessary to fulfill the requirements of §582(g)(1)(C)-(E).***

5. Information about past or present pilot projects related to enhancing the safety and security of the pharmaceutical distribution supply chain.

As was discussed at the April Workshop, in our April 21 comments and elsewhere, HDMA has convened a group of wholesale distributors and manufacturers (referred to as the Traceability Pilot Work Group or "TPWG") to pilot methods for verification of the product identifiers on saleable returns. We attach, for your information, the HDMA Saleable Returns Pilot Study Preview (November 2015) (2019 Pilot Preview) which explains this 2019 Pilot in more detail. (As is to be expected, the 2019 Pilot has been further refined since the initial publication of this Preview in November.)

In the work prefacing the 2019 Pilot, HDMA identified nine possible methods or scenarios by which wholesale distributors could verify product identifiers:

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 connected to each manufacturer).

The TPWG has elected to pilot scenarios 1, 3, 7 and 9. The remainder will be either "tested" in a "desktop" pilot or described in a white paper. The 2019 Pilot Review summarizes many aspects of the 2019 Pilot. Additional elements include the following:

- Ernst & Young was retained as a project manager.
- As returns are being simulated, there is no need for dispensers to participate in the Pilot.
- Each distributor will process – verify the return of – a maximum of 100 units per scenario in which it is participating.
- Metrics will be captured by participants and collated by Ernst & Young.

In our April 21 comment, we discussed information that we hoped might be gleaned from the 2019 Pilot while also being careful to not "over-promise." The 2019 Pilot is narrow in scope, focusing upon the very important process by which wholesale distributors must verify product identifiers on saleable returns. Nevertheless, the 2019 Pilot will be incorporating elements and, hopefully, generating results that may provide useful information as FDA and the supply chain move to development of a secure, interoperable, electronic system for 2023:

- All products in the 2019 Pilot will bear a product identifier that is a 2-D datamatrix encoded with a serialized Global Trade Item Number (SGTIN), lot number and expiration date.[3]
- Scenario 1 will require aggregation.
- Scenario 1 will include an initial utilization of Electronic Product Code Information Services (EPCIS) that follows most of the applicable DSCSA and GS1 standards.
- Global Location Numbers (GLNs) are being used in Scenarios 1, 3 and 9.
- GTINs, GLNs and EPCIS are all subject to GS1 international standards.

Though still under discussion, the TPWG has begun outlining the possible metrics of the 2019 Pilot. These metrics are currently organized around three areas:

- Performance
- One-time costs
- Ongoing costs

To measure performance of each scenario, each participant will record information on each product scanned, by SGTIN, including whether the return could be verified and, if not,

[3] We explained the SGTIN and its components as part of a DSCSA product identifier in more detail in our April 21 comments.

whether the error was due to a scan failure or a data transmission failure, the reason for the failure, and the increased time over current practice to verify the return. Ernst & Young will receive individual company results, compile the data, and report out aggregated results representing the experience of all participants.

Ernst & Young will also gather information from participants about the one-time/set-up and ongoing costs involved in the process for verification of saleable returns and combine that information so that it might be shared. Participants will provide their 2015 expected saleable returns volume to the project manager. Other information that may also be gathered by participants and provided to Ernst & Young includes:

- Up-front and one-time costs, including
    - Costs for
        - Aggregation
        - Equipment
        - Automation
    - Costs to onboard a trading partner
    - Systems implementation cost
    - Costs on reconfiguring packaging lines
    - Distribution center costs

- Ongoing costs, including
    - System maintenance
    - Licensing fees
    - Equipment maintenance

- Cost per scan

HDMA and participating wholesale distributors and manufacturers hope to complete data collection for this 2019 Pilot by September 2016, and thereafter compile and evaluate the findings. The initial results will be presented at the HDMA Traceability Seminar in Washington, D.C. on November 9-11, 2016.

6. Comments relating to FDA's implementation of the DSCSA

HDMA raises three issues regarding FDA's implementation of the DSCSA that are of particular and immediate importance. All relate to urgently needed guidance and regulation we hope that FDA can soon issue.

a. Grandfathering Guidance

FDA is directed to issue guidance "specifying whether and under what circumstances product that is not labeled with a product identifier and that is in the pharmaceutical distribution supply chain at the time of the effective date of the requirements of this section shall be exempted from the requirements of this section." §582(a)(5)(A). Issues surrounding grandfathering are creating much uncertainty in the pharmaceutical supply chain.

For example, though manufacturers must begin serializing product by November 27, 2017, wholesale distributors may continue to transact with unserialized product for two more years, until November 27, 2019. This two-year gap – which aligns with the expiration dating of many drugs – will allow much unserialized product to be used and dispensed before the 2019 deadline. However, HDMA believes that over 30 percent of prescription products have expiration dating beyond two years, which means that some unserialized, saleable products will still be in commerce in 2019. Additionally, even if the product bears the identifier, that product identifier does not need to be included in the seller's transaction information (TI) until November 27, 2023. Thus, for many years, distribution will be complicated by the fact that trading partners will be concurrently transacting with serialized and unserialized products and even if product is serialized, the identifier does not need to be included in TI until 2023.

The grandfathering guidance could ease these implementation challenges that the DSCSA's phased-in timeline poses. The grandfathering guidance will also need to recognize that permitting product to circulate without serialized identifiers and/or data has a "ripple" effect as that product moves, over a period of months or years, from the manufacturer through the wholesale distributor to the dispenser and, possibly, back as a saleable return. HDMA looks forward to working with FDA on sensible grandfathering guidance that accomplishes an orderly transition that avoids confusion, pharmaceutical waste and higher costs.

b. Licensure Regulations

HDMA and its members are finding that the lack of proposed regulations on wholesale distributor and 3PL licensing standards is beginning to undermine the national uniformity Congress intended in enacting the DSCSA as states attempt to fill holes they perceive in existing requirements. Of particular concern is that some dispensers are continuing to act as unlicensed wholesale distributors and are selling products to wholesale distributors and other dispensers without regard to wholesale distributor licensure and other DSCSA requirements. Participants in these types of transactions and even state regulators appear to be under the misapprehension that these transactions are permissible irrespective of the DSCSA's licensure and traceability requirements because state laws and regulations have traditionally allowed them.

We note that unlicensed wholesale distribution was one area of particular concern to Congress when it enacted the DSCSA. Congress intended to bring greater scrutiny to these types of transactions and required that dispensers and other entities engaged in wholesale distribution must be licensed as wholesale distributors and comply with the other requirements of the DSCSA that are applicable to wholesale distributors. In order for the DSCSA to be implemented as Congress intended, we believe it is important for FDA to issue licensure regulations as quickly as possible and correct the persistent misunderstanding that state law can exempt a trading partner from DSCSA wholesale distribution licensure and other requirements.

c. Waiver, Exception and Exemption Guidance

The DSCSA requires FDA to issue a guidance that establishes processes by which the Agency can review and respond to requests for waivers, exceptions and exemptions from DSCSA requirements. § 582(a)(3). HDMA provided suggestions to FDA regarding this guidance in April 2015. There is an urgent need for a documented, transparent process for review of DSCSA waivers, exceptions and exemptions. Recent examples of exemptions, or requests for them, include the *First Responder Guidance*, FDA's decision on the data requirements in 340B transactions, and the information circulated at a recent FDLI conference that the Agency had provided clarification regarding data requirements for drugs first sold by a manufacturer into and then returned from the national stockpile. These are all *very* important decisions. We believe that the process for seeking waivers, exceptions and exemptions from the DSCSA would be significantly aided by clear agency guidance on the processes to follow.

7. Conclusion

HDMA wishes to add one final point for FDA's consideration. In these comments and in those filed on April 21 we, and others within the supply chain, have developed views and recommendations based on the best information available as of this time. The results of pilot studies, such as the HDMA 2019 Pilot on verification of saleable returns described above in point #5, advances in technology, and other new information, may come to light over the next six years. Such new or better information, particularly regarding implementation technology, may support changes in our currently envisioned approach to DSCSA implementation. Thus, we urge FDA to remain flexible in its expectations, including in future guidances, so that together, the pharmaceutical supply chain may reach the ultimate goal of full DSCSA compliance in 2023 with the greatest amount of efficiency and accuracy.

HDMA thanks FDA for this opportunity to submit these comments. If you have any questions or if HDMA can provide further information that may be helpful, please do not hesitate to contact Anita Ducca, Senior Vice President, Regulatory Affairs, at 703-885-0240 or at aducca@hdmanet.org.

Attachment: HDMA Saleable Returns Pilot Study Preview (November 2015)

HDMA Saleable Returns Pilot Study Preview

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

HDMA, 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. HDMA 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, HDMA is sponsoring a pilot study to examine different methods for verifying product identifiers.

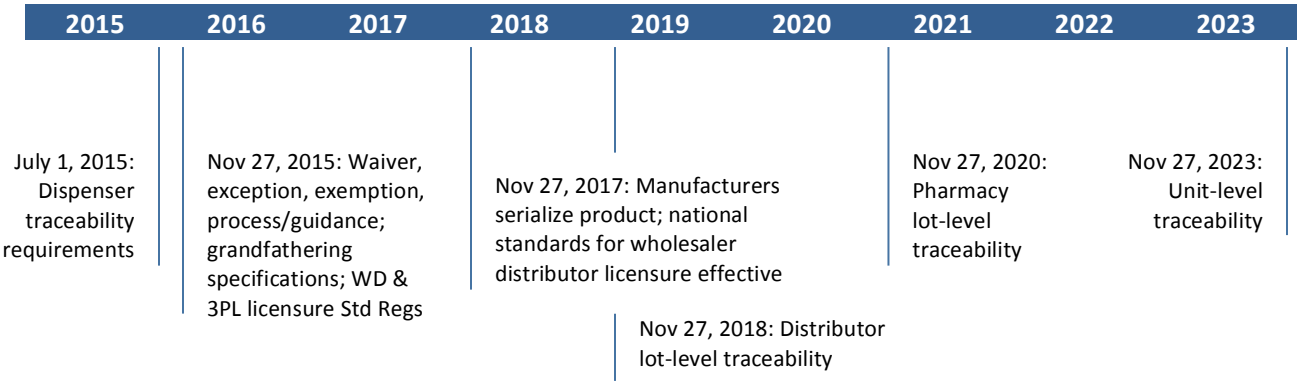
The objectives of this pilot are to gain first-hand, real-world experience with the processes and technologies required to effectively manage saleable returns from the dispenser to the distributor, and coordinate mandatory verification of product identifiers with the manufacturer. The pilot will help 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 $\geq$ 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, HDMA 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 *HDMA 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, HDMA'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 HDMA 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, HDMA 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)

N.B. Since publishing this preview, the TPWG decided to also pilot scenario 9, previously identified as a desktop pilot.

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

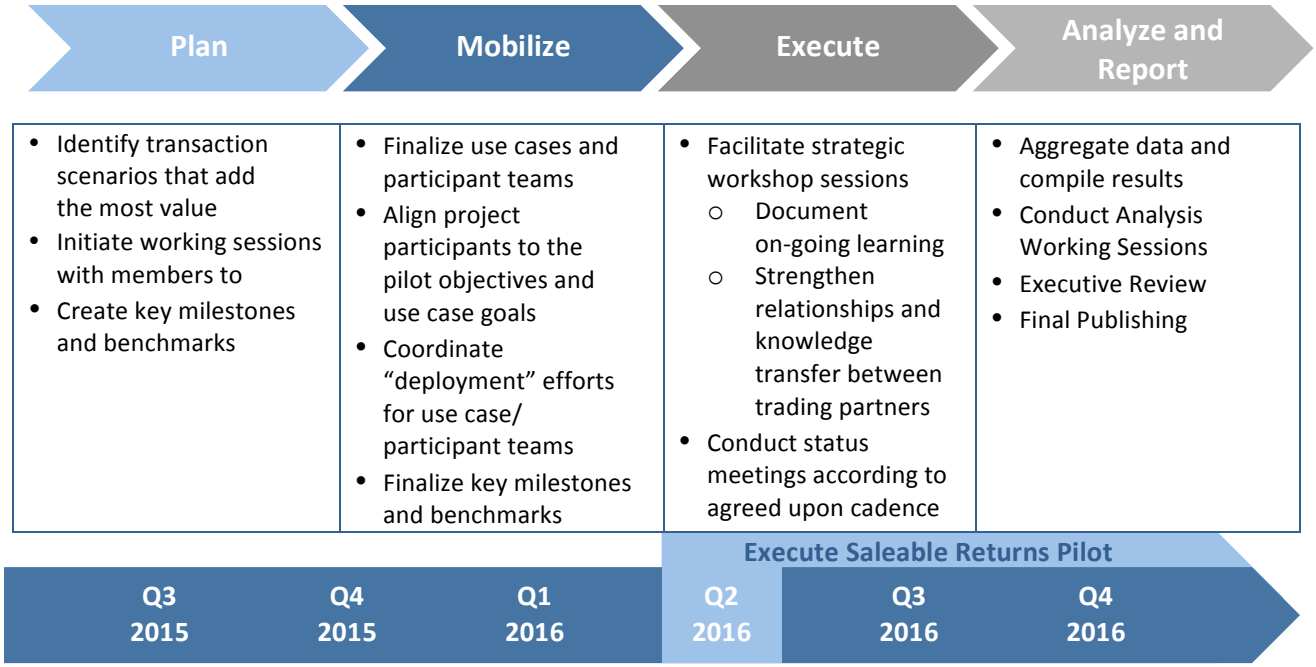
Q4 Define requirements and start development

2016 Q1 Finish solution development

Q2 Execute pilot

Q3 Gather results and finalize report

Q4 Report at HDMA Traceability Seminar



Qualifications for participation

- Willingness to share pilot results broadly through HDMA 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-HDMA third-party provide facilitation and data review

About HDMA

HDMA is the national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors. Each business day, HDMA'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. HDMA 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, HDMA 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, HDMA ASN Exceptions Guidelines for the Drug Supply Chain Security Act* and *HDMA Guidelines for Bar Coding in the Pharmaceutical Supply Chain: Quick Start Guide*.

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