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Drug Supply Chain Security Act: Compliance for Dispensers

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This article is the interpretation and opinion of the authors. Compliance methods therein are suggestions based on the authors' experiences and are meant to assist pharmacies in achieving compliance. These methods have not been evaluated by FDA; alternative methods may also be acceptable.

Goal. The goal of this lesson is to provide an overview of pharmacy's role in the Drug Supply Chain Security Act, including compliance steps and tips for dispensers.

Objectives. At the completion of this activity, the participant will be able to:

1. relate the purpose of the Drug Supply Chain Security Act (DSCSA) and pharmacy's role;
2. recognize significant implementation timelines for dispensers;
3. list compliance steps and tips for dispensers;
4. identify drug products and scenarios that are excluded from the DSCSA requirements; and
5. demonstrate an understanding of how to detect and report suspect or illegitimate products in the supply chain as required by the DSCSA.

Background

Imagine that you or someone you love is being treated for a life-threatening, but treatable, condition. The best possible care team is in place and the most effective treatments are being administered. The condition is not improving and seems to be getting progressively worse. The care team is puzzled by the lack of effectiveness of the treatments. While preparing the next dose of medication, a pharmacy technician notices the label on the vial of medication looks different than usual. She shows it to a pharmacist who then inspects the rest of the stock of that medication. The pharmacist notes differences in font size, color, and misspellings on some of the vials. A MedWatch form is submitted to FDA and the medication is sent out to be analyzed. It is determined that only a fraction of the active ingredient is present, and the product is contaminated with bacteria.

Although the pharmaceutical supply in the United States is one of the safest in the world, there are numerous reports on the FDA website of counterfeit drug products circulating in the U.S. market, and scenarios much like the one above have occurred. Medications such as Avastin®, Procrit®, Viagra®, Lipitor®, and most recently, Botox®, have been counterfeited, distributed, dispensed, and administered in our country and have harmed patients or delayed healing. Counterfeit drugs may be contaminated or contain the wrong or no active ingredient. They could have the right active ingredient but at the wrong dose.

FDA has responded to this threat, and the Drug Quality and Security Act (DQSA) was signed into law by President Obama on November 27, 2013. Title II of the DQSA, the Drug Supply Chain Security Act, outlines critical steps to build an electronic, interoperable system to identify and trace *certain prescription drugs* as they are distributed in the United States.

The DSCSA is being phased in and, 10 years after enactment, the system will facilitate the exchange of information at the individual package level about where a drug has been in the supply chain. The new system will:

- enable verification of the legitimacy of the drug product identifier down to the package level;
- enhance detection and notification of illegitimate products in the drug supply chain; and
- facilitate more efficient recalls of drug products.

There are six key provisions to the law that are to be implemented over the next 10 years, and they include:

- Product Identification. Manufacturers and repackagers to put a unique product identifier on certain prescription drug packages, for example, using a bar code that can be easily read electronically.
- Product Tracing. Manufacturers, wholesale drug distributors, repackagers, and many dispensers (primarily pharmacies) in the drug supply chain to provide information about a drug and who handled it each time it is sold in the U.S. market.
- Product Verification. Manu-

facturers, wholesale drug distributors, repackagers, and many dispensers (primarily pharmacies) to establish systems and processes to be able to verify the product identifier on certain prescription drug packages.

• Detection and Response. Manufacturers, wholesale drug distributors, repackagers, and many dispensers (primarily pharmacies) to quarantine and promptly investigate a drug that has been identified as suspect, meaning that it may be counterfeit, unapproved, or potentially dangerous.

• Notification. Manufacturers, wholesale drug distributors, repackagers, and many dispensers (primarily pharmacies) to establish systems and processes to notify FDA and other stakeholders if an illegitimate drug is found.

• Wholesaler Licensing. Wholesale drug distributors to report their licensing status and contact information to FDA. This information will then be made available in a public database.

Dispensers

The DSCSA has specific requirements for dispensers and defines the term *dispenser* to mean:

> (A) a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor; and
>
> (B) does not include a person who dispenses only products to be used in animals.

Because your pharmacy is considered a dispenser in the U.S. drug supply chain, you need to know all points where *certain prescription drugs* were before they reached your pharmacy, and then you need to continue that chain of information when you supply *certain prescription drugs* to other pharmacies, physician offices, or other locations that will ultimately dispense or administer those drugs to patients.

What is meant by *certain prescription drugs*?

The DSCSA does not apply to all drug products and all types of drug transactions. Some exclusions are:

• Blood or blood components for transfusion;
• Radioactive drugs or radioactive biological products;
• Imaging drugs;
• Medical gases;
• Compounded drugs;
• Dialysis solutions;
• Irrigation solutions;
• Sterile water (irrigation or injectable);
• IV products intended for replenishment of fluids and electrolytes (sodium, chloride, potassium, etc.) or calories (dextrose, amino acids, lipids);
• Combination kits or trays that do not include a controlled substance, i.e., first aid kits, suture kits;
• Drug samples;
• Minimal quantities of product from a licensed retail pharmacy to a licensed practitioner for office use;
• Distribution between facilities under common ownership;
• Distribution to another dispenser for a specific patient need;
• Dispensing or administering the product to the patient.

2015 Implementation Timeline for Dispensers

Beginning **January 1, 2015**, everyone in the drug supply chain must be authorized trading partners. This means manufacturers and repackagers must be registered with FDA, and wholesalers and dispensers (pharmacies) must have a state license.

Manufacturers and wholesale distributors must provide the subsequent owner with Transaction History, Transaction Information, and a Transaction Statement, in a single document in paper or electronic format. Enforcement was then delayed until **May 1, 2015**.

Also beginning **January 1**, **2015**, all members of the drug supply chain must have systems in place that enable them to identify suspect product, quarantine the product, and investigate the product to determine if the product is illegitimate (counterfeit). Illegitimate products must be reported to FDA.

Beginning **July 1, 2015,** dispensers (pharmacies) must receive the Transaction Information and Transaction History from the previous owner and maintain it on file for six years, (**enforcement delayed until November 1, 2015**). Dispensers (pharmacies) must also provide Transaction Information and Transaction History to another dispenser when acting as the supplier. It is important to note that the requirement to provide the Transaction Information and Transaction History when acting as a supplier has NOT been delayed, so you must be receiving and providing this information for any products you may be supplying.

Where should you begin?

Start by compiling a list of all of your drug suppliers. (See Figure 1.) This will likely consist of your wholesalers, manufacturer directs, local hospitals and other pharmacies. It may also consist of purchases you make through the Internet or "gray market," although these types of purchases are highly discouraged and are a main source for counterfeit drugs.

After you've created your list of suppliers, you need to verify their registrations or licensing. FDA registration information for manufacturers and repackagers may be located by going to http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm, type in the manufacturer's name, and you will see all FDA registered sites for that supplier and the expiration dates of their registration. You should print the page and keep it on file as proof

that you verified their registration. You may want to create a spreadsheet and/or a calendar reminder to re-verify and reprint with updated expiration dates when the registration is due for renewal.

For Wholesalers or Terminal Distributor (Pharmacy) Licenses, you will go to the state's license verification website and perform primary source verification just like you do for pharmacist and technician licenses. The license verification website for Ohio, for example, is https://license.ohio.gov/lookup/default.asp?division=96. Again, you will want to print the page, maintain it on file, and keep track of expiration dates, so you can verify they renewed their license. You may find that your Internet and "gray market" sources do not have a license in your state. If that is the case, you must not use them as a supplier.

After compiling your list of drug suppliers and performing validation of their licenses or registrations, you need to contact each of the suppliers to inquire how they will be providing the Transaction Information and History to you. You will find that each of your suppliers may be taking a different approach. They might be sending a paper packing slip, they may be emailing an Advanced Shipping Notice, they may be using a portal on their website, or they may be using a compliance partner that will house the information in a cloud-based system.

After determining how each of your suppliers will be providing you with Transaction Information and History, you will need to create several filing systems to maintain all the different types of Transaction Information and History that you will be receiving. These files must be maintained for at least six years. The file systems will also need to be easily searchable in the event of an FDA request for information. For example, if FDA comes to your pharmacy because they suspect a particular lot number of counterfeit Drug X passed through your pharmacy, how quickly could you produce the Transaction Information and History for that particular drug and lot number over the previous six years?

Figure 1: Compliance Steps

- Create a list of all drug suppliers (Wholesalers, Manufacturer Direct, Gray Market, Internet, local hospitals and pharmacies).
- Obtain current licensing/registration for each supplier.
  - Manufacturers and Repackagers – verify FDA registration information.
  - Perform primary source verification through your state's licensing board.
- Inquire about each supplier's expected process for providing you with the Transaction Information and History. Each supplier will likely have a different process. They may utilize:
  - Packing slips;
  - E-mailed shipping notifications (Advance Shipping Notices);
  - Supplier-owned online repository (written agreement required);
  - Online compliance partner (TraceLink, RxTrace, others) (written agreement required).
- Create and maintain a filing system to maintain the Transaction Information and History for six years.
- Create a list of those to whom you supply medications and determine processes to supply Transaction Information and History.
- Review, update, and implement your pharmacy's policies for drug procurement, receiving, and distribution to outside entities.

Some ways to maintain these files might include:

A to Z paper files in a filing cabinet: If you are being supplied with paper transaction information, you could label hanging files A to Z and file paper transaction information by drug name. This system would require you to make copies of the transaction information for each drug listed on the statement or invoice so each drug listed can be placed in its appropriate file.

File by supplier: If you feel you know which drugs you order from each supplier and would be able to locate the information requested by the FDA more easily in this format, this could be an option.

Scan to computer: You could scan the paper transaction information into a computer and create alphabetical files similar to the hanging files. Again, you would need to scan each statement or invoice for each drug listed.

Supplier portal: Some distributors, particularly wholesalers and repackagers, are sending the transaction information within their own platform where it can be stored and received electronically through their portal. If this is the case, you need to ask the supplier if they will be maintaining the information for the six year retention period, and also ask if you will continue to have access to the information if you should happen to change wholesalers.

Compliance partner: Many distributors, mainly manufacturers, wholesalers, and repackagers, are utilizing a compliance partner to send and store the transaction information in a cloud-based system.

In instances where the information will be sent via the supplier portal or through a compliance partner, you will need to maintain a written agreement on file for this service. The DSCSA states,

"Agreements with third parties. –A dispenser may enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party confidentially maintains the transaction information, transaction history, and transaction statements required to be maintained under this subsection on behalf of the dispenser. If a dispenser enters into such an agreement, the dispenser shall maintain a copy of the written agreement and shall not be relieved of the obligations of the dispenser under this subsection."

Figure 2

EXAMPLE DRUG TRANSFER/SALE

FROM:
Name _____
Address _____
City, State, ZIP _____
DEA # _____
required for CII-CV

SHIP TO:
Name _____
Address _____
City, State, ZIP _____
DEA # _____
required for CII-CV (DEA Form 222 required for CII transactions)

Order Date: _____ Ship Date: _____
Product Name, Strength and Dosage Form: _____
NDC Number: _____ Container Size: _____ Number of Containers: _____
Lot Number: _____ Expiration Date: _____

Transaction History Detail:

_____ Pharmacy/Hospital received this product from:

Previous Seller Name	Previous Seller Address	Invoice Number*	# of Containers*	Previous Transaction Date*	Previous Ship Date*

"above named supplier" received the product from:

Previous Seller Name	Previous Seller Address	Invoice Number*	# of Containers*	Previous Transaction Date*	Previous Ship Date*

"above named supplier" received the product from:

Previous Seller Name	Previous Seller Address	Invoice Number*	# of Containers*	Previous Transaction Date*	Previous Ship Date*

*Information not required if wholesaler received the product directly from the manufacturer, the exclusive distributor of the manufacturer or a repackager that purchased the product directly from the manufacturer.

Transaction History is not available/not required because:

☐This transaction is excluded from the DSCSA (circle reason):

- This product was obtained prior to July 1, 2015
- This product is being supplied to another dispenser for a *specific patient* need and will not be kept as stock
- Minimal quantities of product from a licensed retail pharmacy to a licensed practitioner for office use
- Distribution between facilities under common ownership
- Blood or blood components for transfusion
- Radioactive drugs or radioactive biological products
- Imaging drugs
- Medical gases
- Compounded drugs
- Dialysis solutions
- Irrigation solutions
- Sterile water (irrigation or injectable)
- Combination kits or trays that do not include a controlled substance, i.e., first aid kits, suture kits
- IV products intended for replenishment of fluids and electrolytes (sodium, chloride, potassium, etc.) or calories (dextrose, amino acids, lipids)
- Drug samples

Order Prepared By: _____
Order Received By: _____ Date_____

This transaction is DSCSA compliant

Maintain records for six (6) years

Source: Pharmacy Systems, Inc.

How will you send and maintain Transaction Information when acting as a supplier?

That depends on how you currently send paperwork with the products you supply outside facility ownership. If you currently send a handwritten or typed receipt or invoice, you will need to handwrite or type all the required transaction information and history on that paperwork. That will require you to access the Transaction Information and History from your filing system that was sent to you when you received the product so you can write the Transaction History and other required information. See "Example Drug Transfer/Sale" document above as a possible solution (Figure 2).

Eventually, you will need to begin exploring ways to provide this information electronically as this will be required by the end of the 10-year phase in period.

If you use your wholesaler's invoicing system, you can likely free text this information directly onto the invoice. You will want to explore this functionality as soon as possible.

Or, if you utilize a compliance partner, you may be able to create the required documentation within their system.

You will also want to be able to determine which drugs in your stock were purchased before and which drugs were purchased after July 1, 2015. For drugs purchased before July 1, 2015, you will be responsible for starting the Transaction Information at your location. You do not have to supply the information regarding all the previous owners of those drugs. An easy way to manage this is to utilize the stickers that come with your wholesaler purchases. These stickers should be placed on the corresponding drug during receipt and include the date received and invoice number. This also enables you to quickly locate the Transaction Information and History, so if you supply that drug to an outside party, you can easily identify that this is a drug for which you have Transaction History Information on file and that you need to provide that Transaction History Information when distributing the product. If stickers are not provided from your supplier, you can create your own that include the date received, invoice number, and supplier name.

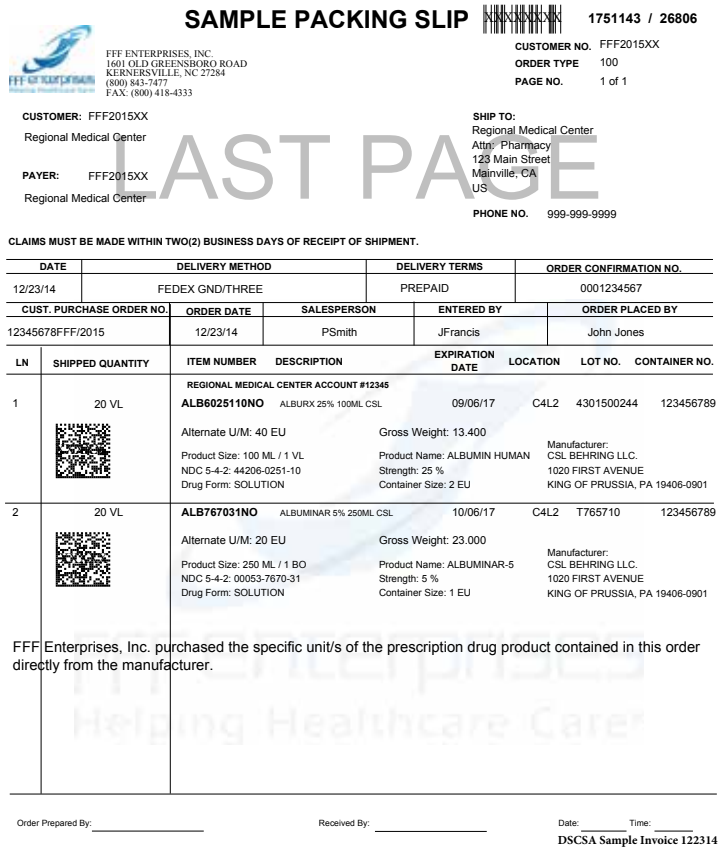
A sample packing slip is illustrated in Figure 3 to illustrate what Transaction Information is required to accompany drug products as they move through the supply chain. If the drug products on this packing slip had changed ownership multiple times, this document would also need to include the Transaction Information for each prior transaction going back to the manufacturer.

A Transaction Statement is basically a line or two that states you are authorized or licensed to supply the product, you received it from an authorized source, and that you did not knowingly ship counterfeit product. It has been proposed that "DSCSA compliant" may be an acceptable transaction statement.

You may already be receiving Transaction Information and History from your suppliers, and beginning July 1, 2015, you must begin keeping it on file. If this information is not provided to you, you must work with the supplier to obtain the required information, or you cannot accept the shipment. It is important to note that wholesalers or repackagers who receive the product directly from the manufacturer or a manufacturer's exclusive distributor, are not required to pro-

Figure 3

To meet the U.S. Drug Supply Chain Security Act (DSCSA) requirements, FFF's Packing Slips will include the following highlighted information as shown below. Under this new law, all records must be kept on file for six years.



SAMPLE PACKING SLIP XXXXXXXX **1751143 / 26806**

FFF ENTERPRISES, INC
1601 OLD GREENSBORO ROAD
KERNERSVILLE, NC 27284
(800) 843-7477
FAX: (800) 418-4333

CUSTOMER NO. FFF2015XX
ORDER TYPE 100
PAGE NO. 1 of 1

CUSTOMER: FFF2015XX
Regional Medical Center

PAYER: FFF2015XX
Regional Medical Center

SHIP TO:
Regional Medical Center
Attn: Pharmacy
123 Main Street
Mainville, CA
US

PHONE NO. 999-999-9999

LAST PAGE

CLAIMS MUST BE MADE WITHIN TWO(2) BUSINESS DAYS OF RECEIPT OF SHIPMENT.

DATE	DELIVERY METHOD	DELIVERY TERMS	ORDER CONFIRMATION NO.
12/23/14	FEDEX GND/THREE	PREPAID	0001234567

CUST. PURCHASE ORDER NO.	ORDER DATE	SALESPERSON	ENTERED BY	ORDER PLACED BY
12345678FFF/2015	12/23/14	PSmith	JFrancis	John Jones

LN	SHIPPED QUANTITY	ITEM NUMBER	DESCRIPTION	EXPIRATION DATE	LOCATION	LOT NO.	CONTAINER NO.
		REGIONAL MEDICAL CENTER ACCOUNT #12345					
1	20 VL	ALB6025110NO	ALBURX 25% 100ML CSL	09/06/17	C4L2	4301500244	123456789
		Alternate U/M: 40 EU	Gross Weight: 13.400				
		Product Size: 100 ML / 1 VL	Product Name: ALBUMIN HUMAN			Manufacturer: CSL BEHRING LLC.	
		NDC 5-4-2: 44206-0251-10	Strength: 25 %			1020 FIRST AVENUE	
		Drug Form: SOLUTION	Container Size: 2 EU			KING OF PRUSSIA, PA 19406-0901	
2	20 VL	ALB767031NO	ALBUMINAR 5% 250ML CSL	10/06/17	C4L2	T765710	123456789
		Alternate U/M: 20 EU	Gross Weight: 23.000				
		Product Size: 250 ML / 1 BO	Product Name: ALBUMINAR-5			Manufacturer: CSL BEHRING LLC.	
		NDC 5-4-2: 00053-7670-31	Strength: 5 %			1020 FIRST AVENUE	
		Drug Form: SOLUTION	Container Size: 1 EU			KING OF PRUSSIA, PA 19406-0901	

FFF Enterprises, Inc. purchased the specific unit/s of the prescription drug product contained in this order directly from the manufacturer.

Order Prepared By: _____ Received By: _____ Date: _____ Time: _____

DSCSA Sample Invoice 122314

Required Transaction Information. 1. Proprietary name of drug product; 2. Strength and dosage form; 3. NDC number; 4. Container size; 5. Number of containers; 6. Lot number; 7. Date of transaction; 8. Date of shipment; 9. Business name and address of supplier; 10. Business name and address of purchaser; 11. Transaction statement. *(Courtesy of FFF Enterprises)*

vide detailed Transaction History. In these cases, they can simply state "this product was received from the manufacturer."

You also must supply this information when you provide drugs outside of your facility's ownership beginning July 1, 2015.

You do *not* need to provide this information when:

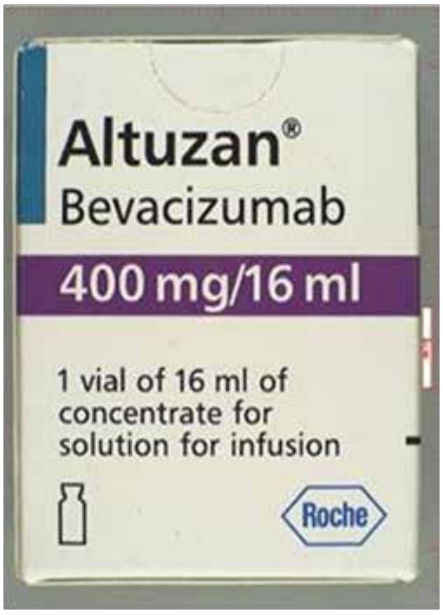
- supplying drugs to a facility-owned physician office or clinic;
- supplying minimal quantities of product to a licensed practitioner for office use (note: "minimal quantities" is not defined in the DSCSA. Recommended for each dispenser to reasonably define this in policy);
- supplying medications to fill a specific patient need.
- distributing drugs between stores or hospitals that have common ownership;
- sending returns to the manufacturer, repackager, or wholesaler;
- sending drugs to a reverse distributor.

Identification of Suspect or Illegitimate Product.

Beginning **January 1, 2015**, DSCSA requires that trading partners must have systems in place that enable them, upon determining that a product in their possession or control is suspect or upon receiving a request for verification from FDA, to quarantine suspect product and promptly conduct an investigation, in coordination with other trading partners, as applicable, to determine whether a suspect product is illegitimate. Your pharmacy must exercise vigilance, maintain awareness about suspicious activity or potential threats to your supply chain, and devote attention and effort to detect suspect product. FDA has an excellent draft guidance document titled *Identification of Suspect Product and Notification* that outlines circumstances that should cause you to question the authenticity of drug products. The web link to access the document is referenced at the end of this article and could serve as a training document for your department.

Tips to Consider.

- Purchase products only from verified trading partners.
- Be alert for offers of product for sale at a very low price or one that is "too good to be true."
- Closely examine the package and the transport container (such as the case or tote):
  - To look for signs that it has been compromised (e.g., opened, broken seal, damaged, repaired, or altered)
  - To see if the packaging or transport container has changed since it was last received for an unexplained reason (e.g., a notification about the change from the manufacturer has not been received)
  - To see if product inserts are missing or do not correspond to the product
  - For shipping addresses, postmarks, or other materials indicating that the product came from an unexpected foreign entity or source
- Closely examine the label on the package, or the label on the individual retail unit, if applicable, for:
  - Any missing information, such as the lot number or other lot identification, NDC, or strength of the drug
  - Any altered product information, such as smudged print or print that is very difficult to read
  - Misspelled words
  - Bubbling on the surface of a label
  - Lack of an Rx symbol



- No NDC number
- Non-FDA approved trade name
- No Rx symbol
- Incorrect manufacturer

http://www.fda.gov/drugs/drugsafety/drugintegrityandsupplychainsecurity/ucm298047.htm

◦ Foreign language with little or no English provided

◦ Foreign language that is used to describe the lot number

◦ A product name that differs from the name of the FDA-approved drug

◦ A product name that is the product name for a foreign version of the drug

◦ Lot numbers and expiration dates on product that do not match the lot numbers and expiration dates of its outer container

Identifying suspect products takes a keen eye, awareness of what products SHOULD look like, and educating all staff members of what to look for.

Purchasing from your verified wholesalers or directly from the manufacturer should not require this higher level of scrutiny. You need to be extremely cautious and vigilant with any gray market or Internet purchases you may make. Again, those types of purchases are highly discouraged.

What steps must you take if you identify suspect or illegitimate product?

If you come across a product that you feel is suspicious, you need to contact all trading partners to whom you may have supplied that drug and alert them that you may have given them a suspect product. You should also quarantine that drug so it is not distributed any further, and begin the notification process.

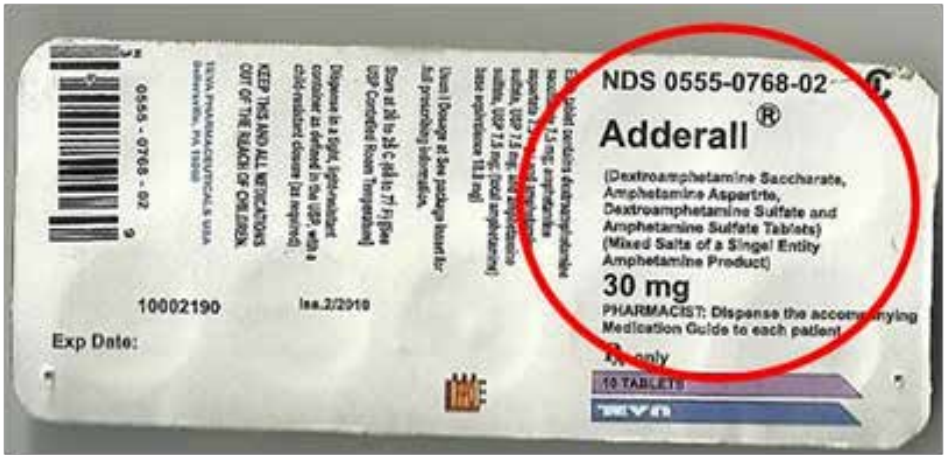
The pharmacy should discuss with immediate trading partners (who they believe may have received the product) other observations, questions, or concerns they have related to the status of drug as a suspect product to aid them in determining whether the drug should be considered a suspect product. Trading partners should also contact regulatory authorities, law enforcement, or other available resources to aid in that determination when additional expertise is called for to make an accurate assessment of the status of a drug as a suspect product.

If a product is determined to be illegitimate, the following process should be used within 24 hours to notify FDA:

- Access FDA's web page at http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm for notifications.
- Follow the instructions on the web page for accessing Form FDA 3911. Using this form, provide information about the person or entity initiating the notification, the product determined to be illegitimate or to pose a high risk of illegitimacy that is the subject of the notification to FDA, and a description of the circumstances surrounding the event that prompted the notification.
- Form FDA 3911 should be submitted by using the method provided in the form or on the web page.

If the pharmacy believes that a notification they made to FDA regarding illegitimate product is no longer necessary:

- Follow the steps outlined above, and
- The pharmacy's submission of a request for termination of a notification will be viewed as a request for consultation with FDA, as required in section 582 of the Food, Drug & Cosmetic Act (FD&C). Additional information might be important to complete the consultation with FDA.



The Adderall 30 mg product may be counterfeit if:

1. The product comes in a blister package.
2. There are misspellings on the package.
   - *NDS* instead of *NDC*
   - *Aspartrte* instead of *Aspartate*
   - *Singel* instead of *Single*
3. The tablets are white in color, round in shape, and are smooth.
4. The tablets have no markings on them.

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm305932.htm

• FDA will review the request and consult with the pharmacy. The response time will depend on the number of requests for termination and the circumstances surrounding the requests for termination that are received by FDA.

At the time of publication, Form FDA 3911 was still in draft form and not currently available on the FDA website. In the meantime, you need to email the notification to DrugNotifications@fda.hhs.gov.

Who will be monitoring compliance with this law?

The Boards of Pharmacy will likely promulgate rules that address this law, so we might expect future pharmacy inspections to include a look at how you verify licenses and registrations of suppliers, as well as ensuring you are maintaining files of the Transaction Information and History for medications you receive as well as those you supply.

Also, if FDA contacts you because they believe you have received or sent illegitimate product and you cannot produce the required documentation, you will likely run into issues. The law states FDA may impose fines or suspend or revoke licenses for violations.

You can monitor your own compliance by ensuring you always have current registrations and licenses on file for all of your suppliers. You could also perform spot checks of your filing systems by randomly picking several drugs from your shelf that were purchased after July 1, 2015 and see if you can easily retrieve the Transaction Information that accompanied that product.

Minimizing the Impact of DSCSA

Concern has been raised that this law will hinder relationships locally between hospital and community pharmacies, and physician offices who occasionally borrow/loan and buy/sell medications from each other in order to provide needed medications to the patients they serve. The extra paperwork required when transferring these drugs has many pharmacies refusing to continue to engage in this practice. Instead of putting these barriers between ourselves, consider working with your local hospitals and pharmacies and physician offices to implement some minimization strategies:

• Purchase only from KNOWN and VERIFIED sources

◦ Significantly decreases the chances of you receiving counterfeit product

• Sticker all purchases with date, invoice #, supplier OR record lot numbers on all received transaction data

◦ Use stickers provided by wholesaler/supplier or create your own

◦ You could receive the same lot # of a particular product on different dates or from different suppliers which would make it impossible to know which product is associated with which Transaction History

◦ Enables you to more quickly and easily locate the exact Transaction Information and History associated with that particular product

• Only buy/sell quantity needed for a specific patient

◦ If you need 30 tablets from another pharmacy to fill a 30-day prescription for a patient, only buy the 30 tablets. Do not purchase a bottle of 100 to keep as stock.

◦ Transaction History exchange is not necessary when the medication is dispensed/administered to a specific patient

◦ Destroy (with documentation) any leftover medication, if any, from the transaction

• Do NOT borrow/loan—sell or buy ONLY

◦ While Transaction History is not needed when supplying medications to another dispenser for a specific patient, the medication used to re-supply must be accompanied with Transaction Information/History

◦ Work out a process to invoice each other for purchases

• Do NOT sell unstickered items that have been distributed as floor stock or to dispensing cabinets in a hospital, or only sell the amount needed for a specific patient

◦ It may be difficult/impossible to locate the correct Transaction History associated with that product

◦ Again, if selling for a specific patient the detailed Transaction History does not need to be exchanged

• Self-audit your processes

◦ Randomly pick items from your shelf to determine how quickly and easily you can locate the Transaction Information/History

◦ Ensure received and sent records are maintained for six years

Conclusion

The Drug Supply Chain Security Act is intended to protect our nation's drug supply from counterfeit medications and ensure the integrity of the drug supply chain. FDA and the public are relying on manufacturers, wholesalers, repackagers, pharmacies…everyone who touches a drug prior to being dispensed or administered to patients, to help protect our drug supply. As pharmacists, we are often the last line of defense before a potentially adulterated or unsafe medication is given to an innocent patient. We must all work together to ensure we are exchanging accurate and complete information, and have a plan in place prior to July 1, 2015 for how we will continue to provide each other with medications when the need arises.

For More Information

FDA continues to issue draft guidance on the law. The drawback with draft guidance is that it is not finalized and is not enforceable, but it is FDA's current thinking on the topic. Currently, there are four FDA draft guidance publications for the DSCSA:

• Identification of Suspect Product and Notification

• The Effect of Section 585

of the FD&C Act on Drug Product Tracing and Wholesale Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers

•DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information

•DSCSA Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers.

And two policy documents for immediate implementation:

•DSCSA Implementation: Product Tracing Requirements — Compliance Policy

•DSCSA Implementation: Product Tracing Requirements for Dispensers — Compliance Policy

These documents may be located at http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm424963.htm.

To obtain more in-depth information, you are encouraged to read the DSCSA and explore FDA's DSCSA website. From this web page, you can access the full text of the law, FDA draft guidance, FDA webinars on the DSCSA, and other DSCSA resources:

http://www.fda.gov/drugs/drugsafety/drugintegrityandsupplychainsecurity/drugsupplychainsecurityact.

Questions regarding the DSCSA may be directed to the FDA Track and Trace Team at: drugtrackandtrace@fda.hhs.gov.

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This lesson is a knowledge-based CPE activity and is targeted to pharmacists in all practice settings.

Program 0129-0000-15-008-H04-P
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CE Hours: 1.5 (0.15 CEU)

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continuing education quiz

Drug Supply Chain Security Act: Compliance for Dispensers

1. The Drug Supply Chain Security Act (DSCSA) is designed to do all of the following EXCEPT:
   a. enable verification of legitimacy of the drug product identifier down to the package level.
   b. enhance detection and notification of illegitimate products in the drug supply chain.
   c. track drug products to a specific patient.
   d. facilitate more efficient recalls of drug products.

2. DSCSA defines "dispenser" to mean:
   a. a retail pharmacy, hospital pharmacy, or a group of chain pharmacies under common ownership.
   b. a person who dispenses only products to be used in animals.
   c. both a and b.

3. All of the following are prescription drugs that are excluded from DSCSA requirements EXCEPT:
   a. compounded drugs. c. drug samples.
   b. opioids. d. intravenous lipids.

4. Beginning January 1, 2015, everyone in the drug supply chain must be licensed by the state or registered with FDA to be considered a(n):
   a. authorized trading partner. c. compliance partner.
   b. authenticated dealer. d. gray market.

5. According to DSCSA, dispensers must receive and maintain Transaction Information and Transaction History for at least:
   a. 10 years. c. 6 years.
   b. 7 years. d. 3 years.

6. Which of the following would not be an acceptable method for a supplier to provide the Transaction Information and History?
   a. Supplier-owned online repository c. Packing slip
   b. E-mailed shipping notification d. Voicemail

7. A dispenser may utilize a third party to maintain the Transaction Information, History and Statements required by DSCSA.
   a. True b. False

Completely fill in the lettered box corresponding to your answer.

1. [a] [b] [c] [d]	6. [a] [b] [c] [d]	11. [a] [b]	
2. [a] [b] [c]	7. [a] [b]	12. [a] [b] [c] [d]	
3. [a] [b] [c] [d]	8. [a] [b] [c] [d]	13. [a] [b] [c] [d]	
4. [a] [b] [c] [d]	9. [a] [b] [c] [d]	14. [a] [b] [c]	
5. [a] [b] [c] [d]	10. [a] [b] [c] [d]	15. [a] [b] [c] [d]	

❑ **I am enclosing $5 for this quiz made payable to Ohio Pharmacists Association.**

1. Rate this lesson: (Excellent) 5 4 3 2 1 (Poor)
2. Did it meet each of its objectives? ❑ yes ❑ no
   If no, list any unmet_____
3. Was the content balanced and without commercial bias?
   ❑ yes ❑ no If no, why?_____
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   ❑ yes ❑ no
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6. Comments/future topics welcome.

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8. Which of the following is NOT required Transaction Information?
   a. NDC number c. Container size
   b. Delivery method d. Number of containers

9. On August 5, 2015, a local hospital would like to purchase a medication that is not excluded from DSCSA to stock, and was on your shelf prior to July 1, 2015. What information must you supply?
   a. Full Transaction History back to the manufacturer
   b. Transaction History back to wholesaler
   c. Transaction Information starting at your location
   d. Absolutely no information or paperwork is required since the product was on the shelf prior to July 1, 2015

10. If stickers are not provided with wholesaler purchases, you can create your own that include all of the following EXCEPT:
   a. date received. c. supplier name.
   b. invoice number. d. purchase price.

11. After July 1, 2015, when you provide drugs outside your facility's ownership, you do not need to supply Transaction Information, History and Statement when sending returns to the manufacturer, repackager or wholesaler.
   a. True b. False

12. Which of the following should raise suspicion of possible illegitimate product?
   a. No foreign language
   b. Lot number on vial matches lot number on outer container
   c. Rx symbol in upper right hand corner
   d. Misspelled words on packaging

13. If a product is determined to be illegitimate, FDA should be alerted within:
   a. one hour. c. 48 hours.
   b. 24 hours. d. seven days.

14. All of the following will be monitoring the DSCSA EXCEPT:
   a. State Boards of Pharmacy. c. FDA.
   b. NABP.

15. All of the following are ways to minimize the impact of DSCSA and maintain local relationships EXCEPT:
   a. consider purchasing only the amount of medication needed to dispense or administer to a specific patient.
   b. communicate your processes with other trading partners, and work together to meet the DSCSA.
   c. consider invoicing trading partners for supplied medications to minimize the additional paperwork needed for borrow/loan transactions.
   d. refuse to buy/sell or borrow/loan medications beginning July 1, 2015.

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