



**U.S. Department of Health and Human Services  
Office of Inspector General**

# **Drug Supply Chain Security: Dispensers Received Most Tracing Information**

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## Drug Supply Chain Security: Dispensers Received Most Tracing Information

### What **OIG** Found

We found that all 40 selected drug dispensers received at least some drug product tracing information from their trading partners, and 26 of these dispensers received all required elements of this information. The remaining 14 dispensers were missing a few of the required elements. Two of these dispensers were unaware of the Drug Supply Chain Security Act (DSCSA) and requirements for drug product tracing. The DSCSA requires that dispensers receive complete tracing information before accepting ownership of a drug product. Although dispensers are generally implementing the requirements for drug product tracing, missing information and a lack of awareness of DSCSA requirements raise concerns that a complete tracing record for a drug product may not always be available to support investigations of suspect and illegitimate drug products in the supply chain. Complete tracing information for drug products should help the Food and Drug Administration (FDA), State agencies, and other Federal agencies investigate and identify harmful drugs in the supply chain to prevent further distribution and facilitate efficient recalls of drugs.

The dispensers in this study received drug product tracing information in a variety of transmission modes and formats. This variety is a result of dispensers and their trading partners using different systems rather than adopting a standardized way to exchange this information. Neither the DSCSA nor FDA guidance requires a uniform transmission mode or format for the exchange of drug product tracing information.

### What **OIG** Recommends

To facilitate dispensers' compliance with the DSCSA, we recommend that FDA offer educational outreach to dispensers where appropriate. Specifically, we recommend that FDA provide education to ensure that dispensers understand their responsibilities to receive complete drug product tracing information from trading partners before taking ownership of drug products. FDA concurred with our recommendation.

### Key Takeaway

We found that selected dispensers are moving toward full implementation of the Drug Supply Chain Security Act's (DSCSA's) requirements for the tracing of drug products. However, some concerns exist about missing information and a lack of awareness of DSCSA requirements. Complete drug product tracing information can help FDA and others respond to potentially harmful drugs in the drug supply chain.

### Why **OIG** Did This Review

Drug diversion, counterfeiting, and the importation of unapproved drugs may result in potentially dangerous drugs entering the drug supply chain, posing a threat to public health and safety. To enhance the security of this supply chain, the DSCSA requires trading partners in the drug supply chain to create a record of each drug product transaction. The FDA can then use such records to investigate suspect and illegitimate drug products and potential diversion.

This study is the second in a series of Office of Inspector General (OIG) examinations of drug supply chain security, each following the implementation of various DSCSA provisions. The previous study found that selected wholesale distributors exchanged drug product tracing information with other trading partners and about one-half of wholesalers exchanged all required information.

Future **OIG** work will test whether drug product tracing information can be used to trace drug products through the entire drug supply chain.

### How **OIG** Did This Review

Between December 2016 and February 2017, we interviewed 40 dispensers. These dispensers varied in size and type and included independent retail pharmacies, chain retail pharmacies, and small and large hospital pharmacies. We requested that dispensers submit examples of drug product tracing information provided by their trading partners.

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# BACKGROUND

## Objective

To describe selected dispensers' exchange of drug product tracing information in the drug supply chain as required by the Drug Supply Chain Security Act (DSCSA).

Potentially dangerous drugs entering the drug supply chain pose a threat to public health and safety. In one example from May 2015, the Food and Drug Administration (FDA) issued a warning that a counterfeit version of Botox may have been sold to doctors' offices and clinics by an unlicensed supplier. FDA stated that these counterfeit versions were unsafe and should not be used.<sup>1</sup> Further, a 2012 congressional report raised concerns about the safety of drugs that pass through complex distribution networks that often involve secondary wholesale distributors that do not always purchase drugs directly from drug manufacturers.<sup>2</sup>

To strengthen drug supply chain security and protect patients from harmful drugs, Congress passed the DSCSA in November 2013.<sup>3</sup> Among other things, the DSCSA established drug product tracing requirements for certain prescription drugs.<sup>4</sup> The DSCSA generally requires that trading partners in the drug supply chain (i.e., drug manufacturers, repackagers, wholesale distributors, and dispensers (primarily pharmacies)) exchange information about each drug every time a transfer of ownership occurs, creating a record of each trading partner's ownership of the drug. This record should help FDA, other appropriate State and Federal agencies, and other stakeholders investigate and identify harmful drugs in the supply chain to prevent further distribution and facilitate efficient drug recalls.

This study is the second in a series of examinations by the Office of Inspector General (OIG) of drug supply chain security and the DSCSA. This series will evolve as new DSCSA provisions become effective. The previous study found that selected wholesale distributors exchanged drug product tracing information and about one-half of them exchanged all required

<sup>1</sup> FDA, Counterfeit Version of Botox Found in the United States, April 16, 2015. Accessed at <https://www.fda.gov/Drugs/DrugSafety/ucm443217.htm> on June 14, 2017.

<sup>2</sup> Senate Staff Report, *Shining Light on the Gray Market*, June 25, 2012. Accessed at <https://democrats-oversight.house.gov/sites/democrats.oversight.house.gov/files/migrated/uploads/7.25.12%20Staff%20Report%20Shining%20Light%20on%20the%20Gray%20Market.pdf> on June 14, 2017.

<sup>3</sup> Drug Quality and Security Act, Title II, P.L. No. 113-54 (enacted November 27, 2013), amending and adding sections 581 through 585 to the Federal Food, Drug, & Cosmetic Act (FD&C Act).

<sup>4</sup> § 582 of the FD&C Act.

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information. Future work will test whether drug product tracing information can be used to trace drugs through the entire drug supply chain.

### The Drug Supply Chain Security Act

The DSCSA created a Federal framework to address vulnerabilities in the drug supply chain. The DSCSA provides FDA and appropriate State and Federal officials with tools to trace drugs through the supply chain. For example, if counterfeit drugs are discovered, this system could provide FDA with information to determine at what point in the drug supply chain the problem originated and identify where the drugs were distributed so they can be quarantined before they cause harm.

The distribution of drugs from the drug manufacturer to the patient involves a variety of trading partners, including drug manufacturers, repackagers, wholesale distributors (hereinafter referred to as wholesalers), and dispensers.<sup>5, 6, 7, 8</sup> Generally, drugs pass between trading partners until they reach the dispensing pharmacy and ultimately the patient. Dispensers are typically the last trading partner in the drug supply chain. Exhibit 1 shows one way drugs might flow through the drug supply chain to the dispenser. In this example, the dispenser purchases the drug from the wholesaler, which purchases the drug directly from the drug manufacturer.

#### Exhibit 1: Example of Drug Supply Chain Process



Source: OIG analysis of the drug supply chain, 2016.

Alternatively, the distribution of drugs may involve additional trading partners in the drug supply chain. For example, some transactions may involve an additional wholesaler or repackager that did not purchase the

<sup>5</sup> A manufacturer is defined as the person who holds a product's FDA-approved application or license or, if a product is unapproved, the person who manufactured the product. This term also includes a co-licensed partner or an affiliate of the application holder. § 581(10) of the FD&C Act.

<sup>6</sup> A repackager is defined as a person who owns or operates an establishment that repacks and relabels a product or package for further sale or distribution without a further transaction. § 581(16) of the FD&C Act.

<sup>7</sup> A wholesale distributor is defined as a person engaged in wholesale distribution. § 581(29) of the FD&C Act.

<sup>8</sup> A dispenser is defined to include a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control, or any person legally authorized to dispense or administer prescription drugs. § 581(3) of the FD&C Act.

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drug directly from the drug manufacturer. Although less typical, drugs also may pass through one dispenser to another dispenser, such as when drugs are not available directly from wholesalers.<sup>9</sup>

### DSCSA Requirements on Dispensers' Exchange of Drug Product Tracing Information

Beginning July 1, 2015, the DSCSA required dispensers and their trading partners to exchange drug product tracing information for transactions involving a product.<sup>10</sup> DSCSA defines a "product" as "a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing" (hereinafter we refer to "product" as a "drug product").<sup>11</sup> DSCSA defines a "transaction" generally as "the transfer of [a drug] product between persons in which a change of ownership occurs."<sup>12</sup>

Drug product tracing information includes three components: transaction information, transaction history, and a transaction statement. Transaction information is composed of 10 elements that describe the transaction, including drug product information, such as the National Drug Code (NDC) and dosage form.<sup>13, 14</sup> Transaction history is a statement that shows the transaction information for each prior transaction.<sup>15</sup> The transaction statement is a statement that the trading partner transferring ownership provides to the subsequent purchaser.<sup>16</sup> See Appendix A for complete definitions.

### DSCSA Requirements on Dispensers' Maintenance of Drug Product Tracing Information

Beginning July 1, 2015, the DSCSA also required dispensers to capture drug product tracing information and maintain it for not less than 6 years after the transaction.<sup>17</sup> Dispensers may contract with a third party to maintain drug product tracing information on their behalf.<sup>18</sup> Dispensers must capture and maintain this information so they can retrieve it in the event of a recall or for the purposes of investigating a suspect or illegitimate drug product.

<sup>9</sup> These transactions are not subject to DSCSA drug product tracing requirements when dispensers sell drugs to another dispenser to fulfill a specific patient need. § 582(d)(1)(A)(ii) of the FD&C Act.

<sup>10</sup> § 582(d)(1) of the FD&C Act.

<sup>11</sup> § 581(13) of the FD&C Act. The definition of product is limited by exemptions listed in Appendix A.

<sup>12</sup> § 581(24)(A) of the FD&C Act.

<sup>13</sup> § 581(26) of the FD&C Act.

<sup>14</sup> Drugs are identified using a unique, three-segment number called NDC, which serves as a universal product identifier for drugs. Definition available at <http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm>.

<sup>15</sup> § 581(25) of the FD&C Act.

<sup>16</sup> § 581(27) of the FD&C Act.

<sup>17</sup> § 582(d)(1)(A)(iii) of the FD&C Act.

<sup>18</sup> § 582(d)(1)(B) of the FD&C Act.

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Upon a request by FDA or other appropriate Federal or State officials, dispensers generally must provide the drug product tracing information within 2 business days.<sup>19</sup> The DSCSA does not require dispensers to capture and maintain drug product tracing information using any specific system or process.

### FDA Guidance on Exchanging Drug Product Tracing Information

FDA guidance outlines general parameters for the interoperable exchange of drug product tracing information but does not require that trading partners exchange drug product tracing information in the same way.<sup>20</sup> Instead, the guidance provides trading partners with latitude to choose how they exchange information. For example, trading partners may exchange drug product tracing information using any transmission mode, including electronic data interchange advance ship notices (EDI/ASN), web portals, and paper. In addition, trading partners may exchange information in any format, including product tracing forms, packing slips, and invoices.

FDA twice delayed enforcement of drug product tracing requirements for dispensers—ultimately postponing action against dispensers that did not comply with DSCSA until March 1, 2016. Most recently, FDA announced that it did not intend to take action against dispensers who, prior to March 1, 2016, accepted ownership of a drug product without receiving tracing information.<sup>21</sup> This delay was in response to smaller, independent dispensers' concerns that they need additional time to work with trading partners to ensure they can capture and maintain the required drug product tracing information.<sup>22</sup>

FDA also has communicated with trading partners, including dispensers, about DSCSA requirements by hosting events and presenting at professional conferences. For example, FDA held a public meeting to provide information to and gather information from trading partners about efforts to implement DSCSA requirements. FDA also held a webinar focused on guidance for identification and notification of suspect drug product.<sup>23</sup>

## Methodology

This study reviewed a nonrepresentative selection of 40 dispensers of varying size and type. The 40 were composed of 15 small independent retail pharmacies; 15 large chain retail pharmacies; 5 small inpatient hospital

<sup>19</sup> § 582(d)(1)(D) of the FD&C Act.

<sup>20</sup> FDA, *DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information Draft Guidance*, November 2014.

<sup>21</sup> FDA, *DSCSA Implementation: Product Tracing Requirements for Dispensers – Compliance Policy Guidance for Industry Revised October 2015*. Accessed at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM453225.pdf> on June 14, 2017.

<sup>22</sup> Ibid.

<sup>23</sup> FDA, *Guidance for Industry Drug Supply Chain Security Act (DSCSA) Implementation: Identification of Suspect Product and Notification*, webinar held December 2016.

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pharmacies; and 5 large inpatient hospitals. We used the National Council for Prescription Drug Program's (NCPDP's) definitions of "independent" pharmacies as dispensers with one to three locations and "chain" pharmacies as dispensers with four or more locations. We designated inpatient hospital dispensers as small or large on the basis of the hospital bed count. For more detail about the sample selection, see Appendix B.

To address our objective, we first requested that dispensers submit examples of drug product tracing information provided to them by their trading partners. Next, we conducted phone interviews with dispensers to ask about the drug product tracing information and about their implementation of the drug product tracing requirements. For chain retail pharmacies and inpatient hospitals, we interviewed staff who were primarily pharmacy directors. For independent retail pharmacies, we interviewed owners or presidents.

We collected this information between December 2016 and February 2017. We conducted our data collection in this timeframe—9 months after FDA began enforcing the dispenser drug product tracing requirements—to give dispensers time to implement and comply with the provisions.

We focused on dispensers' *receipt* of drug product tracing information because this most represents their role at the end of the drug supply chain. During interviews, OIG determined that only one of the 40 selected dispensers sold drug products to other dispensers. We did not include this exchange in our analysis of drug product tracing information.

### Limitations

We based our findings on dispensers' self-reported information from interviews and on examples of drug product tracing information that the dispensers provided. We did not independently verify the responses. Our findings represent only the 40 selected dispensers and cannot be projected to the whole population of dispensers.

## Standards

This study was conducted in accordance with the Quality Standards for Inspection and Evaluation issued by the Council of the Inspectors General on Integrity and Efficiency.



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# FINDINGS

## **All selected dispensers received drug product tracing information, and nearly two-thirds received everything required**

All 40 selected dispensers reported they received at least some drug product tracing information from their trading partners as required by DSCSA, and, of these, 26 dispensers received all required elements (i.e., transaction information, transaction history, and transaction statements). As the last partner in the supply chain, dispensers primarily receive drug product tracing information from wholesalers and manufacturers.

### **Of the 40 dispensers, 14 did not receive all required drug product tracing information**

Fourteen dispensers did not receive one or more required elements of drug product tracing information. DSCSA requires that dispensers receive complete drug product tracing information prior to accepting ownership of a drug product.<sup>24</sup> FDA guidance notes that missing drug product tracing information may be an indication that the drug product is suspect or illegitimate, significantly increases the risk of a suspect product entering the supply chain, and warrants heightened scrutiny.<sup>25</sup> Exhibit 2 (on the next page) shows which drug product tracing information each dispenser was missing.

The 14 dispensers that were missing drug product tracing information included 6 independent, 5 chain, and 3 hospital pharmacies. Two of these fourteen dispensers were independent dispensers that reported not knowing about DSCSA and not being aware of drug product tracing requirements. The invoices they received contained some drug product tracing information.

<sup>24</sup> § 582(d)(1)(A)(i) of the FD&C Act.

<sup>25</sup> FDA, *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry*, December 2016, p. 5. Accessed at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM400470.pdf> on June 15, 2017.

**Exhibit 2: Fourteen Dispensers Were Missing Elements of Drug Product Tracing Information**

Dispenser	Type/Size of Pharmacy	Drug Product Tracing Information				
		Transaction Information			Transaction Statement	Transaction History
		Strength	Dosage Form	Transaction Date		
1	Independent					Missing
2	Independent	Missing				
3*	Independent				Missing	
4	Independent	Missing	Missing			
5	Independent		Missing			
6*	Independent				Missing	
7	Chain			Missing	Missing	
8	Chain				Missing	
9	Chain			Missing		
10	Chain	Missing				
11	Chain				Missing	
12	Hospital/Small		Missing			
13	Hospital/Large		Missing		Missing	
14	Hospital/Large		Missing			
Total dispensers missing information		9			6	1

Source: OIG analysis of dispenser interview notes and product tracing examples, 2017.

\* Dispensers that were unaware of DSCSA drug product tracing requirements.

Nine dispensers were missing one or more elements of transaction information. Dosage form was the most common element of the transaction information that was missing. Dispensers gave some explanations for missing dosage form, noting that the dosage form may be included in the drug product name (e.g., Spiriva HandiHaler, which is an inhaler) or that they can determine the dosage form by looking up information associated with the NDC. Although the NDC is one way to determine the dosage form, the DSCSA requires that the transaction information include both the NDC and dosage form.

Six dispensers were missing a transaction statement, which indicates the seller adhered to the DSCSA and that it, among other things, received transaction information and a transaction statement from the drug product’s prior owner.<sup>26</sup>

**Of the 40 dispensers, 25 do not review drug product tracing information, and they may not be aware of missing information** Twenty-five selected dispensers reported that they never review the drug product tracing information they receive. Of these, 13 dispensers were

<sup>26</sup> § 581(27) of the FD&C Act.

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missing drug product tracing information and 12 had complete drug product tracing information. Although the DSCSA does not explicitly require dispensers to review drug product tracing information, the law prohibits dispensers from accepting ownership of a drug product without having received drug product tracing information prior to, or at the time of, the transaction.<sup>27</sup> Unless dispensers review the drug product tracing information they receive, they cannot know if any information is missing or whether the transaction complies with the DSCSA.

Four dispensers in this study reported that they always review drug product tracing information; these dispensers had complete drug product tracing information. Reviewing drug product tracing information gives dispensers an opportunity to see if information is missing and take additional steps to investigate if necessary. Reviewing drug product tracing information also should help dispensers identify suspect drug products for possible quarantine and investigation and protect public health and safety by decreasing the risk of a dangerous drug product entering the supply chain.

## **Dispensers received drug product tracing information in a variety of ways**

Dispensers in this study received drug product tracing information in a variety of transmission modes and formats—meaning they received drug product tracing information through, for example, paper invoices, packing slips, emails, and web portals. This variety is a result of dispensers and their trading partners using different systems rather than adopting a standardized way to exchange this information. Neither the DSCSA nor FDA’s guidance require the exchange of drug product tracing information in the same way. Drug product tracing information was missing from information transmitted using paper and web portals and among all formats used by dispensers in this study.

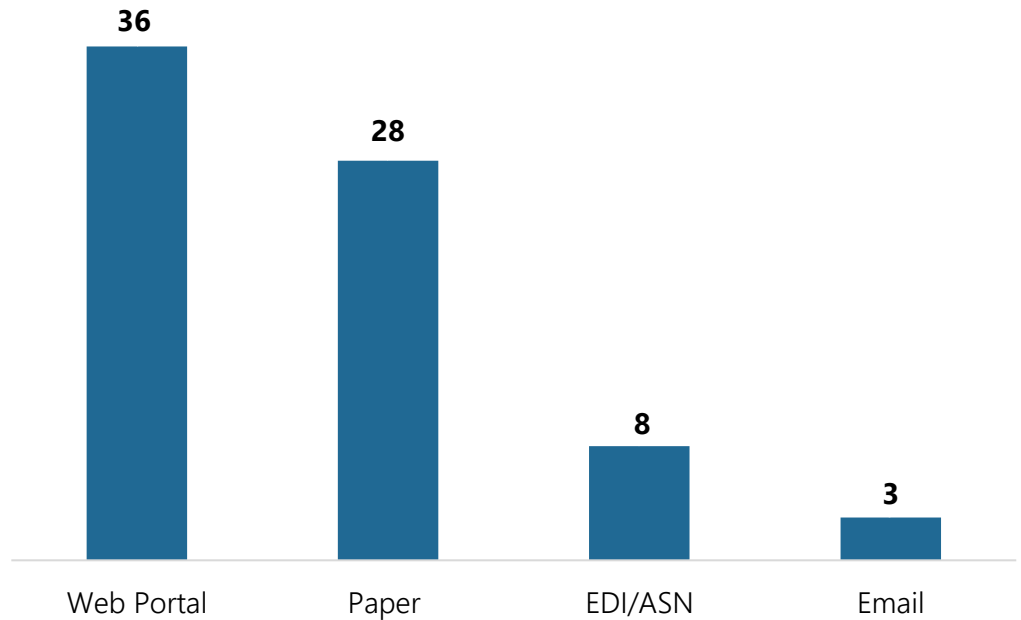
### **Dispensers received drug product tracing information using four different transmission modes: web portals, paper, EDI/ASN, and email**

Dispensers reported receiving drug product tracing information using four different transmission modes—with more than half of dispensers using multiple modes. The mode refers to the manner in which drug product tracing information is transmitted. Exhibit 3 (on the next page) illustrates the modes that the 40 dispensers in this study used to receive drug product tracing information.

<sup>27</sup> § 582(d)(1)(A)(i) of the FD&C Act.

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### Exhibit 3: Dispensers Received Drug Product Tracing Information Using a Variety of Transmission Modes



Source: OIG dispenser interviews and drug product tracing examples, 2017.

Note: Numbers do not add to 40 because dispensers received drug product tracing information in multiple modes.

Web portals are the most common transmission mode reported by dispensers in this study. Dispensers primarily received drug product tracing information through web portals. Wholesalers provide drug product tracing information through the same web portal system that dispensers use to place drug orders. Because they use an existing system, wholesalers and dispensers do not need to have new software to exchange this information.<sup>28</sup>

Paper is the second most common transmission mode reported by dispensers in this study. Paper was most commonly used for drug products shipped directly from manufacturers.

Eight selected dispensers received drug product tracing information through EDI/ASN. These dispensers are chain pharmacies, and one is a large hospital. EDI/ASN is a set of standardized, structured fields used to electronically communicate the contents of a shipment to a customer.<sup>29</sup> No independent pharmacies or small hospitals reported using EDI/ASN, and many were unaware of the technology.

<sup>28</sup> OIG, *Drug Supply Chain Security: Wholesalers Exchanging Most Tracing Information*, OEI-05-14-00640, September 2017.

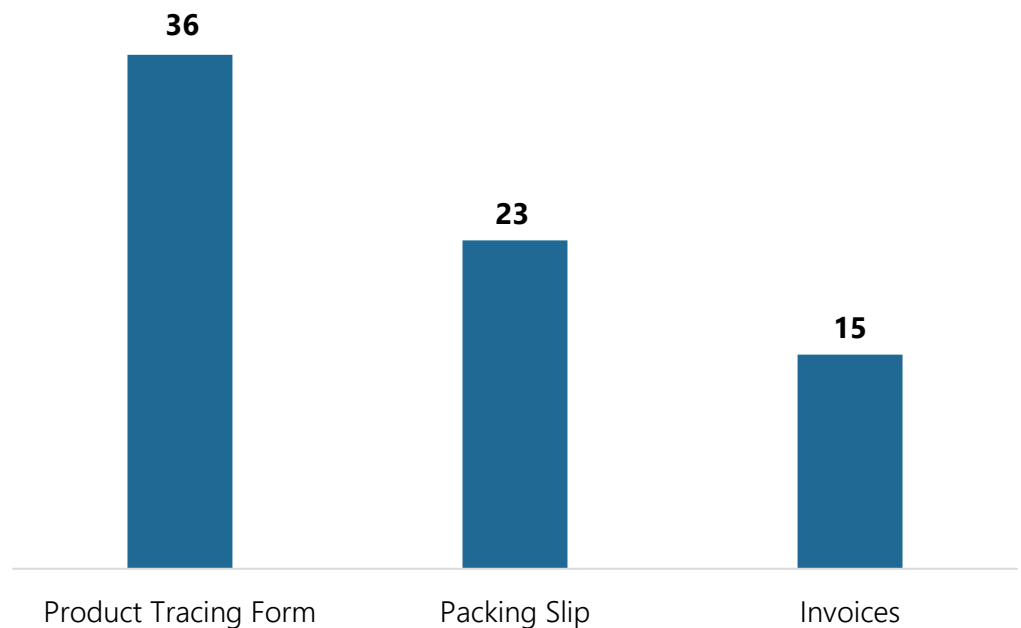
<sup>29</sup> 1EDISource, EDI 856 Overview. Accessed at <http://www.1edisource.com/transaction-sets?tset=856> on May 9, 2017.

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### Dispensers received drug product tracing information in three different formats: product tracing forms, packing slips, and invoices

Dispensers reported receiving drug product tracing information in three formats—with more than half receiving multiple formats. The format refers to the way in which drug product tracing information is organized and presented. Exhibit 4 illustrates the prevalence of each format in which the 40 dispensers in this study received drug product tracing information.

#### **Exhibit 4: Dispensers Received Drug Product Tracing Information in a Variety of Formats**



Source: OIG dispenser interviews and drug product tracing examples, 2017.

Note: Numbers do not add to 40 because dispensers received drug product tracing information in multiple formats.

Dispensers in this study most commonly received drug product tracing information on product tracing forms. Product tracing forms are designed specifically to capture and clearly represent drug product tracing information. See Appendix C for an example of a product tracing form.

Dispensers also reported that they received drug product tracing information on packing slips and invoices. Packing slips detail the contents of shipments. Packing slips were most commonly provided with drug products shipped directly from manufacturers. Invoices include information about the drug products being received and the prices charged for those drug products. Packing slips and invoices can be modified so they include all necessary elements of drug product tracing information. See Appendices D and E, respectively, for examples of a packing slip and invoice.

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**Nearly all dispensers have a system to capture and maintain drug product tracing information and reported they can retrieve it within 2 business days of a request**

Nearly all dispensers reported that they capture and maintain drug product tracing information and can retrieve information within 2 business days of a request. DSCSA requires dispensers to capture and maintain drug product tracing information for at least 6 years and provide it generally within 2 days of a request by FDA or other appropriate Federal or State official.<sup>30, 31</sup> The two independent dispensers unaware of the DSCSA drug product tracing requirements are not actively capturing or maintaining the information and would be unable to independently retrieve it.

Thirty-eight dispensers capture and maintain drug product tracing information on web portals, paper storage, or computer servers. About half of dispensers capture and maintain the information using multiple storage systems. Independent dispensers stated that they rely on their suppliers to capture and maintain drug product tracing information on web portals because they do not have the resources—time, staff, or money—to create and maintain their own storage systems.

The same 38 dispensers reported that they should be able to provide drug product tracing information within 2 business days of a request. Although none of these dispensers have been asked to retrieve the information by FDA or another Federal or State official, most reported that they do not anticipate problems retrieving it because the information is primarily maintained on web portals.

<sup>30</sup> § 582(d)(1)(A)(iii) of the FD&C Act.

<sup>31</sup> § 582(d)(1)(D) of the FD&C Act.

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# CONCLUSION AND RECOMMENDATION

We found that all selected dispensers received drug product tracing information, and nearly two-thirds received all required information. Dispensers received this information in a variety of ways. Further, nearly all dispensers had a way to capture, maintain, and retrieve information.

Although our results show that, on the whole, selected dispensers are moving toward full implementation of drug product tracing requirements, some concerns exist. In particular, a third of dispensers were missing some required information, and two independent dispensers were unaware of DSCSA and the drug product tracing requirements. These results raise concerns that complete drug product tracing information may not always be available to help facilitate a recall or support an investigation by FDA or another agency into suspect and illegitimate drug products in the supply chain. Ultimately, dispensers' receipt and review of complete drug product tracing information can help ensure the security of the drug supply chain and protect patients from harmful drugs that have entered.

This study is the second in a series examining drug supply chain security and the implementation of the DSCSA. In previous work, we determined that all selected wholesalers exchanged drug product tracing information, and about half exchanged all required elements. Building on the results of these studies, future OIG work will determine the extent to which drug product tracing information can be used to trace drugs through the entire supply chain.

For this study, we recommend that FDA provide educational outreach to facilitate dispensers' compliance with the DSCSA. Specifically, we recommend that FDA should:

## **Provide educational outreach to dispensers about DSCSA requirements for receiving drug product tracing information**

FDA should provide educational outreach to dispensers to make sure they are aware of their responsibilities to receive complete drug product tracing information from suppliers prior to, or at the time of, taking ownership. FDA also should consider providing specific educational outreach to independent pharmacies, which may have limited resources for legal advising or other education. The two dispensers in this study that were unaware of DSCSA were independent pharmacies. For instance, FDA could provide additional outreach by holding a webinar, creating a frequently asked questions document, or speaking at a dispenser conference.

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# AGENCY COMMENTS AND OIG RESPONSE

FDA concurred with our recommendation.

FDA intends to review its dispenser communications plan and identify and create opportunities to work with dispenser-centric trade and professional organizations to provide additional education and outreach. FDA also noted that, as the last trading partner in the supply chain before a drug product is dispensed to a patient, dispensers play a vital role in ensuring patient safety; therefore, it is essential that dispensers understand their product tracing responsibilities under DSCSA.

For the full text of FDA's response, see Appendix F.



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# APPENDIX A: DSCSA Definitions

## Transaction (§ 581(24) of the FD&C Act)

Transaction—

(A) In General.—The term “transaction” means the transfer of product between persons in which a change of ownership occurs.

(B) Exemptions.—The term “transaction” does not include—

- (i) intracompany distribution of any product between members of an affiliate or within a manufacturer;
- (ii) the distribution of a product among hospitals or other health care entities that are under common control;
- (iii) the distribution of a product for emergency medical reasons including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;
- (iv) the dispensing of a product pursuant to a prescription executed in accordance with section 503(b)(1);
- (v) the distribution of product samples by a manufacturer or a licensed wholesale distributor in accordance with section 503(d);
- (vi) the distribution of blood or blood components intended for transfusion;
- (vii) the distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use;
- (viii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1986 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
- (ix) the distribution of a product pursuant to the sale or merger of a pharmacy or pharmacies or a wholesale distributor or wholesale distributors, except that any records required to be maintained for the product shall be transferred to the new owner of the pharmacy or pharmacies or wholesale distributor or wholesale distributors;
- (x) the dispensing of a product approved under section 512(c);
- (xi) products transferred to or from any facility that is licensed by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021);

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(xii) a combination product that is not subject to approval under section 505 or licensure under section 351 of the Public Health Service Act, and that is—

(I) a product comprised of a device and 1 or more other regulated components (such as a drug/device, biologic/device, or drug/device/biologic) that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

(II) 2 or more separate products packaged together in a single package or as a unit and comprised of a drug and device or device and biological product; or

(III) 2 or more finished medical devices plus one or more drug or biological products that are packaged together in what is referred to as a 'medical convenience kit' as described in clause (xiii);

(xiii) the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this clause as a 'medical convenience kit') if—

(I) the medical convenience kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with section 510(b)(2);

(II) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970;

(III) in the case of a medical convenience kit that includes a product, the person that manufactures the kit—

(aa) purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

(bb) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

(IV) in the case of a medical convenience kit that includes a product, the product is—

(aa) an intravenous solution intended for the replenishment of fluids and electrolytes;

(bb) a product intended to maintain the equilibrium of water and minerals in the body;

(cc) a product intended for irrigation or reconstitution;

(dd) an anesthetic;

(ee) an anticoagulant;

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(ff) a vasopressor; or

(gg) a sympathomimetic;

(xiv) the distribution of an intravenous product that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

(xv) the distribution of an intravenous product used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

(xvi) the distribution of a product that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

(xvii) the distribution of a medical gas (as defined in section 575); or

(xviii) the distribution or sale of any licensed product under section 351 of the Public Health Service Act that meets the definition of a device under section 201(h).

### Transaction history (§ 581(25) of the FD&C Act)

The term “transaction history” means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

### Transaction information (§ 581(26) of the FD&C Act)

The term “transaction information” means—

(A) the proprietary or established name or names of the product;

(B) the strength and dosage form of the product;

(C) the National Drug Code of the product;

(D) the container size;

(E) the number of containers;

(F) the lot number of the product;

(G) the date of the transaction;

(H) the date of the shipment, if more than 24 hours after the date of the transaction;

(I) the business name and address of the person from whom ownership is being transferred; and

(J) the business name and address of the person to whom ownership is being transferred.

### Transaction statement (§ 581(27) of the FD&C Act)

The “transaction statement” is a statement, in paper or electronic form, that the entity transferring ownership in a transaction—

- 
- (A) is authorized as required under DSCSA;
  - (B) received the product from a person that is authorized as required under the DSCSA;
  - (C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;
  - (D) did not knowingly ship a suspect or illegitimate product;
  - (E) had systems and processes in place to comply with verification requirements under section 582;
  - (F) did not knowingly provide false transaction information; and
  - (G) did not knowingly alter the transaction history.

#### Product (§ 581(13) of the FD&C Act)

The term "product" means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution), but for purposes of section 582, does not include blood or blood components intended for transfusion, radioactive drugs or radioactive biological products (as defined in section 600.3(ee) of title 21, Code of Federal Regulations) that are regulated by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021), imaging drugs, an intravenous product described in clause (xiv), (xv), or (xvi) of paragraph (24)(B), any medical gas (as defined in section 575), homeopathic drugs marketed in accordance with applicable guidance under this Act, or a drug compounded in compliance with section 503A or 503B.

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# APPENDIX B: Detailed Methodology

## Sample Selection

We selected our nonrepresentative, random sample of dispensers from two Centers for Medicare & Medicaid Services sources: Prescription Drug Event (PDE) data and Provider of Services (POS) data.<sup>32</sup> We used PDE data from August 2016 to select retail pharmacies. We used POS data from September 2016 to select hospital pharmacies. To address variations in practices dependent on size of the business, we first categorized each retail pharmacy as independent or chain and each hospital pharmacy as small or large.

*Retail Pharmacies.* To select our random sample of retail pharmacies, we identified dispensers with dates of service between July 2015 and June 2016 to ensure we were selecting active dispensers. We then categorized dispensers using the “independent” and “chain” type codes in NCPDP’s Pharmacy Database File. Independent pharmacies included dispensers with one to three locations operating under common ownership. Chain pharmacies included dispensers with four or more locations operating under common ownership. To obtain dispenser contact information, we used the NCPDP Pharmacy Database File and matched dispensers using their National Provider Identifier from PDE data. NCPDP’s Pharmacy Database File contains information about provider types, provider address, and ownership and affiliation information, among others. We did not include in our sample specific types of dispensers that are not subject to DSCSA drug product tracing requirements, such as compounding pharmacies, which primarily handle exempt products.

*Hospital Pharmacies.* To select our random sample of hospital pharmacies, we selected only hospitals with an active provider status. We categorized hospitals as small or large on the basis of the number of beds reported in POS data. We removed hospitals that reported having zero beds. The median number of beds was 84, so we defined the small group as those with 84 or fewer beds and the large group as those with more than 84 beds.

Exhibit 5, on the next page, describes the number and type of dispensers in our final sample.

<sup>32</sup> Provider of Services data contains characteristics of hospitals, including the facility’s name and address, number of beds, and the type of Medicare services provided.

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**Exhibit 5: Dispenser Sample**

Dispenser Size	Data Source	Sample Size
Small retail pharmacies (i.e., independent pharmacies)	PDE	15
Large retail pharmacies (i.e., chain pharmacies)	PDE	15
Small, inpatient hospital pharmacies	POS	5
Large, inpatient hospital pharmacies	POS	5
Total		40

Source: OIG analysis and sampling of PDE and POS data sources, 2016.

# APPENDIX C: Product Tracing Form

Dispenser's Name

## DSCSA Transaction Data

The Transaction Data in this report is only for Drug Supply Chain Security Act (DSCSA) products.

<b>From:</b>	<b>To:</b>	<b>Transaction Data For:</b>	<b>Transaction Information (TI)</b>
Wholesaler Name & Address	Dispenser Name & Address	Order Number: 371922 Invoice Date: 2/15/2017 Invoice Number: Ship Date: 2/15/2017	

## DSCSA Transaction Details

Transaction History (TH)

Item #	NDC	Description	Quantity	Lot #	Exp Date
050165	68462050165	Calcipotriene 0.005 % CREA (60)	1	Lot #	10/18

Previous Owner Name	Previous Owner Address	PO #	Purchase Date
		P12707092	1/25/2017
			1/12/2017
			1/12/2017

089421	00003089421	Eliquis 5 MG TABS (60)	1	Lot #	09/19
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Previous Owner Name	Previous Owner Address	PO #	Purchase Date
		P42947228	2/8/2017
			2/6/2017

027110	43547027110	ROPINIRole HCl 2 MG TABS (100)	3	Lot #	05/18
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Previous Owner Name	Previous Owner Address	PO #	Purchase Date
		P32240789	11/18/2016

070713	47335070713	Topiramate 25 MG TABS (500)	1	Lot #	04/19
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Previous Owner Name	Previous Owner Address	PO #	Purchase Date
		P37999885	2/9/2017

	<b>Transaction Statement (TS)</b>
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# APPENDIX D: Packing Slip

01/26/2017 15:28 FAX [Redacted] 0002/0002

**Manufacturer** [Redacted] **Transaction History (TH)** **Packing List** **Manufacturer** [Redacted]

PrintDate: 08/25/2016  
PrintTime: 17:10:14  
Page: 1 of 1

**Ship To:** [Redacted] **Shipped From:** [Redacted]  
**Dispenser's Name & Address** **Manufacturer's Name & Address**

**Bill To:** [Redacted] **PURCHASED FROM:** [Redacted]  
**Dispenser's Name & Address** **Manufacturer's Name & Address**

**Transaction Information (TI)**

Anticipated Transaction Date: 09/02/2016

Customer#	Customer PO#	Order#	Delivery#	Package
[Redacted]	[Redacted]	11645373	[Redacted]	1 of 1
Ship Method	Pick Ticket#	Group#	Print Date	CSEG/ASN
1 DAY FEDEX PRIOR-AIR 10:	2029914	3000229503 / 1826606	08/25/2016	601/
DEA License	OOP#	HU#	Patient ID	Service
[Redacted]	[Redacted]	1007408033	[Redacted]	[Redacted]

Product # /NDC /UPC	Lot # Expiry Date	Quantity	Bin/ Section Zone	Serv.	Description
399-65 49281039965	[Redacted] Lot # 04/09/2017	3 EA	PACK AREA T10		Fluzone HD 16-17 180 mcg/0.5mL SUS SYR 1
	Total Quantity:	3 EA			

**Transaction Information (TI)**

**Transaction Statement (TS)**

Transaction Statement: **Manufacturer** [Redacted] has complied with each applicable subsection of FDCA Sec. 501(27)(A)-(G). Complete Transaction History (TH) information is available at shipment from customer service at [Redacted]. For information, inquiries, or to order please call [Redacted] 8:30AM-6PM (EST) M-F, or visit us at [Redacted]. [Redacted] has complied with each applicable subsection of FDCA Sec. 501(27)(A)-(G).



# APPENDIX E: Invoice

**Wholesaler's Name & Address**

[Redacted]

**SOLD TO:** 97909

**Dispenser's Name**

[Redacted]

**Transaction Information (TI)**

**Transaction Information (TI)**

BOXES: 1

INVOICE NO. [Redacted]

DEFAULT / 97116

Permit Number [Redacted]

Permit Number [Redacted]

029276

1/31/18

10am-12pm

Order No.	Purchase Order No.	Ord. Date	DEA No.	Exp. Date	SLMN	Terms	Inv. Date	Due Date
35045781	122716	12/27/16		2/28/18	722	NET 10/ECM	12/27/16	2/10/17

Qty.	Item No.	Description	Size	FM	Compare To	Price	Ext. Amount
1	307321	PRAVASTATIN SODIUM 20MG	90	TB	PRAVACHOL 20MG (Tbac)	[Redacted]	[Redacted]
Mfg: [Redacted]							
1	325596	VALACYCLOVIR HCL 500MG	30	TB	VALTREX 500MG (Citr)	[Redacted]	[Redacted]
Mfg: [Redacted]							
NDC# 57237-0042-30 *CONTRACTED PRICE							

Tracking Numbers: [Redacted]

# LINES: 14 TOTAL AWP: [Redacted] TOTAL GOODS: [Redacted]

1, 2, 2N, 3, 3N, 4, 5 NEXT TO THE ITEM NUMBER DENOTES THAT THE PRODUCT IS A SCHEDULE (I, II, III, IV, V) DRUG THIS WHOLESALE DISTRIBUTOR, OR A MEMBER OF ITS AFFILIATED GROUP, PURCHASED THE PRODUCT DIRECTLY FROM THE MANUFACTURER, EXCLUSIVE DISTRIBUTOR, OR A REPACKAGER THAT PURCHASED DIRECTLY FROM THE MANUFACTURER.

**THIS WHOLESALE DISTRIBUTOR HAS COMPLIED WITH EACH APPLICABLE SUBSECTION OF FDCA SEC. 501(27) (A) - (G).**

PLEASE MAKE CHECKS PAYABLE TO:

[Redacted]

PAGE 2 OF 2

FULFILLED BY: [Redacted]

[Redacted]

[Redacted]

Please Pay This Amount By Due Date → [Redacted] 2/10/17.

# APPENDIX F: Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
10903 New Hampshire Ave  
Silver Spring, MD 20993

**DATE:** December 29, 2017  
**TO:** Daniel R. Levinson, Inspector General  
**FROM:** Deputy Associate Commissioner for Public Health Strategy and Analysis  
**SUBJECT:** Food and Drug Administration's General Comments to OIG Draft Report: *Drug Supply Chain Security: Dispensers Received Most Tracing Information*

Enclosed are the Food and Drug Administration's general comments to the Office of Inspector General's OIG Draft Report: *Drug Supply Chain Security: Dispensers Received Most Tracing Information*.

We appreciate the opportunity to review and comment on this draft report prior to publication.

A handwritten signature in black ink, appearing to read "Lisa Rovin".

Lisa Rovin, J.D.  
Deputy Associate Commissioner for Public Health  
Strategy and Analysis

Attachment

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**FDA's General Comments to OIG Draft Report**

**Drug Supply Chain Security: Dispensers Received Most Tracing Information  
OEI-05-16-00550**

FDA appreciates the opportunity to review and comment on OIG's draft report. We are committed to protecting public health and the quality and authenticity of prescription drug products through rigorous oversight of the drug distribution system. FDA works with stakeholders to ensure effective implementation of the product tracing requirements of the Drug Supply Chain Security Act (Title II of Public Law 113-54). The Agency's response to OIG's recommendation is below.

**Provide education to dispensers about their responsibilities regarding product tracing.**

FDA appreciates the insight from OIG related to dispensers' exchange of product tracing information and concurs with this recommendation. FDA recognizes that dispensers include the largest percentage of trading partners in the drug distribution system. As the last trading partner in the supply chain to see a drug product before it is dispensed to a patient, dispensers play a vital role in ensuring patient safety. It is thus essential that dispensers understand their product tracing responsibilities under the DSCSA.

As OIG noted in its report, FDA has conducted coordinated outreach to dispensers through stakeholder meetings, webinars, guidances, website information, and speaking at national and regional dispenser meetings. FDA will review its dispenser communications plan and identify and create opportunities to work with dispenser-centric trade and professional organizations to provide additional education and outreach.

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# ACKNOWLEDGMENTS

Melissa Baker served as the team leader for this study. Others in the Office of Evaluation and Inspections who conducted the study include Kayla Phelps and Sarah Vogel. Office of Evaluation and Inspections staff who provided support include Althea Hosein, Seta Hovagimian, and Meghan Kearns.

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This report was prepared under the direction of Thomas F. Komaniecki, Regional Inspector General for Evaluation and Inspections in the Chicago regional office, and Laura Kordish and Kelly Waldhoff, Deputy Regional Inspectors General.

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